WORLD ORGANISATION FOR ANIMAL HEALTH

Organisation Mondiale de la Santé Animale World Organisation for Animal Health Organización Mundial de Sanidad Animal

TERRESTRIAL ANIMAL HEALTH CODE

Sixteenth Edition, 2007

First Edition, 1968
Second Edition, 1971
Third Edition, 1976
Fourth Edition, 1982
Fifth Edition, 1986
Sixth Edition, 1992
Seventh Edition, 1998
Eighth Edition, 1999
Ninth Edition, 2000
Tenth Edition, 2001
Eleventh Edition, 2002
Twelfth Edition, 2003
Thirteenth Edition, 2004
Fourteenth Edition, 2005
Fifteenth Edition, 2006

OIE - *Terrestrial Animal Health Code*
Sixteenth Edition, 2007

ISBN 978-92-9044-690-3

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Foreword

The aim of the Terrestrial Animal Health Code *(hereafter referred to as the* Terrestrial Code*) is to assure the sanitary safety of international trade in terrestrial animals (mammals, birds and bees) and their products. This is achieved through the detailing of health measures to be used by the veterinary authorities of importing and exporting countries to avoid the transfer of agents pathogenic for animals or humans, while avoiding unjustified sanitary barriers.*

The health measures in the Terrestrial Code *(in the form of standards, guidelines and recommendations) have been formally adopted by the OIE International Committee, the general assembly of all Delegates of OIE Member Countries, which constitutes the organisation's highest decision-making body. This 16th edition incorporates the modifications to the* Terrestrial Code *agreed by the OIE International Committee during the 75th General Session in May 2007. These include revised chapters on the following subjects: general definitions, zoning and compartmentalisation, rabies, foot and mouth disease, rinderpest, bluetongue, bovine tuberculosis, bovine spongiform encephalopathy, equine influenza, equine infectious anaemia, equine piroplasmosis, equine rhinopneumonitis, glanders, equine viral arteritis and avian influenza. Revised appendices on surveillance for rinderpest and avian influenza, on bovine and small ruminant and porcine semen, on identification and traceability of live animals, on disposal of dead animals, on inactivation of avian influenza virus as well as on animal welfare (including transport of animals by sea, transport of animals by land, slaughter of animals and killing of animals for disease control purposes) have also been included. This edition includes a new appendix on surveillance for bluetongue.*

The development of these standards, guidelines and recommendations is the result of the continuous work of one of the OIE Specialist Commissions, the OIE Terrestrial Animal Health Standards Commission (in brief 'Terrestrial Code Commission'). This Commission, which comprises six elected members experienced in regulatory veterinary science drawn from all OIE regions, meets several times yearly to address its work programme. The Commission draws upon the expertise of internationally renowned specialists to prepare draft texts for new chapters and appendices of the Terrestrial Code *or to revise existing chapters and appendices in the light of advances in veterinary science. The views of the Delegates of Member Countries are systematically sought through the circulation of draft and revised texts. As well, the Terrestrial Code Commission collaborates closely with the OIE Aquatic Animal Health Standards Commission on issues needing a harmonised approach, and with the Biological Standards Commission and the Scientific Commission for Animal Diseases to ensure the Terrestrial Code Commission is utilising the latest scientific information in its work.*

The value of the Terrestrial Code *lies in the fact that measures published in it are the result of consensus among the veterinary authorities of OIE Member Countries.*

The World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) conferred on the OIE new responsibilities under international law by specifying 'the standards, guidelines and recommendations developed under the auspices of the OIE' as the international standards for animal health and zoonoses. The SPS Agreement is aimed at establishing a multilateral framework of rules and disciplines to guide the development, adoption and enforcement of sanitary measures in order to minimise their negative effects on international trade. Essentially, two options are available to Member Countries to provide a scientific justification for an import health measure. The first, and most encouraged by the WTO, is for veterinary authorities to base their import health measures on the OIE's international standards, guidelines and recommendations. Where these do not exist, or in cases where a government chooses to apply stricter measures, the importing country must be able to show that its measure is based on a scientific assessment of the potential health risks. Guidelines for conducting risk analyses are described in the Terrestrial Code. *The* Terrestrial Code *thus forms an integral part of the regulatory reference system established by the WTO.*

The Terrestrial Code *is published annually in the three official OIE languages (English, French and Spanish), and more recently in Russian. The contents of the* Terrestrial Code *are available on the OIE Web site at http://www.oie.int.*

The User's Guide, which follows the foreword, is designed to help Veterinary Authorities and other interested parties to use the various chapters of the Terrestrial Code *efficiently and effectively, and to promote equitable access by all developing and developed countries to the world market in animals and animal products, according to their animal health status.*

We wish to thank the members of the Terrestrial Code Commission for their hard work, Delegates and the members of Working Groups and Ad hoc Groups and other Commissions for their expert advice, and also the staff of the OIE Headquarters for their dedication in producing this 16th edition of the Terrestrial Code.

Dr B. Vallat
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July 2007

User's guide

A. General remarks

1. *The purpose of this guide is to assist the Veterinary Authorities of OIE Member Countries to use the* Terrestrial Animal Health Code *(hereafter referred to as the* Terrestrial Code*) in developing their animal health measures applicable to imports and exports of animals and animal products.*

2. *The recommendations in each of the chapters in Part 2. of the* Terrestrial Code *are designed to prevent the disease in question being introduced into the importing country, taking into account the nature of the commodity and the animal health status of the exporting country. This means that, correctly applied, the recommendations ensure that the intended importation can take place with an optimal level of animal health security, incorporating the latest scientific findings and available techniques.*

3. *The recommendations in the* Terrestrial Code *make reference only to the animal health situation in the exporting country, and assume that either the disease is either not present in the importing country or is the subject of a control or eradication programme. Therefore, when determining its import measures, an importing country should do so in a way that is consistent with the principle of national treatment and the other provisions of the WTO SPS Agreement. An importing country is always free to authorise the importation of animals or animal products into its territory under conditions either more or less stringent than those recommended by the* Terrestrial Code, *but this must be based on a scientific risk analysis and done in accordance with the country's obligations under the SPS Agreement.*

4. *To avoid confusion, key terms and expressions used in the* Terrestrial Code *are defined in Chapter 1.1.1. When preparing model international veterinary certificates, the importing country should endeavour to use these terms and expressions in accordance with the definitions given in the* Terrestrial Code.

5. *In general, at the head of each chapter relating to a specific disease (in Part 2 of the* Terrestrial Code *), there is an article listing either the commodities that the OIE considers capable of transmitting the disease through international trade or those not considered to present a risk. The articles following deal with each of these commodities in the first group, where necessary taking into account the status of the exporting territory. Where there is no article for a particular category of commodity, it means that the OIE has not yet been able to develop a recommendation on the subject and import measures for that commodity should be based on a risk analysis.*

6. *In many of the* Terrestrial Code *chapters, the use of diagnostic tests and vaccines is recommended. In each case, a reference in the first article of the chapter is made to the relevant section in the OIE* Manual of Diagnostic Tests and Vaccines for Terrestrial Animals *(hereafter referred to as the* Terrestrial Manual*). A table summarising the recommended diagnostic tests may be found in Appendix 3.1.1. of the* Terrestrial Code.

7. *Section 1.2. of the* Terrestrial Code *deals with obligations and ethics in international trade. Each Veterinary Authority should have a sufficient number of copies of the* Terrestrial Code *to allow all veterinarians directly involved in such trade to familiarise themselves with the contents. In addition, diagnostic laboratories and vaccine production units should be fully conversant with the technical recommendations in the* Terrestrial Manual.

8. *When, in some parts of this* Terrestrial Code, *the term "(under study)" is applied to an Article or part of an Article, the meaning is that the text has not been adopted by the OIE International Committee and is not part of the* Terrestrial Code. *Accordingly, that recommendation needs not be applied by Member Countries.*

9. *The complete text of the* Terrestrial Code *has been made available on the OIE Web site (address: http://www.oie.int) to ensure wider access.*

B. Disease Information, the Bulletin and World Animal Health

These three OIE publications inform Veterinary Authorities on the animal health situation worldwide. Importing countries can thus have an overview of the animal health status, disease occurrence and control programmes in exporting countries. If it considers

the data available at the international level to be insufficient, the importing country should contact the exporting country directly, or through the OIE Central Bureau, to obtain additional information.

C. International veterinary certificates

1. *An international veterinary certificate is a document, drawn up by the exporting country in accordance with the terms of Chapter 1.2.1. and Chapter 1.2.2. of the* Terrestrial Code, *describing the animal health requirements and, where appropriate, public health requirements for the exported commodity. The assurance given to the importing country that diseases will not be introduced through the importation of animals or animal products depends on the quality of the exporting country's veterinary infrastructure and the rigour with which international veterinary certificates are issued in the exporting country.*

2. *International veterinary certificates are intended to facilitate trade and should not be used to impede it by imposing unjustified health conditions. In all cases, the exporting country and the importing country shall refer to the health conditions recommended in the* Terrestrial Code *before agreeing on the terms of the certificate.*

3. *The steps to be followed when drafting international veterinary certificates are as follows:*

   a) *list the diseases against which the importing country is justified in seeking protection;*

   b) *list the health requirements for each of these diseases, which can be determined by referring to the relevant articles in the* Terrestrial Code. *The* Terrestrial Code *provides for various levels of sanitary status in the case of many diseases: disease free country, zone or compartment, disease free herd, vaccinated or non vaccinated herd;*

   c) *use the model international veterinary certificates presented in Part 4. of the* Terrestrial Code *as a general framework, adapting the contents and form of the paragraphs as required, for example by devoting more space to details of the herd of origin.*

4. *As stated in Article 1.2.2.2. of the* Terrestrial Code, *it is important that international veterinary certificates are kept as simple as possible and are clearly worded, so as to avoid any misunderstanding of the requirements of importing countries. The same article gives advice on how to draft certificates so as to ensure the validity of their contents and prevent forgery.*

D. Notes of guidance for importers and exporters

In order to avoid any misunderstanding of the requirements, it is often advisable to prepare notes of guidance to assist importers and exporters. The notes should set out all the conditions involving importation measures to be applied before and after importation, as well as during transport and unloading, legal obligations and operational procedures. The attention of exporters should also be drawn to the rules governing air transport of animals and animal products.

The notes of guidance should also set out in detail the health certification requirements to be included in the documents accompanying the consignment to its destination.

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PART 1

GENERAL PROVISIONS

SECTION 1.1.

GENERAL DEFINITIONS AND NOTIFICATION OF ANIMAL DISEASES

CHAPTER 1.1.1.

GENERAL DEFINITIONS

Article 1.1.1.1.

For the purposes of the *Terrestrial Code*:

Acceptable risk

means a risk level judged by each Member Country to be compatible with the protection of animal and public health within its territory.

Animal

means a mammal, bird or bee.

Animal for breeding or rearing

means a domesticated or confined *animal* which is not intended for slaughter within a short time.

Animal for slaughter

means an *animal* intended for slaughter within a short time, under the control of the relevant *Veterinary Authority*.

Animal handler

means a person with a knowledge of the behaviour and needs of *animals* who, with appropriate experience and a professional and positive response to an *animal*'s needs, can achieve effective management and good welfare. Competence should be gained through formal training and/or practical experience.

Animal health status

means the status of a country or a *zone* with respect to an animal *disease*, according to the criteria listed in the relevant chapter of the *Terrestrial Code* dealing with the *disease*.

Animal identification

means the combination of the identification and *registration* of an *animal* individually, with a unique identifier, or collectively by its *epidemiological unit* or group, with a unique group identifier.

Animal identification system

means the inclusion and linking of components such as identification of *establishments*/owners, the person(s) responsible for the *animal(s)*, movements and other records with *animal identification*.

Animal traceability

means the ability to follow an *animal* or group of *animals* during all stages of its life.

Antimicrobial agent

means a naturally occurring, semi-synthetic or synthetic substance that exhibits antimicrobial activity (kill or inhibit the growth of micro-organisms). Anthelmintics and substances classed as disinfectants or antiseptics are excluded from this definition.

Apiary

means a hive or group of hives whose management allows them to be considered as a single *epidemiological unit*.

Appropriate level of protection

means the level of protection deemed appropriate by the country establishing a *sanitary measure* to protect human or animal life or health within its territory.

Approved

means officially approved, accredited or registered by the *Veterinary Authority*.

Approved abattoir

means premises used for the slaughter of *animals* for human consumption or animal feeding and approved by the *Veterinary Authority* for export purposes.

Area of direct transit

means a special area established in a *transit country*, approved by the relevant *Veterinary Authority* and placed under its immediate control, where *animals* stay for a short time pending further transport to their final destination.

Artificial insemination centre

means a facility approved by the *Veterinary Authority* and which meets the conditions set out in the *Terrestrial Code* for the collection, processing and/or storage of semen.

Beehive

means a structure for the keeping of honey bee colonies that is being used for that purpose, including frameless hives, fixed frame hives and all designs of moveable frame hives (including nucleus hives), but not including packages or cages used to confine bees for the purpose of transport or isolation.

Biosecurity plan

means a plan that identifies potential pathways for the introduction and spread of *disease* in a *zone* or *compartment*, and describes the measures which are being or will be applied to mitigate the *disease risks*, if applicable, in accordance with the recommendations in the *Terrestrial Code*.

Border post

means any airport, or any port, railway station or road check-point open to *international trade* of *commodities*, where import veterinary inspections can be performed.

Breeding birds

means birds kept for the purpose of producing *hatching eggs*.

Buffer zone

means a *zone* established to protect the health status of animals in a free country or *free zone*, from those in a country or *zone* of a different *animal health status*, using measures based on the epidemiology of the *disease* under consideration to prevent spread of the causative pathogenic agent into a free country or *free zone*. These

measures may include, but are not limited to, vaccination, movement control and an intensified degree of *disease* surveillance.

Case

means an individual *animal* infected by a pathogenic agent, with or without clinical signs.

Central Bureau

means the Permanent Secretariat of the World Organisation for Animal Health which headquarters are:

12, rue de Prony, 75017 Paris, FRANCE
Telephone: 33-(0)1 44 15 18 88
Fax: 33-(0)1 42 67 09 87
Electronic mail: oie@oie.int
WWW: http://www.oie.int

Collecting centre

means a premise or a place where *animals for breeding or rearing* or *animals for slaughter* from different *establishments* or *markets* are collected together.

Collection centre

means a facility approved by the *Veterinary Authority* for the collection of embryos/ova and used exclusively for donor animals which meet the conditions of the *Terrestrial Code.*

Commodity

means *animals*, products of animal origin intended for human consumption, for animal feeding, for pharmaceutical or surgical use or for agricultural or industrial use, semen, embryos/ova, biological products and *pathological material*.

Compartment

means one or more *establishments* under a common biosecurity management system containing an animal *subpopulation* with a distinct health status with respect to a specific *disease* or specific *diseases* for which required surveillance, control and biosecurity measures have been applied for the purpose of *international trade.*

Competent Authority

means the *Veterinary Authority* or other Governmental Authority of a Member Country having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and guidelines in the *Terrestrial Code* in the whole country.

Container

means a non-self-propelled receptacle or other rigid structure for holding *animals* during a *journey* by one or several means of transport.

Containment zone

means a defined zone around and including suspected or infected *establishments*, taking into account the epidemiological factors and results of investigations, where control measures to prevent the spread of the infection are applied.

Day-old birds

means birds aged not more than 72 hours after hatching.

Death

means the irreversible loss of brain activity demonstrable by the loss of brain stem reflexes.

Disease

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

Disinfection

means the application, after thorough cleansing, of procedures intended to destroy the infectious or parasitic agents of animal *diseases*, including *zoonoses*; this applies to premises, *vehicles* and different objects which may have been directly or indirectly contaminated.

Disinfestation

means the application of procedures intended to eliminate arthropods which may cause *diseases* or are potential vectors of infectious agents of animal *diseases*, including *zoonoses*.

Early detection system

means a system under the control of the *Veterinary Services* for the timely detection and identification of animal *diseases*. Characteristics of the system must include:

a) representative coverage of target animal *populations* by field services;

b) ability to undertake effective *disease* investigation and reporting;

c) access to laboratories capable of diagnosing and differentiating relevant *diseases*;

d) a training programme for *veterinarians* and para-veterinarians for detecting and reporting unusual *disease* occurrence.

Emerging disease

means a new *infection* resulting from the evolution or change of an existing pathogenic agent, a known *infection* spreading to a new geographic area or *population*, or a previously unrecognized pathogenic agent or disease diagnosed for the first time and which has a significant impact on animal or public health.

Epidemiological unit

means a group of animals with a defined epidemiological relationship that share approximately the same likelihood of exposure to a pathogen. This may be because they share a common environment (e.g. animals in a pen), or because of common management practices. Usually, this is a herd or a flock. However, an *epidemiological unit* may also refer to groups such as animals belonging to residents of a village, or animals sharing a communal animal handling facitity. The epidemiological relationship may differ from *disease* to *disease*, or even strain to strain of the pathogen.

Equivalence of sanitary measures

means the state wherein the *sanitary measure(s)* proposed by the *exporting country* as an alternative to those of the *importing country*, achieve(s) the same level of protection.

Eradication

means the elimination of a pathogenic agent from a country or *zone*.

Establishment

means the premises in which *animals* are kept.

Exporting country

means a country from which *commodities* are sent to another country.

Flock of birds

means any group of birds continuously housed in one building or part of a building separated from other parts of that building by a solid partition and having its own ventilation system, or, in the case of free range birds, any group of birds having common access to one or more buildings or houses. More than one flock of birds may exist in one *establishment*.

Free compartment

means a *compartment* in which the absence of the animal pathogen causing the *disease* under consideration has been demonstrated by all requirements specified in the *Terrestrial Code* for free status being met.

Free zone

means a zone in which the absence of the *disease* under consideration has been demonstrated by the requirements specified in the *Terrestrial Code* for free status being met. Within the zone and at its borders, appropriate *official veterinary control* is effectively applied for *animals* and animal products, and their transportation.

Fresh meat

means *meat* that has not been subjected to any treatment irreversibly modifying its organoleptic and physicochemical characteristics. This includes frozen meat, chilled meat, minced meat and mechanically recovered meat.

Greaves

means the protein-containing residue obtained after the partial separation of fat and water during the process of rendering.

Hatching eggs

means fertilised bird eggs, suitable for incubation and hatching.

Hazard

means a biological, chemical or physical agent in, or a condition of, an *animal* or animal product with the potential to cause an adverse health effect.

Hazard identification

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

Importing country

means a country that is the final destination to which *commodities* are sent.

Incidence

means the number of new *cases* or *outbreaks* of a *disease* that occur in a population at risk in a particular geographical area within a defined time interval.

Incubation period

means the longest period which elapses between the introduction of the pathogen into the *animal* and the occurrence of the first clinical signs of the *disease*.

Infected zone

means a zone in which the absence of the *disease* under consideration has not been demonstrated by the requirements specified in the *Terrestrial Code* being met.

Infection

means the presence of the pathogenic agent in the host.

Infective period

means the longest period during which an affected animal can be a source of *infection*.

International trade

means importation, exportation and transit of *commodities*.

International veterinary certificate

means a certificate, issued in conformity with the provisions of Chapter 1.2.2., describing the animal health and/or public health requirements which are fulfilled by the exported *commodities*.

Journey

An *animal* transport journey commences when the first *animal* is loaded onto a *vehicle/vessel* or into a *container* and ends when the last *animal* is unloaded, and includes any stationary resting/holding periods. The same *animals* do not commence a new journey until after a suitable period for rest and recuperation, with adequate feed and water.

Killing

means any procedure which causes the death of an *animal*.

Laboratory

means a properly equipped institution staffed by technically competent personnel under the control of a specialist in veterinary diagnostic methods, who is responsible for the validity of the results. The *Veterinary Authority* approves and monitors such laboratories with regard to the diagnostic tests required for *international trade*.

Lairage

means pens, yards and other holding areas used for accommodating *animals* in order to give them necessary attention (such as water, feed, rest) before they are moved on or used for specific purposes including slaughter.

Laying birds

means birds kept for the purpose of producing eggs not intended for hatching.

Listed diseases

means the list of transmissible *disease* agreed by the OIE International Committee and set out in Chapter 2.1.1. of the *Terrestrial Code*.

Loading/unloading

Loading means the procedure of moving *animals* onto a *vehicle/vessel* or into a *container* for transport purposes, while unloading means the procedure of moving *animals* off a *vehicle/vessel* or out of a *container*.

Market

means a place where *animals* are assembled for the purpose of trade or sale

Meat

means all edible parts of an *animal*.

Meat-and-bone meal

means the solid protein products obtained when animal tissues are rendered, and includes any intermediate protein product other than peptides of a molecular weight less than 10,000 daltons and amino-acids.

Meat products

means *meat* that has been subjected to a treatment irreversibly modifying its organoleptic and physicochemical characteristics.

Milk

means the normal mammary secretion of milking animals obtained from one or more milkings without either addition to it or extraction from it.

Milk product

means the product obtained by any processing of *milk*.

Modified stamping-out policy

see *stamping-out policy*.

Monitoring

means the continuous investigation of a given *population* or *subpopulation*, and its environment, to detect changes in the *prevalence* of a *disease* or characteristics of a pathogenic agent.

Notifiable disease

means a *disease* listed by the *Veterinary Authority*, and that, as soon as detected or suspected, must be brought to the attention of this *Authority*, in accordance with national regulations.

Notification

means the procedure by which:

a) the *Veterinary Authority* informs the *Central Bureau*,

b) the *Central Bureau* informs *Veterinary Authority*,

of the occurrence of an *outbreak of disease or infection*, according to the provisions of Chapter 1.1.2. of the *Terrestrial Code*.

Official control programme

means a programme which is approved, and managed or supervised by the *Veterinary Authority* of a country for the purpose of controlling a vector, pathogen or *disease* by specific measures applied throughout that country, or within a *zone* or *compartment* of that country.

Official Veterinarian

means a veterinarian authorised by the *Veterinary Authority* of the country to perform certain designated official tasks associated with animal health and/or public health and inspections of *commodities* and, when appropriate, to certify in conformity with the provisions of Section 1.2. of the *Terrestrial Code*.

Official veterinary control

means that the *Veterinary Services* knows the location of the *animals* and the identity of their owner or responsible keeper and is able to apply appropriate animal health measures, as required.

Outbreak of disease or infection

means the occurrence of one or more *cases* of a *disease* or an *infection* in an *epidemiological unit*.

Pathological material

means samples obtained from live or dead animals, containing or suspected of containing infectious or parasitic agents, to be sent to a *laboratory*.

Place of shipment

means the place where the *commodities* are loaded into the *vehicle* or handed to the agency that will transport them to another country.

Population

means a group of *units* sharing a common defined characteristic.

Post-journey period

means the period between *unloading* and either recovery from the effects of the *journey* or slaughter (if this occurs before recovery).

Pre-journey period

means the period during which *animals* are identified, and often assembled for the purpose of *loading* them.

Prevalence

means the total number of *cases* or *outbreaks of a disease* that are present in a population at risk, in a particular geographical area, at one specified time or during a given period.

Qualitative risk assessment

means an assessment where the outputs on the likelihood of the outcome or the magnitude of the consequences are expressed in qualitative terms such as 'high', 'medium', 'low' or 'negligible'.

Quality

is defined by International Standard ISO 8402 as 'the totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs'.

Quantitative risk assessment

means an assessment where the outputs of the *risk assessment* are expressed numerically.

Quarantine station

means a facility under the control of the *Veterinary Services* where animals are maintained in isolation with no direct or indirect contact with other animals, to prevent the transmission of specified pathogen(s) while the *animals* are undergoing observation for a specified length of time and, if appropriate, testing and treatment.

Registration

is the action by which information on *animals* (such as identification, animal health, movement, certification, epidemiology, *establishments*) is collected, recorded, securely stored and made appropriately accessible and able to be utilised by the *Competent Authority*.

Resting point

means a place where the *journey* is interrupted to rest, feed or water the *animals*; the *animals* may remain in the *vehicle/vessel* or *container*, or be unloaded for these purposes.

Restraint

means the application to an *animal* of any procedure designed to restrict its movements.

Risk

means the likelihood of the occurrence and the likely magnitude of the consequences of an adverse event to animal or human health in the *importing country* during a specified time period, as a result of a *hazard*.

Risk analysis

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

Risk assessment

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

Risk communication

is the interactive exchange of information on risk among risk assessors, risk managers and other interested parties.

Risk management

means the process of identifying, selecting and implementing measures that can be applied to reduce the level of risk.

Sanitary measure

means any measure applied to protect animal or human health or life within the territory of the Member Country from *risks* arising from the entry, establishment or spread of a *hazard*. *[Note: A detailed definition of sanitary measure may be found in the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization.]*

Slaughter

means any procedure which causes the death of an *animal* by bleeding.

Slaughterhouse/abattoir

means premises, including facilities for moving or lairaging *animals*, used for the slaughter of *animals* to produce animal products and approved by the *Veterinary Services* or other *Competent Authority*.

Space allowance

means the measure of the floor area and height allocated per individual or body weight of *animals*.

Specific surveillance

means the surveillance targeted to a specific *disease* or *infection*.

Stamping-out policy

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

This policy should be accompanied by the cleansing and *disinfection* procedures defined in the *Terrestrial Code*.

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

Stocking density

means the number or body weight of *animals* per unit area on a *vehicle/vessel* or *container*.

Stunning

means any mechanical, electrical, chemical or other procedure which causes immediate loss of consciousness; when used before slaughter, the loss of consciousness lasts until death from the slaughter process; in the absence of slaughter, the procedure would allow the *animal* to recover consciousness.

Subpopulation

means a distinct part of a *population* identifiable according to specific common animal health characteristics.

Surveillance

means the investigation of a given *population* or *subpopulation* to detect the presence of a pathogenic agent or *disease*; the frequency and type of *surveillance* will be determined by the epidemiology of the pathogenic agent or *disease*, and the desired outputs.

Surveillance zone

means a *zone* established within, and along the border of, a *free zone* separating the *free zone* from an *infected zone*.

The *surveillance zone* should have an intensified degree of surveillance.

Terrestrial Code

means the OIE *Terrestrial Animal Health Code*.

Terrestrial Manual

means the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*.

Transit country

means a country through which *commodities* destined for an *importing country* are transported or in which a stopover is made at a *border post*.

Transparency

means the comprehensive documentation of all data, information, assumptions, methods, results, discussion and conclusions used in the *risk analysis*. Conclusions should be supported by an objective and logical discussion and the document should be fully referenced.

Transport

means the procedures associated with the carrying of *animals* for commercial purposes from one location to another by any means.

Transporter

means the person licensed by the *Competent Authority* to transport *animals*.

Travel

means the movement of a *vehicle/vessel* or *container* carrying *animals* from one location to another.

Uncertainty

means the lack of precise knowledge of the input values which is due to measurement error or to lack of knowledge of the steps required, and the pathways from *hazard* to *risk*, when building the scenario being assessed.

Unit

means an individually identifiable element used to describe, for example, the members of a *population* or the elements selected when sampling; examples of *units* include individual animals, herds, flocks and *apiaries*.

Vaccination

means the successful immunisation of susceptible animals through the administration of a vaccine comprising antigens appropriate to the *disease* to be controlled.

Variability

means a real-world complexity in which the value of an input is not the same for each case due to natural diversity in a given population.

Vehicle/vessel

means any means of conveyance including train, truck, aircraft or ship that is used for carrying *animal(s)*.

Veterinarian

means a person registered or licensed by the relevant *veterinary statutory body* of a country to practice veterinary medicine/science in that country.

Veterinary Authority

means the Governmental Authority of a Member Country, comprising *veterinarians*, other professionals and para-professionals, having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and guidelines in the *Terrestrial Code* in the whole country.

Veterinary para-professional

means a person who, for the purposes of the *Terrestrial Code*, is authorised by the *veterinary statutory body* to carry out certain designated tasks (dependent upon the category of *veterinary para-professional*) in a country, and delegated to them under the responsibility and direction of a *veterinarian*. The tasks authorized for each category of *veterinary para-professional* should be defined by the *veterinary statutory body* depending on qualifications and training, and according to need.

Veterinary Services

means the governmental and non-governmental organisations that implement animal health and welfare measures and other standards and guidelines in the *Terrestrial Code* in the country. The Veterinary Services are under the overall control and direction of the *Veterinary Authority*. Private sector organisations are normally accredited or approved to deliver functions by the *Veterinary Authority*.

Veterinary statutory body

means an autonomous authority regulating *veterinarians* and *veterinary para-professionals*.

Zone/region

means a clearly defined part of a country containing an animal *subpopulation* with a distinct health status with respect to a specific *disease* for which required surveillance, control and biosecurity measures have been applied for the purpose of *international trade*.

Zoonosis

means any *disease* or *infection* which is naturally transmissible from animals to humans.

CHAPTER 1.1.2.

NOTIFICATION OF DISEASES AND EPIDEMIOLOGICAL INFORMATION

Article 1.1.2.1.

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

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

Article 1.1.2.2.

1. Countries shall make available to other countries, through the OIE, whatever information is necessary to minimise the spread of important animal *diseases* and to assist in achieving better worldwide control of these *diseases*.
2. To achieve this, countries shall comply with the *notification* requirements specified in Article 1.1.2.3.
3. To assist in the clear and concise exchange of information, reports shall conform as closely as possible to the official OIE *disease* reporting format.
4. Recognising that scientific knowledge concerning the relationship between disease agents and *diseases* is constantly developing and that the presence of an infectious agent does not necessarily imply the presence of a *disease*, countries shall ensure through their reports that they comply with the spirit and intention of paragraph 1 above.
5. In addition to notifying new findings in accordance with Article 1.1.2.3., countries shall also provide information on the measures taken to prevent the spread of diseases; including quarantine measures and restrictions on the movement of *animals*, animal products and biological products and other miscellaneous objects which could by their nature be responsible for transmission of disease. In the case of diseases transmitted by vectors, the measures taken against such vectors shall also be specified.

Article 1.1.2.3.

Veterinary Authorities shall send to the *Central Bureau*:

1. *notification* from the Delegate of the country by telegram, fax or e-mail, within 24 hours, of any of the following events:
   a) first occurrence of a *listed disease* and/or *infection* in a country, a *zone* or a *compartment*;
   b) re-occurrence of a *listed disease* and/or *infection* in a country, a *zone* or a *compartment* following a report declared the *outbreak* ended;
   c) first occurrence of a new strain of a pathogen of an OIE *listed disease* in a country, a *zone* or a *compartment*;
   d) a sudden and unexpected increase in the distribution, incidence, morbidity or mortality of a *listed disease* prevalent within a country, a *zone* or a *compartment*;
   e) an *emerging disease* with significant morbidity or mortality, or zoonotic potential;
   f) evidence of change in the epidemiology of a *listed disease* (including host range, pathogenicity, strain) in particular if there is a zoonotic impact;

2. weekly reports by telegram, fax or e-mail subsequent to a *notification* under point 1 above, to provide further information on the evolution of an incident which justified urgent *notification*; these reports should continue until the situation has been resolved through either the disease being eradicated or it becoming endemic so that six-monthly reporting under point 3 will satisfy the obligation of the country to the OIE; in any case, a final report on the incident should be submitted;

3. a six-monthly report on the absence or presence, and evolution of *diseases listed by the OIE* and information of epidemiological significance to other countries;

4. an annual report concerning any other information of significance to other countries.

Article 1.1.2.4.

1. The *Veterinary Authority* of a territory in which an *infected zone* was located shall inform the *Central Bureau* when this zone is free from the *disease*.

2. An *infected zone* for a particular *disease* shall be considered as such until a period exceeding the *infective period* specified in the *Terrestrial Code* has elapsed after the last reported *case*, and when full prophylactic and appropriate animal health measures have been applied to prevent possible reappearance or spread of the disease. These measures will be found in detail in the various chapters of Section 2.2. of the *Terrestrial Code*.

3. A country may be considered to regain freedom from a specific *disease* when all conditions given in the relevant chapters of the *Terrestrial Code* have been fulfilled.

4. The *Veterinary Authority* of a country which sets up one or several *free zones* shall inform the OIE giving necessary details, including the criteria on which the free status is based, the requirements for maintaining the status and indicating clearly the location of the zones on a map of the country.

Article 1.1.2.5.

1. The *Central Bureau* shall send by telegram, fax, e-mail or *Disease Information* to the *Veterinary Authorities* concerned, all *notifications* received as provided in Articles 1.1.2.2. to 1.1.2.4.

2. The *Central Bureau* shall dispatch to the Delegates information on new *outbreaks* of *listed diseases*.

3. The *Central Bureau*, on the basis of information received and of any official communication, shall prepare an annual report concerning the application of the *Terrestrial Code* and its effects on *international trade*.

Article 1.1.2.6.

All telegrams or faxes sent by *Veterinary Authorities* in pursuance of Articles 1.1.2.3. and 1.1.2.5. shall receive priority in accordance with the circumstances. Communications by telephone, telegram or fax, sent in the case of exceptional urgency when there is danger of spread of a notifiable epizootic *disease*, shall be given the highest priority accorded to these communications by the International Arrangements of Telecommunications.

SECTION 1.2.

OBLIGATIONS AND ETHICS IN INTERNATIONAL TRADE

CHAPTER 1.2.1.

GENERAL OBLIGATIONS

Article 1.2.1.1.

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

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

These requirements should be included in the model certificates approved by the OIE which form Part 4 of the *Terrestrial Code*.

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

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

Article 1.2.1.2.

Responsibilities of the importing country

1. The import requirements included in the *international veterinary certificate* should assure that *commodities* introduced into the *importing country* comply with the national level of protection that it has chosen for animal and human health. *Importing countries* should restrict their requirements to those justified for such level of protection.
2. The *international veterinary certificate* should not include requirements for the exclusion of pathogens or animal *diseases* which are present within the territory of the *importing country* and are not subject to any *official control programme*. The requirements applying to pathogens or *diseases* subject to *official control programmes* in a country or *zone* should not provide a higher level of protection on imports than that provided for the same pathogens or *diseases* by the measures applied within that country or *zone*.
3. The *international veterinary certificate* should not include requirements for disease agents or *diseases* which are not OIE listed, unless the *importing country* has identified the disease agent as presenting a significant risk for that country, after conducting a scientifically based import risk analysis according to the guidelines in Section 1.3.
4. The transmission by the *Veterinary Authority* of certificates or the communication of import requirements to persons other than the *Veterinary Authority* of another country, necessitates that copies of these documents are

also sent to the *Veterinary Authority*. This important procedure avoids delays and difficulties which may arise between traders and *Veterinary Authorities* when the authenticity of the certificates or permits is not established.

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

Article 1.2.1.3.

Responsibilities of the exporting country

1. An *exporting country* should be prepared to supply the following information to *importing countries* on request:

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

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

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

   d) information on the structure of the *Veterinary Services* and the authority which they exercise;

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

2. *Veterinary Authorities* of *exporting countries* should:

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

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

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

3. The Head of the *Veterinary Service* of the *exporting country* is ultimately accountable for veterinary certification used in *international trade*.

Article 1.2.1.4.

Responsibilities in case of an incident occurring after importation

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

Equally, if a *disease* condition appears in imported stock within a time period after importation consistent with the recognised *incubation period* of the *disease*, the *Veterinary Authority* of the *exporting country* should be informed so as to enable an investigation to be made, since this may be the first available information on the occurrence of the *disease* in a previously free herd. The *Veterinary Authority* of the *importing country* should be informed of the result of the investigation since the source of infection may not be in the *exporting country*.

CHAPTER 1.2.2.

CERTIFICATION PROCEDURES

Article 1.2.2.1.

Protection of the professional integrity of the certifying veterinarian

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

It is essential not to include in the requirements additional specific matters which cannot be accurately and honestly signed by a veterinarian. For example, these requirements should not include certification of an area as being free from non-notifiable diseases the occurrence of which the signing veterinarian is not necessarily informed about. Equally, to ask certification for events which will take place after the document is signed is unacceptable when these events are not under the direct control and supervision of the signing veterinarian.

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

The note of guidance referred to in Article 1.2.1.1. is not only to inform the signing veterinarian but also to safeguard professional integrity.

Article 1.2.2.2.

Preparation of international veterinary certificates

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

1. Paper certificates should be pre-printed, if possible on one sheet of paper, serially numbered, and issued by the *Veterinary Authority* on officially headed notepaper and, if possible, printed using techniques which prevent forgery. Electronic certification procedures should include equivalent safeguards.

2. They should be written in terms that are as simple, unambiguous and easy to understand as possible, without losing their legal meaning.

3. If so required, they should be written in the language of the *importing country*. In such circumstances, they should also be written in a language understood by the certifying veterinarian.

4. They should require appropriate identification of *animals* and animal products except where this is impractical (e.g. *day-old birds*).

5. They should not require a veterinarian to certify matters that are outside his/her knowledge or which he/she cannot ascertain and verify.

6. Where appropriate, they should be accompanied, when presented to the certifying veterinarian, by notes of guidance indicating the extent of enquiries, tests or examinations expected to be carried out before the certificate is signed.

7. Their text should not be amended except by deletions which must be signed and stamped by the certifying veterinarian. The signature and stamp must be in a colour different to that of the printing of the certificate.

8. Only original certificates are acceptable.

Article 1.2.2.3.

Certifying veterinarians

Certifying veterinarians should:

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

Article 1.2.2.4.

Electronic certification

1. Certification may be provided by electronic documentation sent directly from the *Veterinary Authority* of the *exporting country* to the *Veterinary Authority* of the *importing country*. Such systems also normally provide an interface with the commercial organisation marketing the *commodity* for provision of information to the certifying authority. The certifying veterinarian must have access to all information such as laboratory results and animal identification data.
2. Electronic certificates should carry the same information as conventional certificates.
3. The *Veterinary Authority* must have in place systems for the security of electronic certificates against access by unauthorised persons or organisations.
4. The certifying veterinarian must be officially responsible for the secure use of his/her electronic signature.

SECTION 1.3.

RISK ANALYSIS

CHAPTER 1.3.1.

GENERAL CONSIDERATIONS

Article 1.3.1.1.

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 in-house procedure for settlement of disputes.

Chapter 1.3.2. provides guidelines and principles for conducting transparent, objective and defensible *risk analyses* for *international trade*. The components of *risk analysis* described in that Chapter are *hazard identification*, *risk assessment*, *risk management* and *risk communication* (Figure 1).

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

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

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

Article 1.3.1.2.

The Agreement on the Application of Sanitary and Phytosanitary Measures and role and responsibility of the OIE

The SPS Agreement encourages WTO Members to base their *sanitary measures* on international standards, guidelines and recommendations, where they exist. Members may choose to adopt a higher level of protection than that provided by international texts if there is a scientific justification or if the level of protection provided by the relevant international texts is considered to be inappropriate. In such circumstances, Members are subject to obligations relating to *risk assessment* and to a consistent approach of *risk management*.

The SPS Agreement encourages Governments to make a wider use of *risk analysis*: WTO Members shall undertake an assessment as appropriate to the circumstances of the actual *risk* involved.

The SPS Agreement recognises the OIE as the relevant international organisation responsible for the development and promotion of international animal health standards, guidelines, and recommendations affecting trade in live *animals* and animal products.

Article 1.3.1.3.

The OIE in-house procedure for settlement of disputes

OIE shall maintain its existing voluntary in-house mechanisms for assisting Member Countries to resolve differences. In-house procedures which will apply are that:

1. Both parties agree to give the OIE a mandate to assist them in resolving their differences.

2. If considered appropriate, the Director General of the OIE recommends an expert, or experts, and a chairman, as requested, agreed by both parties.

3. Both parties agree on the terms of reference and working programme, and to meet all expenses incurred by the OIE.

4. The expert or experts are entitled to seek clarification of any of the information and data provided by either country in the assessment or consultation processes, or to request additional information or data from either country.

5. The expert or experts shall submit a confidential report to the Director General, who will transmit it to both parties.

CHAPTER 1.3.2.

GUIDELINES FOR IMPORT RISK ANALYSIS

Article 1.3.2.1.

Introduction

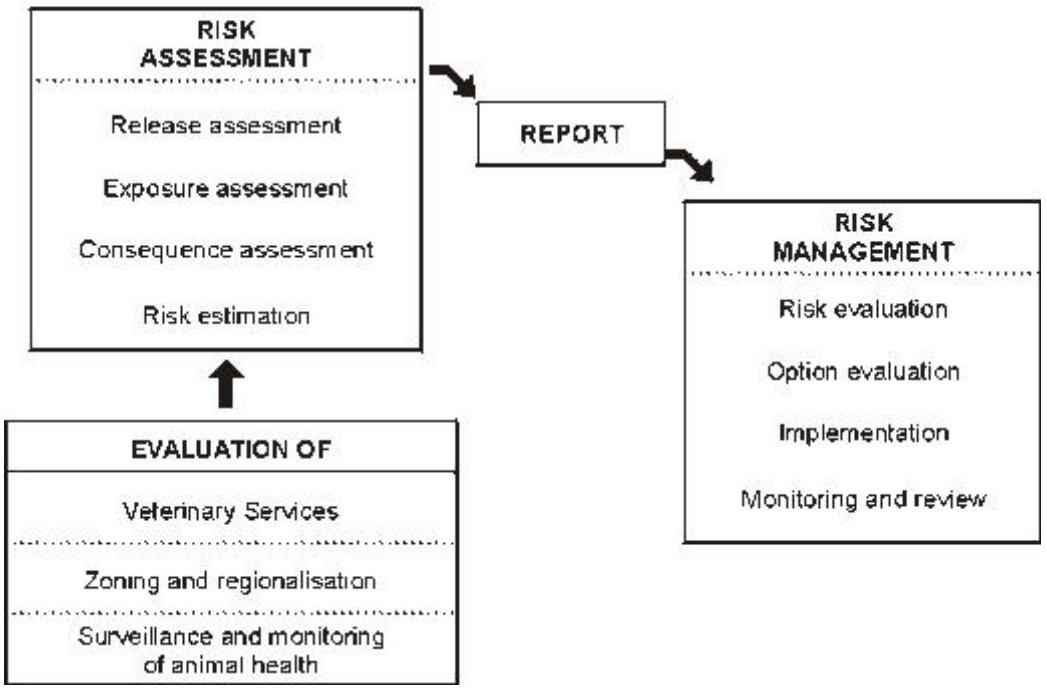
An import risk analysis begins with a description of the *commodity* proposed for import and the likely annual quantity of trade. It must be recognised that whilst an accurate estimate of the anticipated quantity of trade is desirable to incorporate into the risk estimate, it may not be readily available, particularly where such trade is new.

Hazard identification is an essential step which must be conducted before the *risk assessment*.

The *risk assessment* process consists of four interrelated steps. These steps clarify the stages of the *risk assessment*, describing them in terms of the events necessary for the identified potential *risk(s)* to occur, and facilitate understanding and evaluation of the outputs. The product is the *risk assessment* report which is used in *risk communication* and *risk management*.

The relationships between *risk assessment* and *risk management* processes are outlined in Figure 1.

Fig. 1. ***The relationship between risk assessment and risk management processes***



Article 1.3.2.2.

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 1.3.2.3.

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* must 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.

Article 1.3.2.4.

Risk assessment steps

1. Release assessment

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 release assessment describes the probability of the 'release' 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 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 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 release assessment demonstrates no significant *risk*, the *risk assessment* conclude.

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:

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 must 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 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 1.3.2.5.

Principles of risk management

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

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

Article 1.3.2.6.

Risk management components

1. Risk evaluation - the process of comparing the *risk* estimated in the *risk assessment* with the Member Country's appropriate level of protection.

2. Option evaluation - the process of identifying, evaluating the efficacy and feasibility of, and selecting measures in order to reduce the *risk* associated with an importation in line with the Member Country's 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.

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 1.3.2.7.

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.

CHAPTER 1.3.3.

EVALUATION OF VETERINARY SERVICES

Article 1.3.3.1.

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

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

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

These fundamental principles are presented in Article 1.3.3.2. Other factors affecting quality are described in Part 1. (notification, principles of certification, etc.).

The quality of *Veterinary Services* can be measured through an evaluation, whose general principles are described in Article 1.3.3.3. and in Article 1.3.3.4.

Guidelines for the evaluation of *Veterinary Services* are described in Chapter 1.3.4.

A procedure for evaluating *Veterinary Services* by OIE experts, on a voluntary basis, is described in Article 1.3.3.5.

Article 1.3.3.2.

Fundamental principles of quality

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

1. Professional judgement

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

2. Independence

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

3. Impartiality

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

4. Integrity

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

5. Objectivity

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

6. General organisation

   The *Veterinary Services* must be able to demonstrate by means of appropriate legislation, sufficient financial resources and effective organisation that they are in a position to have control of the establishment and

application of animal health measures, and of international veterinary certification activities. Legislation should be suitably flexible to allow for judgements of equivalence and efficient responses to changing situations. In particular, they should define and document the responsibilities and structure of the organisations in charge of the animal identification system, control of animal movements, animal disease control and reporting systems, epidemiological surveillance and communication of epidemiological information.

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

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

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

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

7. Quality policy

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

8. Procedures and standards

The *Veterinary Services* should develop and document appropriate procedures and standards for all providers of relevant activities and associated facilities. These procedures and standards may for example relate to:

a) programming and management of activities, including international veterinary certification activities;

b) prevention, control and notification of disease *outbreaks*;

c) risk analysis, epidemiological surveillance and zoning;

d) inspection and sampling techniques;

e) diagnostic tests for animal *diseases*;

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

g) border controls and import regulations;

h) *disinfection* and *disinfestation*;

i) treatments intended to destroy, if appropriate, pathogens in animal products.

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

9. Information, complaints and appeals

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

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

10. Documentation

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

11. Self-evaluation

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

    A procedure for evaluating *Veterinary Services* by OIE experts, on a voluntary basis, is described in Article 1.3.3.5.

12. Communication

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

13. Human and financial resources

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

Article 1.3.3.3.

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

Any evaluation of *Veterinary Services* should be conducted having regard to the OIE Guidelines for the evaluation of *Veterinary Services* presented in Chapter 1.3.4.

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

Article 1.3.3.4.

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

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

The evaluation process should take into account the fundamental principles and other factors of quality laid down in Article 1.3.3.1. and in Article 1.3.3.2. It should also take into consideration the specific circumstances regarding quality, as described in Article 1.3.3.1., prevailing in the countries concerned.

The outcome of the evaluation conducted by a Member Country should be provided in writing as soon as possible, and in any case within 4 months of receipt of the relevant information, to the Member Country which has undergone the evaluation. The evaluation report should detail any findings which affect trade prospects. The Member Country which conducts the evaluation should clarify in detail any points of the evaluation on request.

In the event of a dispute between two Member Countries over the conduct or the conclusions of the evaluation of the *Veterinary Services*, the matter should be dealt with having regard to the procedures set out in Article 1.3.1.3.

Article 1.3.3.5.

Evaluation facilitated by OIE experts under the auspices of the OIE

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

The OIE International Committee endorses a list of approved experts to facilitate the evaluation process.

Under these procedures, the Director General of the OIE recommends an expert(s) from that list.

The expert(s) facilitate(s) the evaluation of the *Veterinary Services* of the Member Country based on the provisions in Chapter 1.3.4., using the Performance, Vision and Strategy [PVS] Instrument.

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

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

CHAPTER 1.3.4.

GUIDELINES FOR THE EVALUATION OF VETERINARY SERVICES

Article 1.3.4.1.

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 1.3.3.

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 guidelines 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 guidelines 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 guidelines should be used by OIE experts when facilitating an evaluation under the auspices of the OIE, following a request of a Member Country. In applying these guidelines for the evaluation, the Performance, Vision and Strategy [PVS] Instrument 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 resource adequacy, management capability, legislative and administrative infrastructures, independence in the exercise of official functions and performance history, including disease reporting.

5. Competence and integrity are qualities on which others base their confidence in individuals or organisations. Mutual confidence between relevant official *Veterinary Services* of trading partner countries contributes fundamentally to stability in *international trade* in *animals* and animal-related products. In this situation, scrutiny is directed more at the *exporting country* than at the *importing country*.

6. Although quantitative data can be provided on *Veterinary Services*, the ultimate evaluation will be essentially qualitative. While it is appropriate to evaluate resources and infrastructure (organisational, administrative and legislative), it is also appropriate to place emphasis on the evaluation of the quality of outputs and performance of *Veterinary Services*. Evaluation should take into consideration any quality systems used by *Veterinary Services*.

7. An *importing country* has a right of assurance that information on sanitary/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 1.3.4.2.

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;
   - functional capabilities and legislative support;
   - animal health and veterinary public health controls;
   - formal quality systems including quality policy;
   - performance assessment and audit programmes;
   - participation in OIE activities and compliance with OIE Member Countries' obligations.
2. To complement the evaluation of *Veterinary Services*, the organisational structure and functioning of the *veterinary statutory body* should also be considered.
3. Article 1.3.4.14. 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 experts or regional organisations.

Article 1.3.4.3.

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 Chapter 1.1.1. 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 1.3.4.4.

Evaluation criteria for quality systems

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

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

Article 1.3.4.5.

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 must 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 1.3.4.6.

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 1.3.4.14. 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.

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* must 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 1.3.4.7.

Functional capabilities and legislative support

1. Animal health 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. 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 Section 1.2. 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.

Article 1.3.4.8.

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* must 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 Country, failure to provide the necessary animal health reports consistent with OIE requirements will detract from the overall outcome of the evaluation of the country.

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

2. Animal health control

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

3. National animal disease reporting systems

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

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

Article 1.3.4.9.

Veterinary public health controls

1. Food hygiene

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

2. Zoonoses

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

3. Chemical residue testing programmes

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

4. Veterinary medicines

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

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

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

5. Integration between animal health controls and veterinary public health

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

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

Article 1.3.4.10.

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.

Article 1.3.4.11.

Participation in OIE activities

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

Article 1.3.4.12.

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.

Article 1.3.4.13.

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

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

3. In the case of evaluation for the purposes of *international trade*, the authorities of an *importing country* should use the principles elaborated above as the basis for the evaluation and should attempt to acquire information according to the model questionnaire outlined in Article 1.3.4.14. 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 must 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 must be willing to defend any position taken on the basis of this type of information, if challenged by the other party.

Article 1.3.4.14.

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 to these private veterinarians.]*
         - other *veterinarians*.

iii) Animal health:

Numbers associated with farm livestock sector on a majority time basis in a veterinary capacity, by geographical area *[Show categories and numbers to differentiate staff involved in field service, laboratory, administration, import/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);
- international recognition of veterinary degree.

vii) Veterinary professional associations.

b) Graduate personnel (non-veterinary)

Details to be provided by category (including biologists, biometricians, economists, engineers, lawyers, other science graduates and others) on numbers within the *Veterinary Authority* and available to the *Veterinary Authority*.

c) Veterinary para-professionals employed by the Veterinary Services

i) Animal health:

- Categories and numbers involved with farm livestock on a majority time basis:
  - by geographical area;
  - proportional to numbers of field Veterinary Officers in the *Veterinary Services*, by geographical area.
- Education/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 official or 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.

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. <u>Functional capabilities and legislative support</u>

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;
- 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.

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.

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*.

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.

11. Other assessment criteria

CHAPTER 1.3.5.

ZONING AND COMPARTMENTALISATION

Article 1.3.5.1.

Introduction

For the purposes of the *Terrestrial Code*, 'zoning' and 'regionalisation' have the same meaning.

Given the difficulty of establishing and maintaining a *disease* free status for an entire country, especially for *diseases* the entry of which is difficult to control through measures at national boundaries, there may be benefits to a Member Country in establishing and maintaining a *subpopulation* with a distinct health status within its territory. *Subpopulations* may be separated by natural or artificial geographical barriers or, in certain situations, by the application of appropriate management practices.

Zoning and compartmentalisation are procedures implemented by a country under the provisions of this chapter with a view to defining *subpopulations* of distinct health status within its territory for the purpose of *disease* control and/or *international trade*. While zoning applies to an animal *subpopulation* defined primarily on a geographical basis (using natural, artificial or legal boundaries), compartmentalisation applies to an animal *subpopulation* defined primarily by management and husbandry practices related to biosecurity. In practice, spatial considerations and good management play important roles in the application of both concepts.

This chapter is to assist OIE Member Countries wishing to establish and maintain different *subpopulations* within their territory using the principles of compartmentalisation and zoning. These principles should be applied in accordance with the measures recommended in the relevant *disease* chapter(s). This chapter also outlines a process through which trading partners may recognise such *subpopulation*. This process is best implemented by trading partners through establishing parameters and gaining agreement on the necessary measures prior to *disease outbreaks*.

Before trade in animals or their products may occur, an *importing country* needs to be satisfied that its *animal health status* will be appropriately protected. In most cases, the import regulations developed will rely in part on judgements made about the effectiveness of sanitary procedures undertaken by the *exporting country*, both at its borders and within its territory.

As well as contributing to the safety of *international trade*, zoning and compartmentalisation may assist *disease* control or eradication within Member Countries. Zoning may encourage the more efficient use of resources within certain parts of a country and compartmentalisation may allow the functional separation of a *subpopulation* from other domestic or wild animals through biosecurity measures, which a *zone* (through geographical separation) would not achieve. Following a *disease outbreak*, the use of compartmentalisation may allow a Member Country to take advantage of epidemiological links among *subpopulations* or common practices relating to biosecurity, despite diverse geographical locations, to facilitate *disease* control and/or the continuation of trade.

Zoning and compartmentalisation cannot be applied to all *diseases* but separate requirements will be developed for each *disease* for which the application of zoning or compartmentalisation is considered appropriate.

To regain free status following a *disease outbreak* in a *zone* or *compartment*, Member Countries should follow the recommendations in the relevant *disease* chapter in the *Terrestrial Code*.

Article 1.3.5.2.

General considerations

The *Veterinary Services* of an *exporting country* which is establishing a *zone* or *compartment* within its territory for *international trade* purposes should clearly define the *subpopulation* in accordance with the recommendations in the relevant chapters in the *Terrestrial Code*, including those on surveillance, and the identification and traceability of live animals. The *Veterinary Services* of an *exporting country* should be able to explain to the *Veterinary Services* of an *importing country* the basis for its claim of a distinct *animal health status* for the *zone* or *compartment* in such terms.

The procedures used to establish and maintain the distinct *animal health status* of a *zone* or *compartment* should be appropriate to the particular circumstances, and will depend on the epidemiology of the *disease*, environmental factors and applicable biosecurity measures.

The authority, organisation and infrastructure of the *Veterinary Services*, including laboratories, must be clearly documented in accordance with the chapter on the evaluation of *Veterinary Services* of the *Terrestrial Code*, to provide confidence in the integrity of the *zone* or *compartment*. The final authority of the *zone* or *compartment*, for the purposes of domestic and *international trade*, lies with the *Veterinary Authority*.

In the context of maintaining the health status of a *population*, references to 'import', 'importation' and 'imported animals/products' found in the *Terrestrial Code* apply both to importation into a country and to the movement of animals and their products into *zones* and *compartments*. Such movements should be the subject of appropriate measures to preserve the *animal health status* of the *zone/compartment*.

The *exporting country* should be able to demonstrate, through detailed documentation provided to the *importing country*, that it has implemented the recommendations in the *Terrestrial Code* for establishing and maintaining such a *zone* or *compartment*.

An *importing country* should recognise the existence of this *zone* or *compartment* when the appropriate measures recommended in the *Terrestrial Code* are applied and the *Veterinary Authority* of the *exporting country* certifies that this is the case.

The *exporting country* should conduct an assessment of the resources needed and available to establish and maintain a *zone* or *compartment* for *international trade* purposes. These include the human and financial resources, and the technical capability of the *Veterinary Services* (and of the relevant industry, in the case of a *compartment*) including *disease* surveillance and diagnosis.

Biosecurity and surveillance are essential components of zoning and compartmentalisation, and the arrangements should be developed through cooperation of industry and *Veterinary Services*.

Industry's responsibilities include the application of biosecurity measures, quality assurance schemes, monitoring the efficacy of the measures, documenting corrective actions, conducting surveillance, rapid reporting and maintenance of records in a readily accessible form.

The *Veterinary Services* should provide movement certification, periodic inspections of facilities, biosecurity measures, records and surveillance procedures. *Veterinary Services* should conduct or audit surveillance, reporting and laboratory diagnostic examinations.

Article 1.3.5.3.

Principles for defining a zone or compartment

In conjunction with the above considerations, the following principles should apply when Member Countries define a *zone* or a *compartment*.

1. The extent of a *zone* and its geographical limits should be established by the *Veterinary Authority* on the basis of natural, artificial and/or legal boundaries, and made public through official channels.
2. The factors defining a *compartment* should be established by the *Veterinary Authority* on the basis of relevant criteria such as management and husbandry practices related to biosecurity, and made public through official channels.
3. Animals and herds belonging to such *subpopulations* need to be recognisable as such through a clear epidemiological separation from other animals and all things presenting a *disease risk*. For a *zone* or *compartment*, the *Veterinary Authority* should document in detail the measures taken to ensure the identification of the *subpopulation* and the establishment and maintenance of its health status through a *biosecurity plan*. The measures used to establish and maintain the distinct *animal health status* of a *zone* or *compartment* should be appropriate to the particular circumstances, and will depend on the epidemiology of the *disease*, environmental factors, the health status of animals in adjacent areas, applicable biosecurity measures (including movement controls, use of natural and artificial boundaries, the spatial separation of animals, and commercial management and husbandry practices), and surveillance.
4. Relevant animals within the *zone* or *compartment* should be identified in such a way that their history can be audited. Depending on the system of production, identification may be done at the herd, flock lot or

individual animal level. Relevant animal movements into and out of the *zone* or *compartment* should be well documented, controlled and supervised. The existence of a valid animal identification system is a prerequisite to assess the integrity of the *zone* or *compartment*.

5. For a *compartment*, the *biosecurity plan* should describe the partnership between the relevant industry and the *Veterinary Authority*, and their respective responsibilities. It should also describe the routine operating procedures to provide clear evidence that the surveillance conducted, the live *animal identification* and *traceability* system, and the management practices are adequate to meet the definition of the *compartment*. In addition to information on animal movement controls, the plan should include herd or flock production records, feed sources, surveillance results, birth and death records, visitor logbook, morbidity and mortality history, medications, vaccinations, documentation of training of relevant personnel and any other criteria necessary for evaluation of *risk* mitigation. The information required may vary according to the species and *disease(s)* under consideration. The *biosecurity plan* should also describe how the measures will be audited to ensure that the *risks* are regularly re-assessed and the measures adjusted accordingly.

Article 1.3.5.4.

Sequence of steps to be taken in establishing a zone/compartment and having it recognised for international trade purposes

There is no single sequence of steps which should be followed in establishing a *zone* or a *compartment*. The steps that the *Veterinary Services* of the *importing country* and the *exporting country* choose and implement will generally depend on the circumstances existing within the countries and at their borders, and their trading history. The recommended steps are:

1. <u>For zoning</u>

   a) The *exporting country* identifies a geographical area within its territory, which it considers to contain an animal *subpopulation* with a distinct health status with respect to a specific *disease*/specific *diseases*, based on surveillance.

   b) The *exporting country* describes in the *biosecurity plan* for the *zone* the measures which are being, or will be, applied to distinguish such an area epidemiologically from other parts of its territory, in accordance with the recommendations in the *Terrestrial Code*.

   c) The *exporting country* provides:

      i) the above information to the *importing country*, with an explanation of why the area can be treated as an epidemiologically separate *zone* for *international trade* purposes;

      ii) access to enable the procedures or systems that establish the *zone* to be examined and evaluated upon request by the *importing country*.

   d) The *importing country* determines whether it accepts such an area as a *zone* for the importation of *animals* and animal products, taking into account:

      i) an evaluation of the *exporting country*'s *Veterinary Services*;

      ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;

      iii) its own animal health situation with respect to the *disease(s)* concerned; and

      iv) other relevant OIE standards.

   e) The *importing country* notifies the *exporting country* of its determination and the underlying reasons, within a reasonable period of time, being:

      i) recognition of the *zone*; or

      ii) request for further information; or

      iii) rejection of the area as a *zone* for *international trade* purposes.

f) An attempt should be made to resolve any differences over recognition of the *zone*, either in the interim or finally, by using an agreed mechanism to reach consensus such as the OIE in-house procedure for settlement of disputes (Article 1.3.1.3.).

g) The *Veterinary Authorities* of the *importing* and *exporting countries* should enter into a formal agreement recognizing the *zone*.

2. For compartmentalisation

a) Based on discussions with the relevant industry, the *exporting country* identifies within its territory a *compartment* of one or more *establishments* or other premises which operates under common management practices related to biosecurity and which contains an identifiable animal *subpopulation* with a distinct health status with respect to a specific *disease*/specific *diseases*; the *exporting country* describes how this status is maintained through a partnership between the relevant industry and the *Veterinary Authority* of the *exporting country*.

b) The *exporting country* examines the *compartment*'s *biosecurity plan* and confirms through an audit that:

i) the *compartment* is epidemiologically closed throughout its routine operating procedures as a result of effective implementation of its *biosecurity plan*; and

ii) the surveillance and monitoring programme in place is appropriate to verify the status of such *establishment*(s) with respect to such *disease(s)*.

c) The *exporting country* describes the *compartment*, in accordance with the recommendations in the *Terrestrial Code*.

d) The *exporting country* provides:

i) the above information to the *importing country*, with an explanation of why such an *establishment(s)* can be treated as an epidemiologically separate *compartment* for *international trade* purposes; and

ii) access to enable the procedures or systems that establish the *compartment* to be examined and evaluated upon request by the *importing country*.

e) The *importing country* determines whether it accepts such *establishment(s)* as a *compartment* for the importation of *animals* and animal products, taking into account:

i) an evaluation of the *exporting country*'s *Veterinary Services*;

ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;

iii) its own animal health situation with respect to the *disease(s)* concerned; and

iv) other relevant OIE standards.

f) The *importing country* notifies the *exporting country* of its determination and the underlying reasons, within a reasonable period of time, being:

i) recognition of the *compartment*; or

ii) request for further information; or

iii) rejection of such *establishment(s)* as a *compartment* for *international trade* purposes.

g) An attempt should be made to resolve any differences over recognition of the *compartment*, either in the interim or finally, by using an agreed mechanism to reach consensus such as the OIE in-house procedure for settlement of disputes (Article 1.3.1.3.).

h) The *Veterinary Authorities* of the *importing* and *exporting countries* should enter into a formal agreement recognizing the *compartment*.

CHAPTER 1.3.6.

GUIDELINES FOR REACHING A JUDGEMENT OF EQUIVALENCE OF SANITARY MEASURES

Article 1.3.6.1.

Introduction

The importation of *animals* and animal products involves a degree of *risk* to the animal health status of an *importing country*. The estimation of that *risk* and the choice of the appropriate *risk management* option(s) are made more difficult by differences among the animal health and production systems in OIE Member Countries. It is now recognised that significantly different animal health and production systems can provide equivalent animal and human health protection for the purpose of *international trade*, with benefits to both the *importing country* and the *exporting country*.

These guidelines are to assist OIE Member Countries to determine whether *sanitary measures* arising from different animal health and production systems may provide the same level of animal and human health protection. They discuss principles which might be utilised in a judgement of equivalence, and outline a step-wise process for trading partners to follow in facilitating a judgement of equivalence. These guidelines are applicable whether equivalence applies at the level of specific measures or on a systems-wide basis, and whether equivalence applies to specific areas of trade or *commodities*, or generally.

Article 1.3.6.2.

General considerations

Before trade in *animals* or their products may occur, an *importing country* must be satisfied that its *animal health status* will be appropriately protected. In most cases, the *risk management* measures drawn up will rely in part on judgements made about the animal health and production system(s) in the *exporting country* and the effectiveness of sanitary procedures undertaken there. Systems operating in the *exporting country* may differ from those in the *importing country* and from those in other countries with which the *importing country* has traded. Differences may be with respect to infrastructure, policies and/or operating procedures, laboratory systems, approaches to the pests and *diseases* present, border security and internal movement controls.

International recognition of the legitimacy of different approaches to achieving the *importing country*'s *appropriate level of protection* (ALOP) has led to the principle of equivalence being included in trade agreements, including the Agreement on Application of Sanitary and Phytosanitary Measures (the SPS Agreement) of the World Trade Organization (WTO).

Benefits of applying equivalence may include:

1. minimising costs associated with *international trade* by tailoring animal health measures to local circumstances;
2. maximising animal health outcomes for a given level of resource input;
3. facilitating trade by achieving the required health protection through less trade restrictive *sanitary measures*; and
4. decreased reliance on relatively costly *commodity* testing and isolation procedures in bilateral or multilateral agreements.

The *Terrestrial Code* recognises equivalence by recommending alternative *sanitary measures* for many *diseases* and pathogenic agents. Equivalence may be gained, for example, by enhanced surveillance and monitoring, by the use of alternative test, treatment or isolation procedures, or by combinations of the above. To facilitate the judgement of equivalence, Member Countries should base their *sanitary measures* on OIE standards, guidelines and recommendations.

It is essential to apply a scientific risk analysis to the extent practicable in establishing the basis for a judgement of equivalence.

Article 1.3.6.3.

Prerequisite considerations in a judgement of equivalence

1. Application of risk assessment

   Application of the discipline of *risk assessment* provides a structured basis for judging equivalence among different *sanitary measures* as it allows a close examination to be made of the effect of a measure(s) on a particular step(s) in the importation pathway, and the relative effects of proposed alternative measure(s) on the same or related steps.

   A judgement of equivalence needs to assess the *sanitary measure* in terms of its effectiveness regarding the particular *risk* or group of *risks* against which the measure is designed to protect. Such an assessment may include the following elements: the purpose of the measure, the level of protection achieved by the measure and the contribution the measure makes to achieving the ALOP of the *importing country*.

2. Categorisation of sanitary measures

   Proposals for equivalence may be in terms of a measure comprising a single component of a measure (e.g. an isolation procedure, a test or treatment requirement, a certification procedure) or multiple components (e.g. a production system for *commodity*), or a combination of measures. Multiple components or combinations of measures may be applied consecutively or concurrently.

   Sanitary measures are those described in each Chapter of the *Terrestrial Code* which are used for risk reduction and are appropriate for particular *diseases*. *Sanitary measures* may be applied either alone or in combination and include test requirements, processing requirements, inspection or certification procedures, quarantine confinements, and sampling procedures.

   For the purposes of judging equivalence, *sanitary measures* can be broadly categorised as:

   a) infrastructure: including the legislative base (e.g. animal health law) and administrative systems (e.g. organisation of national and regional animal health authorities, emergency response organisations);

   b) programme design/implementation: including documentation of systems, performance and decision criteria, laboratory capability, and provisions for certification, audit and enforcement;

   c) specific technical requirement: including requirements applicable to the use of secure facilities, treatment (e.g. retorting of cans), specific test (e.g. ELISA) and procedures (e.g. pre-export inspection).

   A *sanitary measure(s)* proposed for a judgement of equivalence may fall into one or more of these categories, which are not mutually exclusive.

   In some cases, a comparison of specific technical requirements may suffice. In many instances, however, a judgement as to whether the same level of protection is likely to be achieved may only be able to be determined through an evaluation of all relevant components of an *exporting country*'s animal health and production system. For example, a judgement of equivalence for a specific *sanitary measure* at the programme design/implementation level may require a prior examination of infrastructure while a judgement of equivalence for a specific measure at the specific technical requirement level may require that the specific measure be judged in its context through examination of infrastructure and programmes.

Article 1.3.6.4.

Principles for judgement of equivalence

In conjunction with the above considerations, judgement of the equivalence of *sanitary measures* should be based on application of the following principles:

1. an *importing country* has the right to set the level of protection it deems appropriate (its ALOP) in relation to human and animal life and health in its territory; this ALOP may be expressed in qualitative or quantitative terms;

2. the *importing country* should be able to describe the reason for each *sanitary measure* i.e. the level of protection intended to be achieved by application of the identified measure against a *hazard*;
3. an *importing country* should recognise that *sanitary measures* different from the ones it has proposed may be capable of providing the same level of protection;
4. the *importing country* should, upon request, enter into consultations with the *exporting country* with the aim of facilitating a judgement of equivalence;
5. any *sanitary measure* or combination of *sanitary measures* can be proposed for judgement of equivalence;
6. an interactive process should be followed that applies a defined sequence of steps, and utilises an agreed process for exchange of information, so as to limit data collection to that which is necessary, minimise administrative burden, and facilitate resolution of claims;
7. the *exporting country* should be able to demonstrate objectively how the alternative *sanitary measure(s)* proposed as equivalent will provide the same level of protection;
8. the *exporting country* should present a submission for equivalence in a form that facilitates judgement by the *importing country*;
9. the *importing country* should evaluate submissions for equivalence in a timely, consistent, transparent and objective manner, and according to appropriate *risk assessment* principles;
10. the *importing country* should take into account any knowledge of and prior experience with the *Veterinary Authority* or other *Competent Authority* of the *exporting country*;
11. the *exporting country* should provide access to enable the procedures or systems which are the subject of the equivalence judgement to be examined and evaluated upon request of the *importing country*;
12. the *importing country* should be the sole determinant of equivalence, but should provide to the *exporting country* a full explanation for its judgement;
13. to facilitate a judgement of equivalence, Member Countries should base their *sanitary measures* on relevant OIE standards;
14. to allow the judgement of equivalence to be reassessed if necessary, the *importing country* and the *exporting country* should keep each other informed of significant changes to infrastructure, health status or programmes which may bear on the judgement of equivalence; and
15. an *importing country* should give positive consideration to a request by an exporting developing country for appropriate technical assistance that would facilitate the successful completion of a judgement of equivalence.

Article 1.3.6.5.

Sequence of steps to be taken in judgement of equivalence

There is no single sequence of steps which must be followed in all judgements of equivalence. The steps that trading partners choose will generally depend on the circumstances and their trading experience. The interactive sequence of steps described below may be useful for all *sanitary measures* irrespective of their categorisation as infrastructure, programme design/implementation or specific technical requirement components of an animal health and production system.

This sequence assumes that the *importing country* is meeting its obligations under the WTO SPS Agreement and has in place a transparent measure based either on an international standard or a *risk analysis.*

Recommended steps are:

1. the *exporting country* identifies the measure(s) for which it wishes to propose an alternative measure(s), and requests from the *importing country* a reason for its *sanitary measure* in terms of the level of protection intended to be achieved against a *hazard(s)*;
2. the *importing country* explains the reason for the measure(s), in terms which would facilitate comparison with an alternative *sanitary measure(s)* and consistent with the principles set out in these guidelines;
3. the *exporting country* demonstrates the case for equivalence of an alternative *sanitary measure(s)* in a form which facilitates analysis by an *importing country*;

4. the *exporting country* responds to any technical concerns raised by the *importing country* by providing relevant further information;
5. judgement of equivalence by the *importing country* takes into account as appropriate:
   a) the impact of biological *variability* and *uncertainty*;
   b) the expected effect of the alternative *sanitary measure(s)* on all relevant *hazards*;
   c) OIE standards;
   d) application of solely qualitative frameworks where it is not possible or reasonable to conduct *quantitative risk assessment*;
6. the *importing country* notifies the *exporting country* of its judgement and the underlying reasons within a reasonable period of time:
   a) recognition of the equivalence of the *exporting country*'s alternative *sanitary measure(s)*;
   b) request for further information; or
   c) rejection of the case for equivalence of the alternative *sanitary measure(s)*;
7. an attempt should be made to resolve any differences of opinion over judgement of a case, either interim or final, by using an agreed mechanism to reach consensus (e.g. the OIE dispute settlement mechanism), or by referral to an agreed expert;
8. depending on the category of measures involved, the *importing country* and the *exporting country* may enter into a formal equivalence agreement giving effect to the judgement or a less formal acknowledgement of the equivalence of a specific measure(s) may suffice.

An *importing country* recognising the equivalence of an *exporting country*'s alternative *sanitary measure(s)* needs to ensure that it acts consistently with regard to applications from third countries for recognition of equivalence applying to the same or very similar measure(s). Consistent action does not mean however that a specific measure(s) proposed by several *exporting countries* should always be judged as equivalent as a measure(s) should not be considered in isolation but as part of a system of infrastructure, policies and procedures.

SECTION 1.4.

IMPORT/EXPORT PROCEDURES

CHAPTER 1.4.1.

ANIMAL HEALTH MEASURES APPLICABLE BEFORE AND AT DEPARTURE

Article 1.4.1.1.

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

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

3. Observation of the *animals* before leaving the country may be carried out either in the *establishment* where they were reared, or in a *quarantine station*. When they have been found to be clinically healthy and free from *diseases listed by the OIE* by an *Official Veterinarian* during the period of observation, the *animals* should be transported to the *place of shipment* in specially constructed *vehicles*, previously cleansed and disinfected. This must be done without delay and without the *animals* coming into contact with other susceptible animals, unless these animals have animal health guarantees similar to those of the transported *animals*.

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

Article 1.4.1.2.

Countries should only undertake the export from its territory of:

a) semen,

b) embryos/ova,

c) *hatching eggs*,

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

Article 1.4.1.3.

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

Article 1.4.1.4.

Before the departure of *animals*, semen, embryos/ova, *hatching eggs* and brood-combs of bees, an *Official Veterinarian* should, within the 24 hours prior to shipment, provide an *international veterinary certificate* conforming with the models approved by the OIE (as shown in Part 4 of the *Terrestrial Code*) and worded in the languages agreed upon between the *exporting country* and the *importing country*, and, where necessary, with the *transit countries*.

Article 1.4.1.5.

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

2. The *Veterinary Authority* referred to in point 1 above shall take necessary measures to:

   a) prevent the shipment of *animals* affected or suspected of being affected with any *disease listed by the OIE* or with any other infectious disease;

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

Article 1.4.1.6.

1. Countries should only authorise the export from their territory of *meat* and products of animal origin intended for human consumption, which are fit for human consumption. They must be accompanied by an *international veterinary certificate* conforming with the models approved by the OIE (as shown in Part 4. of the *Terrestrial Code*). These must be worded in the languages agreed upon between the *exporting country* and the *importing country*, and, where necessary, with the *transit countries*.

2. Products of animal origin intended for use in animal feeding, or for pharmaceutical or surgical or agricultural or industrial use, should be accompanied by an *international veterinary certificate* conforming with the models approved by the OIE (as shown in Part 4. of the *Terrestrial Code*).

CHAPTER 1.4.2.

ANIMAL HEALTH MEASURES APPLICABLE DURING TRANSIT FROM THE PLACE OF DEPARTURE IN THE EXPORTING COUNTRY TO THE PLACE OF ARRIVAL IN THE IMPORTING COUNTRY

Article 1.4.2.1.

1. Any country through which the transit of *animals* is required, and which normally conducts commercial transactions with the *exporting country*, should not refuse transit, subject to the reservations mentioned below and on condition that advance notice is given of the proposed transit to the *Veterinary Authority* in charge of *border posts*.

   This advance notice shall state the species and number of *animals*, the methods of transport and the *border posts* of entry and exit in accordance with a previously arranged and authorised itinerary in the *transit country*.

2. Any country through which transit is to take place may refuse if it considers that certain *diseases* exist in the *exporting country*, or in a *transit country* which precedes it in the itinerary, which are capable of being transmitted to its own animals.

3. Any *transit country* may require the presentation of *international veterinary certificates*. Such a country may, in addition, cause an examination to be made by an *Official Veterinarian* of the health status of *animals* in transit, except in cases where transport in sealed *vehicles* or *containers* is a condition of transit.

4. Any *transit country* may refuse passage through its territory of *animals* presented at one of its *border posts* if an examination carried out by an *Official Veterinarian* shows that the *animal* or consignment of *animals* in transit is affected by or infected with any of the notifiable epizootic diseases, or if the *international veterinary certificate* is inaccurate and/or unsigned.

   In these circumstances, the *Veterinary Authority* of the *exporting country* shall be informed immediately, thereby providing an opportunity for checking the findings or correcting the *certificate*.

   If the diagnosis of an epizootic disease is confirmed, or if the *certificate* cannot be corrected, the *animal* or consignment of *animals* in transit shall either be returned to the *exporting country* or be slaughtered or destroyed.

5. This Article does not apply to bees that are transported in securely closed *vehicles* or *containers*.

Article 1.4.2.2.

1. Any *transit country* may require railway wagons and road *vehicles* used for the transit of *animals* through its territory to be so constructed as to prevent the escape and dispersion of excrement.

2. The *unloading* of *animals* in transit shall be permitted in the territory of the *transit country* only for purposes of watering and feeding or for welfare or other essential reasons. This must be under the effective control of an *Official Veterinarian* of the *transit country*, who should ensure that the *animals* have no contact with any other animals. The *importing country* shall be informed of any unforeseen *unloading* in the *transit country*.

Article 1.4.2.3.

Any country through which transit is required of the following *commodities*:

a) semen,

b) embryos/ova,

c) *hatching eggs*,

d) brood-combs of bees,

e) animal products,

and which allows the importation of those products, should not refuse their transit, subject to the following conditions:

1. Advance notice shall be given of the proposed transit to the *Veterinary Authority* in charge of the control of the *border posts*.

   This advance notice shall contain information on the identification of the species and the quantity of the products, the method of transport, and the *border posts* of entry into and exit from the country, in accordance with a previously arranged and authorised itinerary in the *transit country*.

2. If inspection indicates that the above-mentioned products are capable of being dangerous to the health of persons or animals, the *Veterinary Authority* of the *transit country* may order their return to the *exporting country*.

   If they cannot be returned, the *Veterinary Authority* of the *exporting country* shall be informed immediately, thereby providing an opportunity for confirming the findings before destruction of the products.

3. Strict health requirements need not apply to the transit of the products mentioned above when they are transported in sealed *vehicles* or *containers*.

Article 1.4.2.4.

Vessels stopping in a port or passing through a canal or other navigable waterway situated in the territory of a country, on their way to a port situated in the territory of another country, must comply with the conditions required by the *Veterinary Authority*, especially to prevent the *risk* of introduction of *diseases* transmitted by insects.

Article 1.4.2.5.

1. If, for reasons beyond the control of its captain, a ship or aircraft calls or lands somewhere other than at a port or airport, or at a port or airport other than that at which it should normally call or land, the captain of the ship or aircraft shall immediately notify the nearest *Veterinary Authority* or other public authority of the new port of call or place of landing.

2. As soon as the *Veterinary Authority* is notified of the calling or landing place, it shall take appropriate action.

3. Except for the circumstances mentioned in point 5 below, the *animals* and the attendants on board the ship or aircraft shall not be permitted to leave the vicinity of the docking or landing place. The removal from the vicinity, of any equipment, bedding or feedstuffs accompanying them shall not be permitted.

4. When the measures prescribed by the *Veterinary Authority* have been carried out, the ship or aircraft shall be permitted, for animal health purposes, to proceed to the port or airport at which it would normally have called or landed. If there are technical reasons why this cannot be done, it may be permitted to proceed to a port or an airport that is more suitable.

5. In an emergency, the captain of the ship or aircraft shall take all necessary measures to maintain the health and safety of the passengers, crew, attendants and *animals* on board.

CHAPTER 1.4.3.

BORDER POSTS AND QUARANTINE STATIONS IN THE IMPORTING COUNTRY

Article 1.4.3.1.

1. Countries and their *Veterinary Authorities* shall, wherever possible, take the necessary action to ensure that the *border posts* and *quarantine stations* in their territory shall be provided with an adequate organisation and sufficient equipment for the application of the measures recommended in the *Terrestrial Code.*

2. Each *border post* and *quarantine station* shall be provided with facilities for the feeding and watering of *animals*.

Article 1.4.3.2.

When justified by the amount of *international trade* and by the epidemiological situation, *border posts* and *quarantine stations* shall be provided with a *Veterinary Service* comprising personnel, equipment and premises as the case may be and, in particular, means for:

a) making clinical examinations and obtaining specimens of material for diagnostic purposes from live *animals* or carcasses of *animals* affected or suspected of being affected by an epizootic disease, and obtaining specimens of animal products suspected of contamination;

b) detecting and isolating *animals* affected by or suspected of being affected by an epizootic disease;

c) carrying out *disinfection* and possibly *disinfestation* of *vehicles* used to transport *animals* and animal products.

In addition to this, each port and international airport should ideally be provided with equipment for the sterilisation or incineration of swill or any other material dangerous to animal health.

Article 1.4.3.3.

When required for the transit of *commodities* in *international trade*, airports shall be provided, as soon as possible, with *areas of direct transit*. These must, however, comply with the conditions required by *Veterinary Authorities*, especially to prevent the *risk* of introducing *diseases* transmitted by insects.

Article 1.4.3.4.

Each *Veterinary Authority*, when requested, shall make available for the *Central Bureau* and any interested country on request:

a) a list of *border posts, quarantine stations, approved abattoirs* and storage depots in its territory which are approved for *international trade*;

b) the period of time required for notice to be given for the application of the arrangements contained in point 2 of Articles 1.4.4.1. to 1.4.4.4.;

c) a list of airports in its territory which are provided with an *area of direct transit*.

CHAPTER 1.4.4.

ANIMAL HEALTH MEASURES APPLICABLE ON ARRIVAL

Article 1.4.4.1.

1. An *importing country* should only accept into its territory *animals* which have been subjected to a health examination by an *Official Veterinarian* of the *exporting country* and which are accompanied by an *international veterinary certificate* provided by the *Veterinary Authority* of the *exporting country*.

2. An *importing country* may require adequate advance notice regarding the proposed date of entry into its territory of *animals*, stating the species, quantity, means of transport and the name of the *border post* to be used.

   In addition, *importing countries* shall publish a list of the *border posts* equipped to conduct control operations related to importation and enabling the importation and transit procedures to be carried out in the quickest and most effective way.

3. An *importing country* may prohibit the introduction into its territory of *animals* if it considers that certain *diseases* exist in the *exporting country*, or *transit countries* which precede it in the itinerary, which are capable of being transmitted to its own animals. In the case of *transit countries*, the prohibition should not apply to bees which are transported in securely closed *vehicles* or *containers*.

4. An *importing country* may prohibit the introduction into its territory of *animals* if these are found, on examination at the *border post* by an *Official Veterinarian*, to be affected by, suspected of being affected by or infected with a *disease* capable of being transmitted to the animals in its territory.

   Animals which are not accompanied by an *international veterinary certificate* conforming with the requirements of the *importing country* may also be refused entry.

   In these circumstances, the *Veterinary Authority* of the *exporting country* shall be informed immediately, thereby providing an opportunity for confirming the findings or correcting the *certificate*.

   However, the *importing country* may prescribe that the importation be placed immediately in quarantine in order to carry out clinical observation and biological examinations with a view to establishing a diagnosis.

   If the diagnosis of an epizootic disease is confirmed, or if the *certificate* cannot be corrected, the *importing country* may take the following measures:

   a) return the *animals* to the *exporting country*, if this measure does not involve transit through a third country;

   b) slaughter and destroy in cases where return to the *exporting country* would be dangerous from the health point of view or impossible from a practical point of view.

5. *Animals*, accompanied by a valid *international veterinary certificate* and found to be healthy by the *Veterinary Authority* at the *border post*, shall be permitted to be imported and transported in accordance with the requirements of the *importing country* to the point of destination.

Article 1.4.4.2.

1. Any *importing country* should only accept into its territory:

   a) semen,

   b) embryos/ova,

   c) *hatching eggs*,

   d) brood-combs of bees,

   which are accompanied by an *international veterinary certificate*.

2. An *importing country* may require adequate advance notice regarding the proposed date of entry into its territory of any consignment of the above-mentioned products, stating the species, quantity, nature and packaging of the products, and the name of the *border post* to be used.

3. A country may prohibit the importation of the above-mentioned products into its territory if it considers that certain *diseases* exist in the *exporting country*, or in the *transit countries* which precede it in the itinerary, which are capable of being introduced by these products into its territory.

4. A country may prohibit the introduction into its territory of the above-mentioned products presented at one of its *border posts*, if they are not accompanied by an *international veterinary certificate* complying with the requirements of the *importing country*.

   In these circumstances, the *Veterinary Authority* of the *exporting country* shall be notified at once, and the products may be returned to the *exporting country* or placed in quarantine and/or destroyed.

Article 1.4.4.3.

1. An *importing country* should only accept into its territory *meat* and products of animal origin intended for human consumption which comply with point 1 of Article 1.4.1.6.

2. An *importing country* may require adequate advance notice regarding the proposed date of entry into its territory of a consignment of *meat* or products of animal origin intended for human consumption together with information on the nature, quantity and packaging of the *meat* or products, and the name of the *border post* to be used.

3. If inspection of the consignment shows that the *meat* or the products of animal origin intended for human consumption might be a danger to the health of persons or animals, or if the *international veterinary certificate* is not correct or does not apply to the products, the *Veterinary Authority* of the *importing country* may cause the *meat* or products to be returned or be subjected to adequate treatment to ensure that they are safe. When the products are not returned, the *Veterinary Authority* of the *exporting country* shall be informed immediately, thereby providing an opportunity for confirming the findings.

Article 1.4.4.4.

1. An *importing country* should only accept into its territory products of animal origin intended for use in animal feeding, or for pharmaceutical or surgical or agricultural or industrial use which are accompanied by an *international veterinary certificate* provided by the relevant *Veterinary Authority* of the *exporting country*.

2. An *importing country* may require adequate advance notice regarding the proposed date of entry into its territory of a consignment of products of animal origin intended for use in animal feeding, or for pharmaceutical or surgical or agricultural or industrial use, together with information on the nature, quantity and packaging of these products, and the name of the *border post* to be used.

3. An *importing country* may prohibit the importation into its territory of products of animal origin intended for use in animal feeding, or for pharmaceutical or surgical or agricultural or industrial use if it considers that certain *diseases* exist in the *exporting country*, which are capable of being introduced by these products. There may also be prohibition of transit through countries where these *diseases* exist, except where the transport is carried out in sealed *vehicles* or *containers*.

4. When the *international veterinary certificates* have been examined and found to be correct, the importation of the above-mentioned products shall be permitted.

5. An *importing country* may require that the products of animal origin intended for use in animal feeding, or for pharmaceutical or surgical or agricultural or industrial use, be consigned to establishments approved by the *Veterinary Authority* and under its supervision.

6. If inspection of the consignment shows that the products are capable of endangering the health of persons or animals, or if the *international veterinary certificates* are not correct or do not apply to the products, the *Veterinary Authority* of the *importing country* may either return the products to the *exporting country* or cause them to be made safe.

When the products are not returned, the *Veterinary Authority* of the *exporting country* shall be informed immediately, thereby providing an opportunity for confirming the findings or correcting the *certificate*.

Article 1.4.4.5.

On the arrival at a *border post* of a *vehicle* transporting an *animal* or *animals* infected with any *disease listed by the OIE*, the *vehicle* shall be considered as contaminated, and the *Veterinary Authority* shall apply the following measures:

1. *unloading* of the *vehicle* and immediate transportation of the *animal* or *animals*, in a leak-proof *vehicle* direct to:

   a) an establishment approved by the *Veterinary Authority* for the slaughter of the *animal* or *animals* and the destruction or possibly sterilisation of their carcasses; or

   b) a *quarantine station* or, in the absence of a *quarantine station*, to a place assigned in advance which is well isolated and near the *border post*;

2. *unloading* of the *vehicle* and immediate transportation of the litter, forage and any other potentially contaminated material to an establishment assigned in advance for their destruction, and strict application of the animal health measures required by the *importing country*;

3. *disinfection* of:

   a) all baggage of the attendants;

   b) all parts of the *vehicle* which were used in the transport, feeding, watering, moving and *unloading* of the *animal* or *animals*;

4. *disinfestation*, in cases where any insect vector *diseases* are present.

Article 1.4.4.6.

On the arrival at a *border post* of a *vehicle* transporting an *animal* or *animals* suspected of being affected with any *disease listed by the OIE*, the *vehicle* shall be considered as being contaminated, and the *Veterinary Authority* may apply the measures provided in Article 1.4.4.5.

Article 1.4.4.7.

The *vehicle* shall no longer be considered as contaminated when the measures prescribed by the *Veterinary Authority* in accordance with Article 1.4.4.5. have been carried out.

The *vehicle* may then be allowed to enter.

Article 1.4.4.8.

Ships and aircraft should not be refused access to a port or airport for animal health reasons in cases of emergency.

Nevertheless, the ship or aircraft should be subjected to all of the animal health measures which the port or airport *Veterinary Authority* may consider necessary.

Article 1.4.4.9.

1. An aircraft transporting *animals* or animal products need not be regarded as coming from an *infected zone* solely because it landed in such a zone at one or more airports as long as these airports are not infected.

   This should be considered direct transit provided no offloading of *animals* and animal products takes place.

2. Any aircraft coming from a foreign country where animal *diseases* transmitted by insect vectors are present shall be subjected to *disinfestation* immediately after landing, except when such *disinfestation* was carried out immediately before departure or during the flight.

CHAPTER 1.4.5.

INTERNATIONAL TRANSFER AND LABORATORY CONTAINMENT OF ANIMAL PATHOGENS

Article 1.4.5.1.

Object

To prevent the introduction and spread of animal *diseases* caused by pathogens.

Article 1.4.5.2.

Introduction

1. The consequences of the introduction into a country of an infectious disease or an animal pathogen or new strain of animal pathogen from which it is currently free, are potentially very serious. This is because animal health, human health, the agricultural economy and trade may all be adversely affected to a greater or a lesser degree. Countries will already have in place a range of measures, such as requirements for pre-import testing and quarantine, to prevent such introductions through the importation of live *animals* or their products.
2. However, there is also the risk that disease may occur as a result of the accidental release of animal pathogens from laboratories that are using them for various purposes such as research, diagnosis or the manufacture of vaccines. Such pathogens may already occur in the country or they may have been imported deliberately or inadvertently. It is therefore necessary to have in place measures to prevent their accidental release. These measures may be applied either at national borders by prohibiting or controlling the importation of specified pathogens or their carriers (see Article 1.4.5.7.) or within national boundaries by specifying the conditions under which laboratories must handle them. In practice, a combination of external and internal controls is likely to be applied depending on the risk to animal health posed by the pathogen in question.

Article 1.4.5.3.

Purpose

1. To provide guidance on the laboratory containment of animal pathogens according to the risk they pose to animal health and the agricultural economy of a country, particularly when the disease they cause is not enzootic.
2. To provide guidance on the import conditions applicable to animal pathogens.
3. Where animal pathogens also pose a risk to human health, guidance on their laboratory containment should be sought from the *Terrestrial Manual* and other relevant published documents.

Article 1.4.5.4.

Classification of animal pathogens

1. Animal pathogens should be categorised on the risk they pose to animal health, should they be introduced into a country or accidentally released from a laboratory. In categorising pathogens into four groups according to containment requirements, the following factors should be taken into account: the organism's pathogenicity, the biohazard it presents, its ability to spread, the economic aspects and the availability of prophylactic and therapeutic treatments.

2. Some pathogens need to be transmitted by specific vectors or require intermediate hosts to complete their life cycles before they can infect animals and cause disease. In countries where such vectors or intermediate hosts do not occur, or where climatic or environmental factors mitigate against their survival, the pathogen poses a lower risk to animal health than in countries where such vectors or intermediate hosts occur naturally or could survive.

3. When categorising animal pathogens into specific groups, the following criteria should be taken into account:

   a) Group 1 animal pathogens

      Disease producing organisms which are enzootic but not subject to official control.

   b) Group 2 animal pathogens

      Disease producing organisms which are either exotic or enzootic but subject to official control and which have a low risk of spread from the laboratory.

      i) They do not depend on vectors or intermediate hosts for transmission.

      ii) There is a very limited or no transmission between different animal species.

      iii) Geographical spread if released from the laboratory is limited.

      iv) Direct animal to animal transmission is relatively limited.

      v) The need to confine diseased or infected non-diseased animals is minimal.

      vi) The disease is of limited economic and/or clinical significance.

   c) Group 3 animal pathogens

      Disease producing organisms which are either exotic or enzootic but subject to official control and which have a moderate risk of spread from the laboratory.

      i) They may depend on vectors or intermediate hosts for transmission.

      ii) Transmission between different animal species may readily occur.

      iii) Geographical spread if released from the laboratory is moderate.

      iv) Direct animal to animal transmission occurs relatively easily.

      v) The statutory confinement of diseased, infected and in-contact animals is necessary.

      vi) The disease is of severe economic and/or clinical significance.

      vii) Prophylactic and/or therapeutic treatments are not readily available or of limited benefit.

   d) Group 4 animal pathogens

      Disease producing organisms which are either exotic or enzootic but subject to official control and which have a high risk of spread from the laboratory.

      i) They may depend on vectors or intermediate hosts for transmission.

      ii) Transmission between different animal species may occur very readily.

      iii) Geographical spread if released from the laboratory is widespread.

      iv) Direct animal to animal transmission occurs very easily.

      v) The statutory confinement of diseased, infected and in-contact animals is necessary.

      vi) The statutory control of animal movements over a wide area is necessary.

      vii) The disease is of extremely severe economic and/or clinical significance.

      viii) No satisfactory prophylactic and/or therapeutic treatments are available.

Article 1.4.5.5.

Containment levels

1. The principal purpose of containment is to prevent the escape of the pathogen from the laboratory into the national animal population. Some animal pathogens can infect man. In these instances the risk to human health may demand additional containment than would otherwise be considered necessary from purely animal health considerations.
2. The level of physical containment and biosecurity procedures and practices should be related to the group into which the pathogen has been placed, and the detailed requirements should be appropriate to the type of organism (i.e. bacterium, virus, fungus or parasite). The lowest containment level will be required for pathogens in group 1 and the highest level for those in group 4. Guidance on the containment requirements for groups 2, 3 and 4 is provided in Table 1.
3. Arthropods may be pathogens or vectors for pathogens. If they are a vector for a pathogen being used in the laboratory, the appropriate containment level for the pathogen will be necessary in addition to the containment facilities for the arthropod.

Article 1.4.5.6.

Possession and handling of animal pathogens

1. A laboratory should be allowed to possess and handle animal pathogens in group 3 or 4 only if it can satisfy the relevant authority that it can provide containment facilities appropriate to the group. However, depending on the particular circumstances of an individual country, the authority might decide that the possession and handling of certain pathogens in group 2 should also be controlled. The authority should first inspect the facilities to ensure they are adequate and then issue a licence specifying all relevant conditions. There should also be a requirement for appropriate records to be kept and for the authority to be notified if it is suspected that a material being handled contains a pathogen not covered by the licence. The authority should visit the laboratory periodically to ensure licence conditions are being complied with. It is important that authority staff carrying out the visit should not have any contact with species susceptible to the pathogens being handled at the laboratory for a specified period after visiting the laboratory. The length of this period will depend on the pathogen.
2. Licences should specify:
   a) how the pathogen is to be transported and the disposal of the packaging;
   b) the name of the person responsible for the work;
   c) whether the pathogen may be used *in vivo* (and if so whether in laboratory animals or other animals) and/or only *in vitro*;
   d) how the pathogen and any experimental animals should be disposed of when the work is completed;
   e) limitations on contact by laboratory staff with species susceptible to the pathogens being used;
   f) conditions for the transfer of pathogens to other laboratories;
   g) specific conditions relating to the appropriate containment level and biosecurity procedures and practices.

Article 1.4.5.7.

Importation of animal pathogens

1. The importation of any animal pathogen, *pathological material* or organisms carrying the pathogen should be permitted only under an import licence issued by the relevant authority. The import licence should contain conditions appropriate to the risk posed by the pathogen and, in relation to air transport, the appropriate standards of the International Air Transport Association concerning the packaging and transport of hazardous substances. The import licence for group 2, 3 or 4 should only be granted to a laboratory that is licensed to handle the particular pathogen as in Article 1.4.5.6.

2. When considering applications to import *pathological material* from other countries, the authorities should have regard to the nature of the material, the animal from which it is derived, the susceptibility of that animal to various diseases and the animal health situation of the country of origin. It may be advisable to require that material is pre-treated before import to minimise the risk of inadvertent introduction of a pathogen.

Table 1. ***Guidance on the laboratory requirements for the different containment groups***

	REQUIREMENTS OF THE LABORATORY	CONTAINMENT GROUP		
		2	3	4
A)	**Laboratory siting and structure**			
1.	Not next to known fire hazard	Yes	Yes	Yes
2.	Workplace separated from other activities	Yes	Yes	Yes
3.	Personnel access limited	Yes	Yes	Yes
4.	Protected against entry/exit of rodents and insects	Yes	Yes	Yes
5.	Liquid effluent must be sterilised		Yes and monitored	Yes and monitored
6.	Isolated by airlock. Continuous internal airflow		Yes	Yes
7.	Input and extract air to be filtered using HEPA or equivalent		Single on extract	Single for input, double for extract
8.	Mechanical air supply system with fail-safe system		Yes	Yes
9.	Laboratory sealable to permit fumigation		Yes	Yes
10.	Incinerator for disposal of carcasses and waste	Available	Yes	Yes on site
B)	**Laboratory facilities**			
11.	Class 1/2/3 exhaust protective cabinet available	Yes	Yes	Yes
12.	Direct access to autoclave	Yes	Yes with double doors	Yes with double doors
13.	Specified pathogens stored in laboratory	Yes	Yes	Yes
14.	Double ended dunk tank required		Preferable	Yes
15.	Protective clothing not worn outside laboratory	Yes	Yes	Yes
16.	Showering required before exiting laboratory			Yes
17.	Safety Officer responsible for containment	Yes	Yes	Yes
18.	Staff receive special training in the requirements needed	Yes	Yes	Yes
C)	**Laboratory discipline**			
19.	Warning notices for containment area	Yes	Yes	Yes
20.	Laboratory must be lockable	Yes	Yes	Yes
21.	Authorised entry of personnel	Yes	Yes	Yes
22.	On entering all clothing removed and clean clothes put on		Yes	Yes
23.	On exiting all laboratory clothes removed, individual must wash and transfer to clean side		Yes	

Table 1. ***Guidance on the laboratory requirements for the different containment groups (contd)***

	REQUIREMENTS OF THE LABORATORY	CONTAINMENT GROUP		
		2	**3**	**4**
C)	**Laboratory discipline (contd)**			
24.	Individual must shower prior to transfer to clean side			Yes
25.	All accidents reported	Yes	Yes	Yes
D)	**Handling of specimens**			
26.	Packaging requirements to be advised prior to submission	Yes	Yes	Yes
27.	Incoming packages opened by trained staff	Yes	Yes	Yes
28.	Movement of pathogens from an approved laboratory to another requires a licence	Yes	Yes	Yes
29.	Standard Operating Procedures covering all areas must be available	Yes	Yes	Yes

CHAPTER 1.4.6.

QUARANTINE MEASURES APPLICABLE TO NON-HUMAN PRIMATES

Article 1.4.6.1.

General Principles

The present Appendix defines the standards to be followed in the case of a non-human primate being imported directly from a country within the natural range of the animal's species concerned, and where only limited health guarantees can be given, or in cases where Article 2.10.1.2., last paragraph, applies.

Quarantine programmes are designed to both facilitate the detection of communicable diseases and to make accurate assessments of the overall health status of individuals and/or groups entering a new population. Prudence dictates that for public health and safety the infectious disease status of all incoming animals is considered at best uncertain.

Quarantines are defined by their duration and by the activities and procedures practised to assess health status.

The minimal duration of the quarantine period, as defined by Articles 2.10.1.4., 2.10.1.5. and 2.10.1.6., may be extended until any adverse events during the quarantine period are fully investigated and resolved, and no evidence of transmission of infectious agents within the quarantined group exists.

Quarantine activities and procedures should be directed towards defining as much as possible the health status of quarantined animals, while protecting persons and other animals from inadvertent exposure to communicable agents and providing for the health and well-being of quarantined animals. Therefore, quarantine practices should:

1. encompass measures which effectively isolate animals or groups of animals thereby preventing the spread of communicable diseases;
2. protect the health of personnel working in the quarantine;
3. encompass measures to promote the health and welfare of quarantined animals.

At a minimum, quarantine programmes should have the following key components:

Article 1.4.6.2.

Management policies

Management should restrict access to the quarantine facility to authorised and essential personnel, who do not pose a communicable disease risk to non-human primates.

Management should instruct personnel about the potential risks of working in the quarantine facility, and the need to conduct all activities in a safe manner. There should be periodic retraining of personnel.

Management may prohibit persons who may be at increased risk of acquiring infections or for whom an infection might be unusually hazardous from the quarantine facility. Management may require other personnel health promotion activities, such as those mentioned in point 5 of Article 2.10.1.7.

Article 1.4.6.3.

Quarantine facility infrastructure design and equipment

1. The construction or location, and the operation of the quarantine facility should provide for strict segregation and isolation of quarantined animals from other animals and from personnel not essential to the operation of the quarantine.

2. Methods to attain this isolation include:

   a) The use of security measures such as physical barriers and procedural access control systems.

   b) As part of the security system, a hazard warning sign should be posted at the entrance to the quarantine stating that exposure to infectious diseases may occur in the quarantine. The names and telephone numbers of contact persons responsible for the quarantine area should be provided, and all special requirements for entering the quarantine area should be listed.

   c) The implementation of an effective rodent, feral animal, and insect control programme, which does not pose a health risk to the quarantined animals.

   d) The complete physical separation of groups of quarantined animals from other groups of quarantined animals to prevent exposure to and the introduction of infectious agents from one group to another during the quarantine period. As a rule, only animals arriving in one shipment from the same exporter should be grouped together. Animals may not be exchanged between groups or groups mixed during the quarantine period, unless the newly formed group restarts the entire quarantine process.

3. The quarantine facility should be designed to allow for the secure holding of quarantined animals and to allow for the safe, easy and efficient cleaning and decontamination of the animal holding area and the access area during and after use.

   a) A quarantine facility should consist of a minimum of two discrete areas physically separated from the outside and from each other, including an access area where clothes, footwear and protective articles are changed, and where locker, hand-washing and, if possible, showering facilities are provided.

      Procedures should be in place to prevent the cross-contamination of clothes and footwear worn outside the quarantine facility from potentially contaminated protective clothing worn inside the animal holding area.

   b) Animal holding room wall, floor, and ceiling surfaces should be water resistant to facilitate cleaning and disinfecting. Any holes or penetrations in these surfaces should be sealed or be capable of being sealed to facilitate fumigation or space decontamination. Doors to animal rooms should open inward, and should always be kept closed when animals are present. Any windows should be closed and sealed, unless the facility is sufficiently separated (distance, fences, other means of separation) from non-quarantined area.

   c) In facilities that are operated with the windows closed and sealed, a ventilation system should be operated and monitored in such a manner to assure the provision of an optimal isolation of these animals, while also providing for their health and comfort. The direction of the airflow in the quarantine facility should be inward from the outside of the quarantine facility, to quarantine access areas, to animal holding rooms. Air exhausted or re-circulated within the facility must be filtered. In addition, exhaust air should be dispersed away from the building and other occupied areas. Heating, ventilating, and air-conditioning systems should be designed so that their operation can be continued, even at reduced capacity in the event of electrical or other support system failure.

   d) If floor drains are present, their drain traps should always be filled with water or a suitable disinfectant.

   e) A hand washing sink should be available in the animal holding room for personnel usage.

   f) Adequate equipment and space should be available both in the animal holding area and in the quarantine facility in general for the adequate decontamination and the proper disposal or processing and storing of all supplies and equipment used in the quarantine.

Article 1.4.6.4.

Personnel protection practices

1. Eating, drinking, smoking and storing of food for human use should not be permitted in the quarantine facility.

2. All staff entering the quarantine should wear (preferably disposable) protective clothing and devices.

3. Protective clothing, gloves, and mucus membrane protection should not be used in more than one quarantine animal holding room. This may require the changing of protective clothing by staff as they go between rooms in the performance of their duties.

4. Foot or shoe baths should be provided and used at the exits of the animal holding area and of each animal holding room. They should be changed often enough to remain fresh and free of organic matter.

5. Showering after contact with non-human primates, their body waste or secretions or at a minimum before leaving the quarantine facility is highly recommended.

6. Intermittent and frequent hand washing while working in the quarantine facility is highly recommended. This is especially important as protective gloves may become inadvertently torn or ruptured.

7. Baseline serum samples from quarantine personnel should be collected and stored. Additional serum samples may be collected periodically, as an aid to epidemiological investigations.

8. Management should encourage quarantine staff developing signs of illness to seek medical attention.

Article 1.4.6.5.

Husbandry and animal care practices

1. If a quarantine facility maintains more than one animal holding room, husbandry practices should be designed so as to minimise the risk of transmission of zoonotic diseases between rooms. In particular, there should be separate cleaning tools and other animal care equipment for each room. All cages and other non-disposable equipment should be decontaminated when removed from the room.

2. All husbandry and animal care procedures should be carefully performed to minimise the creation of aerosols and limit the spread of potentially infectious materials, while also providing for the appropriate care and well-being of the animals concerned.

   Waste, uneaten food, and other potentially contaminated materials leaving the quarantine area must be suitably contained, while being transported to a site of physical or chemical decontamination, or incineration.

3. Work surfaces should always be decontaminated after use or whenever soiled. Equipment should not be stored on the floor.

4. Care should be taken to avoid scratches, bites or other injuries from non-human primates through anaesthesia, tranquillisation or physical restraint of the animals during handling. Physical restraint should only be performed by personnel knowledgeable and experienced in handling non-human primates, and it should never be done by persons working alone.

5. Caution must be used to prevent injury to personnel or the spread of infectious materials between animals through the use of potentially contaminated needles, scalpels, or other sharp instruments, particularly during the disposal of these items. Only single use disposable syringes and needles, scalpel blades, and other sharp items should be used. They should never be recapped, bent, broken or otherwise manipulated by hand, and they should be discarded into puncture-resistant containers kept as close to the work site as practical. Containers should be decontaminated before disposal.

6. If multiple-dose vials of materials or medications are used, care must be taken to avoid contamination of such vials and their contents between uses.

7. Dead animals should be removed from their animal holding room and taken to a dedicated necropsy room in a sealed, impervious, leakproof container or bag.

8. Responsible quarantine officials should immediately notify the *Veterinary Authority* of any severe and/or unusual illnesses and deaths occurring in quarantined non-human primates.

9. After animals are removed from quarantine, a thorough decontamination of the animal holding room is necessary whether there is a history of communicable disease presence in the room or not.

SECTION 1.5.

RISK ANALYSIS FOR BIOLOGICALS FOR VETERINARY USE

CHAPTER 1.5.1.

GENERAL CONSIDERATIONS

Article 1.5.1.1.

All products, including biologicals for veterinary use, derived from animals have some capacity to transmit animal disease. The level of this capacity depends on the inherent nature of the products, their source, the treatment that they might have undergone, and the purpose for which they are intended. Biologicals for *in vivo* use in particular will have the highest probability of exposure to animals and as such present the highest risk. Products used for *in vitro* purposes can introduce disease into animal populations through deliberate or inadvertent use *in vivo*, contamination of other biologicals, or spread by other means. Even products for diagnosis and research have the potential for close contact with animals. Exotic micro-organisms, some highly pathogenic, which may be held for research and diagnostic purposes in countries free from infection or the diseases they cause, could possibly contaminate other biological products.

Veterinary Authorities of *importing countries* shall make available specific procedural requirements for approval or licensing of biologicals for veterinary use. They may limit supply to registered institutions or *in vitro* use or for non-veterinary purposes where such assurance cannot be provided.

CHAPTER 1.5.2.

RISK ANALYSIS FOR VETERINARY VACCINES

Article 1.5.2.1.

Introduction

Risk analysis for veterinary vaccines has to be founded on the principles of quality assurance, which includes quality control, in the production of veterinary vaccines. These recommendations are focused mainly on the risk related to the contamination of vaccines by infectious agents particularly in regard to the risk of importing exotic diseases. The major risk of introducing a disease into a country is through importation of live *animals* or animal products and rarely through veterinary vaccines. Veterinary vaccines can however be contaminated by disease agents if master seeds, strains, cell cultures, animals or ingredients of animal origin such as foetal calf serum used in production are contaminated or if cross contamination occurs during the production process.

Article 1.5.2.2.

Principles

Exporting countries and *importing countries* should agree on a system of classification of risks associated with veterinary vaccines taking into account factors such as purification procedures which have been applied.

Exporting countries and *importing countries* should agree on risk analysis models to address specific issues and products. Such risk analysis models should include a scientific risk assessment and formalised procedures for making risk management recommendations and communicating risk. The regulation of veterinary vaccines should include the use of either qualitative or quantitative models.

Risk analysis should be as objective and transparent as possible. Step risk and scenario tree methods should be used in risk assessment whenever appropriate, as they identify the critical steps in the production and use of the products where risks arise and help to characterise those risks.

The same conclusions about risk analysis may be reached by differing methods. Where methods may differ in countries, the concept of equivalence should apply wherever possible and the methods should be validated to ensure they are of comparable sensitivity.

Article 1.5.2.3.

Manufacturing practices

The manufacture of veterinary vaccines has special characteristics which should be taken into consideration when implementing and assessing the quality assurance system. Due to the large number of animal species and related pathogenic agents, the variety of products manufactured is very wide and the volume of manufacture is often low; hence, work on a group basis is common. Moreover, because of the very nature of this manufacture (cultivation steps, lack of terminal sterilisation, etc.), the products must be particularly well protected against contamination and cross contamination. The environment must also be protected especially when the manufacture involves the use of pathogenic or exotic biological agents and the worker must be particularly well-protected when the manufacture involves the use of biological agents pathogenic to man.

These factors, together with the inherent variability of immunological products, means that the role of the quality assurance system is of the utmost importance. It is important that vaccines should be manufactured in accordance with a recognised codified system that includes specifications regarding equipment, premises, qualification of personnel as well as quality assurance and regular inspections.

A commonly agreed system of facility inspection carried out by qualified and specialised inspectors must be in place to assure confidence.

Article 1.5.2.4.

Information to be submitted when applying for registration in the importing country

The manufacturer or *Veterinary Authority* of the *exporting country* should make available to the *importing country* the pharmacopoeia it uses. For the *importing country* it is necessary to have documented both the quality control methods used and the source of each batch of starting materials. The key steps of the manufacturing process of veterinary vaccines should be described in detail to help risk analysis. Risk analysis has to be focused on the quality and safety parts of the application file. Laboratory safety testing should cover target and non-target organisms to obtain sufficient biological data. All test procedures used should correspond with the state of scientific knowledge at the time and should be validated.

The description of the method of preparation of the finished product should include an adequate characterisation of the substances needed to prepare the working seeds, the description of the treatments applied to starting materials to prevent contamination, and a statement of the stages of manufacture at which sampling is carried out for process control tests.

The results of control tests during production and on finished product, as well as the sensitivity of these tests, have to be available for risk analysis. The stepwise procedures of the control tests should also be available.

Article 1.5.2.5.

Categorisation of veterinary vaccines

To assist in risk analysis, countries should establish a system of categorisation of veterinary vaccines taking into account criteria such as pathogens used as active ingredients, their inherent characteristics and the risk they pose.

In case of live vectored vaccines, the safety of the vector to the targeted and non-targeted species and to human beings must be assessed. Special attention should be paid to potential tissue tropism or host range modification of the recombinant.

Article 1.5.2.6.

Vaccinovigilance

Exporting countries and *importing countries* should ensure that a reliable system of vaccinovigilance (post licensing monitoring) is established to identify, at the earliest stage, any serious problems encountered from the use of veterinary vaccines. Vaccinovigilance should be ongoing and an integral part of all regulatory programmes for veterinary vaccines, especially live vaccines.

Article 1.5.2.7.

Risk communication

Reliable data in support of applications submitted in *importing countries* should be provided by the manufacturer or the *Veterinary Authority* of the *exporting country*. Relevant data on risk analysis, changes in animal health situations and vaccinovigilance should be shared by *Veterinary Authorities* on a continuous basis.

CHAPTER 1.5.3.

RISK ANALYSIS FOR BIOLOGICALS FOR VETERINARY USE OTHER THAN VACCINES

Article 1.5.3.1.

Introduction

For the purpose of this chapter, the term 'biologicals' means 'biologicals for veterinary use other than veterinary vaccines'.

Article 1.5.3.2.

Categorisation of biologicals

Categorisation provides a means of facilitating risk analysis for the *international trade* in biologicals.

The categorisation system should take into account the source, the nature and the stated purpose of the biologicals. By conducting generic risk analyses, and by developing generic certification and quality assurance, continued supply of products can be made available without the need for repeated risk assessments that are expensive and consume significant resources. Once made, the risk assessment can be linked to appropriate manufacturing and testing parameters. Categories of biologicals for veterinary use into which generic risk assessments could apply may include (not in order of risk):

1. synthetic material;
2. amino acids, alcohols, esters, sugars and vitamins;
3. cosmetics;
4. plant extracts and processed biochemicals of plant origin;
5. products derived by microbial fermentation;
6. diagnostic, analytical and immunochemical kits for *in vitro* use;
7. material of human origin;
8. therapeutics;
9. implantables of animal origin;
10. antibodies and immunoglobulins;
11. deoxyribonucleic acid (DNA), ribonucleic acid (RNA), restriction enzymes and other products of molecular biology;
12. cell-lines and hybridomas;
13. animal proteins, hormones, enzymes, albumins, tissue extracts and culture media containing animal material;
14. animal serum;
15. micro-organisms (conventional or genetically modified);
16. probiotics;
17. preserved specimens, microscope slides and smears.

All of these materials may contain pathogens depending on their source and processing procedures.

Article 1.5.3.3.

Information to be submitted when applying for an import licence

When undertaking risk analysis for biologicals, *Veterinary Authorities* should follow the *Terrestrial Manual*. The manufacturer or the *Veterinary Authority* of the *exporting country* should make available detailed information, in confidence if necessary, on the source of the materials used in the manufacture of the product (e.g. substrates). They should make available details of the method of manufacture (and where appropriate inactivation) of the substrates and component materials, the quality assurance procedures for each step in the process, final product testing regimes, and the pharmacopoeia with which the product must conform in the country of origin. They should also make available challenge organisms, their biotypes and reference sera, and other means of appropriate product testing.

Article 1.5.3.4.

Risk analysis process

Risk analysis should be as objective and transparent as possible and should be performed in accordance with Section 1.3. of the *Terrestrial Code*, and certification in line with Section 1.2. of the *Terrestrial Code*. Of necessity, assessment of the country and commodity factors and risk reduction measures will be based largely on manufacturers' data. These data depend on quality assurance at all stages of manufacture, rather than on testing of the final product alone.

Domestic exposure may be influenced by the approved usage of the product. *Veterinary Authorities* may place limits on usage of some products (e.g. restricting usage to institutions of appropriate biosecurity).

Article 1.5.3.5.

Biocontainment

Suitable biocontainment may be necessary for many forms of biologicals. In particular, the importation of exotic micro-organisms should be carried out in accordance with Chapter 1.4.5.

PART 2

RECOMMENDATIONS APPLICABLE TO SPECIFIC DISEASES

SECTION 2.1.

OIE LISTED DISEASES

CHAPTER 2.1.1.

CRITERIA FOR LISTING DISEASES

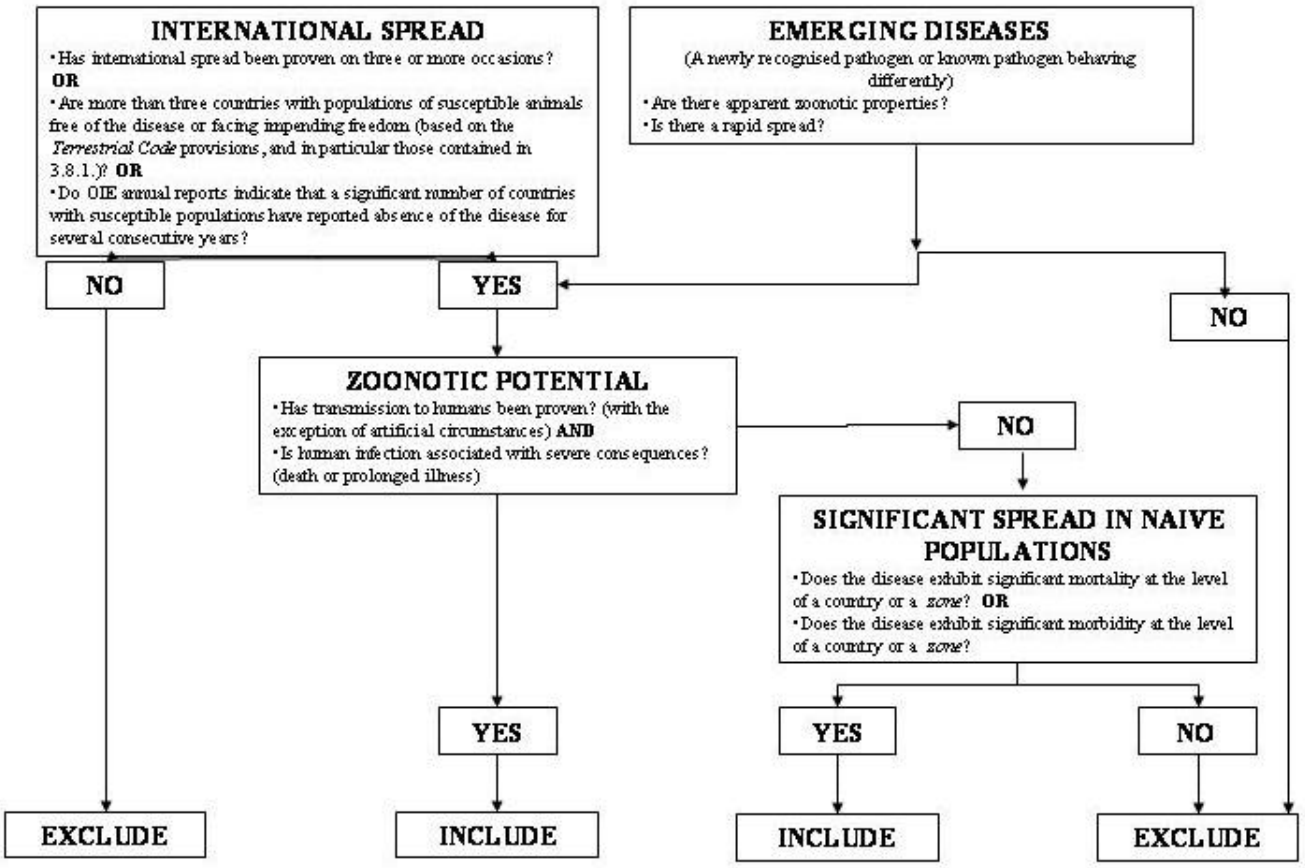
Article 2.1.1.1.

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

Basic criteria	**Parameters (at least one 'yes' answer means that the criterion has been met)**
International Spread	Has international spread been proven on three or more occasions? **OR** Are more than three countries with populations of susceptible animals free of the disease or facing impending freedom (based on the relevant provisions of the *Terrestrial Code*, and in particular those contained in Appendix 3.8.1.)? **OR** Do OIE annual reports indicate that a significant number of countries with susceptible populations have reported absence of the disease for several consecutive years?
Zoonotic Potential	Has transmission to humans been proven? (with the exception of artificial circumstances) **AND** Is human infection associated with severe consequences? (death or prolonged illness)
Significant Spread within Naïve Populations	Does the disease exhibit significant mortality at the level of a country or a *zone*? **OR** Does the disease exhibit significant morbidity at the level of a country or a *zone*?
Emerging Diseases	Are there apparent zoonotic properties or is there a rapid spread?

Article 2.1.1.2.

The criteria in Article 2.1.1.1. above are applied according to the decision-making model shown below:



Article 2.1.1.3.

The following diseases are included in the OIE List.

1. The following diseases are included within the category of multiple species diseases:
   - Anthrax
   - Aujeszky's disease
   - Bluetongue
   - Brucellosis (*Brucella abortus*)
   - Brucellosis (*Brucella melitensis*)
   - Brucellosis (*Brucella suis*)
   - Crimean Congo haemorrhagic fever
   - Echinococcosis/hydatidosis
   - Foot and mouth disease
   - Heartwater
   - Japanese encephalitis
   - Leptospirosis
   - New world screwworm (*Cochliomyia hominivorax*)
   - Old world screwworm (*Chrysomya bezziana*)

- Paratuberculosis
- Q fever
- Rabies
- Rift Valley fever
- Rinderpest
- Trichinellosis
- Tularemia
- Vesicular stomatitis
- West Nile fever.

2. The following diseases are included within the category of cattle diseases:
   - Bovine anaplasmosis
   - Bovine babesiosis
   - Bovine genital campylobacteriosis
   - Bovine spongiform encephalopathy
   - Bovine tuberculosis
   - Bovine viral diarrhoea
   - Contagious bovine pleuropneumonia
   - Enzootic bovine leukosis
   - Haemorrhagic septicaemia
   - Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
   - Lumpy skin disease
   - Malignant catarrhal fever (Wildebeest only)
   - Theileriosis
   - Trichomonosis
   - Trypanosomosis (tsetse-transmitted).
3. The following diseases are included within the category of sheep and goat diseases:
   - 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 are included within the category of equine diseases:
   - African horse sickness
   - Contagious equine metritis

- Dourine
- Equine encephalomyelitis (Eastern)
- Equine encephalomyelitis (Western)
- Equine infectious anaemia
- Equine influenza
- Equine piroplasmosis
- Equine rhinopneumonitis
- Equine viral arteritis
- Glanders
- Surra (*Trypanosoma evansi*)
- Venezuelan equine encephalomyelitis.

5. The following diseases are included within the category of swine diseases:
   - 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 are included within the category of avian diseases:
   - Avian chlamydiosis
   - Avian infectious bronchitis
   - Avian infectious laryngotracheitis
   - Avian mycoplasmosis (*Mycoplasma gallisepticum*)
   - Avian mycoplasmosis (*Mycoplasma synoviae*)
   - Duck virus hepatitis
   - Fowl cholera
   - Fowl typhoid
   - Highly pathogenic avian influenza in birds and low pathogenicity notifiable avian influenza in poultry as defined in Chapter 2.7.12.
   - Infectious bursal disease (Gumboro disease)
   - Marek's disease
   - Newcastle disease
   - Pullorum disease
   - Turkey rhinotracheitis.
7. The following diseases are included within the category of lagomorph diseases:
   - Myxomatosis
   - Rabbit haemorrhagic disease.
8. The following diseases are included within the category of bee diseases:
   - 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 are included within the category of other diseases:
   - Camelpox
   - Leishmaniosis.

SECTION 2.2.

MULTIPLE SPECIES DISEASES

CHAPTER 2.2.1.

ANTHRAX

Article 2.2.1.1.

There is no evidence that anthrax is transmitted by animals before the onset of clinical and pathological signs. Early detection of *outbreaks*, quarantine of affected premises, destruction of diseased animals and fomites, and implementation of appropriate sanitary procedures at *abattoirs* and dairy factories will ensure the safety of products of animal origin intended for human consumption.

For the purposes of the *Terrestrial Code*, the *incubation period* for anthrax shall be 20 days.

Anthrax should be notifiable in the whole country.

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

Article 2.2.1.2.

Veterinary Authorities of *importing countries* should require:

for ruminants, equines and pigs

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of anthrax on the day of shipment;
2. were kept for the 20 days prior to shipment in an *establishment* where no *case* of anthrax was officially declared during that period; or
3. were vaccinated, not less than 20 days and not more than 6 months prior to shipment.

Article 2.2.1.3.

Veterinary Authorities of *importing countries* should require:

for products of animal origin (from ruminants, equines and pigs) intended for agricultural or industrial use

the presentation of an *international veterinary certificate* attesting that the products:

1. originate from animals not showing clinical signs of anthrax; or
2. have been processed to ensure the destruction of both bacillary and spore forms of *Bacillus anthracis*, in conformity with one of the procedures referred to in Appendix X.X.X. (under study).

Article 2.2.1.4.

Veterinary Authorities of *importing countries* should require:

for *fresh meat* and *meat products* destined for human consumption

the presentation of an *international veterinary certificate* attesting that the products originate from animals which:

1. have shown no sign of anthrax during ante-mortem and post-mortem inspections;
2. come from *establishments* which are not placed under quarantine on account of anthrax control and in which:
   a) there has been no *case* of anthrax during the 20 days prior to slaughter;
   b) no vaccination against anthrax has been carried out during the 42 days prior to slaughter.

Article 2.2.1.5.

Veterinary Authorities of *importing countries* should require:

for hides, skins and hair (from ruminants, equines and pigs)

the presentation of an *international veterinary certificate* attesting that the products originate from animals which:

1. have shown no sign of anthrax during ante-mortem and post-mortem inspections;
2. come from *establishments* which are not placed under quarantine on account of anthrax control.

Article 2.2.1.6.

Veterinary Authorities of *importing countries* should require:

for wool

the presentation of an *international veterinary certificate* attesting that the products:

1. originate from animals showing no clinical signs of anthrax at the time of shearing;
2. originate from *establishments* where no *case* of anthrax has been reported since the previous shearing of all animals.

Article 2.2.1.7.

Veterinary Authorities of *importing countries* should require:

for *milk* and *milk products* intended for human consumption

the presentation of an *international veterinary certificate* attesting that the products:

1. originate from animals showing no clinical signs of anthrax at the time of milking; or
2. were processed using a heat treatment at least equivalent to pasteurisation (under study).

CHAPTER 2.2.2.

AUJESZKY'S DISEASE

Article 2.2.2.1.

The Aujeszky's disease (AD) free or provisionally free status of a country or *zone* can only be determined if the following conditions are fulfilled:

1. a *risk assessment* has been conducted identifying all potential factors for AD occurrence and their historic perspective;
2. AD is notifiable in the whole country, and all clinical cases suggestive of AD are subjected to field and laboratory investigations;
3. an on-going awareness programme is in place to encourage reporting of all cases suggestive of AD in susceptible species;
4. the *Veterinary Authority* has current knowledge of, and authority over, all *establishments* containing pigs in the whole country;
5. domestic pigs are properly identified when leaving their *establishment* of origin with an indelible mark giving the identification number of their herd of origin; a reliable tracing back procedure is in place for all pigs leaving their *establishment* of origin.

An AD infected *establishment* means an *establishment* in which the virus has been isolated or identified, or a positive serological result (total or gE antibodies) has been confirmed in a *laboratory*.

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

Article 2.2.2.2.

AD free country or zone

1. Qualification

   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:

   a) it has been a *notifiable disease*;

   b) an early detection system has been in place;

   c) measures to prevent the introduction of the AD virus into the country or zone have been in place;

   d) no vaccination against the disease has been carried out;

   e) infection is not known to be established in wild swine, or measures have been implemented to prevent any transmission of the AD virus from wild swine to domestic pigs.

   A country or *zone* which does not meet the conditions of the above paragraph may be considered free from AD when:

   f) animal health regulations to control the movement of *commodities* listed in Article 2.2.2.6. in order to prevent the introduction of infection into the *establishments* of the country or *zone* have been in place for at least 2 years;

   g) vaccination against AD has been banned for all domestic pigs in the country or *zone* for at least 2 years;

   h) 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 guidelines in Appendix 3.8.X. (under study) no more than 3 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

i) 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 guidelines in Appendix 3.8.X. (under study) and demonstrate that no *establishments* within the country or zone have had any clinical, virological or serological evidence of AD for at least 2 years.

In order for a country to reach free status, all of its *zones* must have reached AD free status.

In countries or *zones* with wild swine, measures should be implemented to prevent any transmission of the AD virus from wild swine to domestic 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 guidelines in Appendix 3.8.X. (under study);

b) the importation of the *commodities* listed in Article 2.2.2.6. 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 swine to domestic 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 5-kilometre radius of 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;

iii) all vaccinated animals have been slaughtered;

iv) during and after the application of the measures described in points i) to iii) 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 5-kilometre radius of the *outbreak*, demonstrating that these *establishments* are not infected.

Article 2.2.2.3.

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* listed in Article 2.2.2.6. in order to prevent the introduction of infection into the *establishments* of the country or *zone* have been in place for at least 2 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 guidelines in Appendix 3.8.X. (under study) (at a level of confidence not sufficient to meet requirements for freedom); 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 1% for at least 3 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% of the *establishments* in the country or *zone* are qualified free;

d) in countries or *zones* with wild swine, measures should be taken to prevent any transmission of the AD virus between wild swine and domestic 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 $\leq$1%;

c) the importation of the *commodities* listed in Article 2.2.2.6. 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 1% 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 $\leq$1% for at least 6 months, and this result is confirmed by a serological survey conducted in conformity with point 1c) above.

Article 2.2.2.4.

AD infected country or zone

Countries and *zones* which do not fulfil the conditions to be considered free or provisionally free of AD should be considered as infected.

Article 2.2.2.5.

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 number 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 guidelines in Appendix 3.8.X. (under study); these tests must have been carried out on two occasions, at an interval of 2 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 5-kilometre radius of 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 zone, the testing procedure described in point 1e) above should be carried out every 4 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.

3. Recovery of free status

Should a free *establishment* become infected, or should an *outbreak* occur within a 5-kilometre radius of 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 in the 5-kilometre radius zone: 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 2.2.2.6.

Veterinary Authorities of countries shall consider whether there is a risk with regard to AD in accepting importation or transit through their territory, from other countries, of the following *commodities*:

1. domestic and wild swine;
2. semen of domestic and wild swine;
3. embryos/ova of domestic and wild swine;
4. offal (head, and thoracic and abdominal viscera) of swine and products containing swine offal;
5. *pathological material* and biological products (see Chapter 1.4.5. and Section 1.5.).

Other *commodities* should be considered as not having the potential to spread AD when they are the subject of *international trade*.

Article 2.2.2.7.

When importing from AD free countries or zones, *Veterinary Authorities* should require:

for domestic pigs

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 2.2.2.8.

When importing from AD provisionally free countries or zones, *Veterinary Authorities* should require:

for domestic pigs for breeding or rearing

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 2.2.2.9.

When importing from AD infected countries or zones, *Veterinary Authorities* should require:

for domestic pigs for breeding or rearing

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 2.2.2.10.

When importing from AD provisionally free countries or zones or AD infected countries or zones, *Veterinary Authorities* should require:

for domestic pigs for slaughter

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 *establishments* 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.]*

Article 2.2.2.11.

When importing from AD free countries or zones, *Veterinary Authorities* should require:

for wild swine

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 2.2.2.12.

When importing from AD free countries or zones, *Veterinary Authorities* should require:

for semen of pigs

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 Appendix 3.2.2.

Article 2.2.2.13.

When importing from AD provisionally free countries or zones, *Veterinary Authorities* should require:

for semen of pigs

the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:
   a) have been kept for at least 4 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 4 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 Appendix 3.2.2.

Article 2.2.2.14.

When importing from AD infected countries or zones, *Veterinary Authorities* should require:

for semen of pigs

the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:
   a) were kept in an AD free *establishment* for at least 6 months prior to entering the *artificial insemination centre*;
   b) have been kept for at least 4 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 4 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 Appendix 3.2.2.

Article 2.2.2.15.

When importing from AD free countries or zones, *Veterinary Authorities* should require:

for *in vivo* derived embryos of pigs

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 Appendix 3.3.1.

Article 2.2.2.16.

When importing from AD provisionally free countries or zones, *Veterinary Authorities* should require:

for *in vivo* derived embryos of pigs

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 3 months prior to collection;
2. the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.2.2.17.

When importing from AD infected countries or zones, *Veterinary Authorities* should require:

for *in vivo* derived embryos of pigs

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 3 months prior to collection;
   c) were subjected to a serological test to the whole AD virus, with negative results, within 10 days prior to collection;
2. the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.2.2.18.

When importing from AD free countries or zones, *Veterinary Authorities* should require:

for offal (head, and thoracic and abdominal viscera) of pigs or products containing pig offal

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 2.2.2.19.

When importing from AD provisionally free countries or zones or from AD infected countries or zones, *Veterinary Authorities* should require:

for offal (head, and thoracic and abdominal viscera) of pigs

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 2.2.2.20.

When importing from AD provisionally free countries or zones or from AD infected countries or zones, *Veterinary Authorities* should require:

for products containing pig offal (head, and thoracic and abdominal viscera)

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 2.2.2.19.; 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.

CHAPTER 2.2.3.

ECHINOCOCCOSIS/HYDATIDOSIS

Article 2.2.3.1.

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

Article 2.2.3.2.

Veterinary Authorities of *importing countries* should require:

for dogs, cats and other domestic or wild carnivores

the presentation of an *international veterinary certificate* attesting that the animals were treated against echinococcosis/hydatidosis prior to shipment, and that the treatment used is recognised as being effective.

CHAPTER 2.2.4.

LEPTOSPIROSIS

Article 2.2.4.1.

Under study.

CHAPTER 2.2.5.

RABIES

Article 2.2.5.1.

For the purposes of the *Terrestrial Code*, the *incubation period* for rabies shall be 6 months, and the *infective period* in domestic carnivores starts 15 days before the onset of the first clinical signs and ends when the animal dies.

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

Article 2.2.5.2.

Rabies free country

A country may be considered free from rabies when:

1. the disease is notifiable;
2. an effective system of disease surveillance is in operation;
3. all regulatory measures for the prevention and control of rabies have been implemented including effective importation procedures;
4. no *case* of indigenously acquired rabies infection has been confirmed in man or any animal species during the past 2 years; however, this status would not be affected by the isolation of a European Bat Lyssavirus (EBL1 or EBL2);
5. no imported *case* in carnivores has been confirmed outside a *quarantine station* for the past 6 months.

Article 2.2.5.3.

When importing from rabies free countries, *Veterinary Authorities* should require:

<u>for domestic mammals, and wild mammals reared under confined conditions</u>

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 or for the 6 months prior to shipment in a rabies free country or were imported in conformity with the regulations stipulated in Articles 2.2.5.5., 2.2.5.6. or 2.2.5.7.

Article 2.2.5.4.

When importing from rabies free countries, *Veterinary Authorities* should require:

<u>for wild mammals not reared under confined conditions</u>

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of rabies on the day of shipment;
2. have been captured in a rabies free country, at a sufficient distance from any infected country. The distance should be defined according to the species exported and the reservoir species in the infected country.

Article 2.2.5.5.

When importing from countries considered infected with rabies, *Veterinary Authorities* should require:

for dogs and cats

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of rabies within 48 hours of shipment;

AND EITHER

2. were vaccinated against rabies:
   a) not less than 6 months and not more than one year prior to shipment in the case of a primary vaccination, which should have been carried out when the animals were at least 3 months old;
   b) not more than one year prior to shipment in the case of a booster vaccination;
   c) with an inactivated virus vaccine or with a recombinant vaccine expressing the rabies virus glycoprotein and were identified by a permanent mark (including a microchip) before the vaccination (their identification number shall be stated in the certificate);
3. were subjected not less than 3 months and not more than 24 months prior to shipment to an antibody test as prescribed in the *Terrestrial Manual* with a positive result equivalent to at least 0.5 IU/ml;

OR

4. have not been vaccinated against rabies or do not meet all the conditions set out in points 1, 2 and 3 above; in such cases, the *importing country* may require the placing of the animals in a *quarantine station* located on its territory, in conformity with the conditions stipulated in its animal health legislation.

Article 2.2.5.6.

When importing from countries considered infected with rabies, *Veterinary Authorities* should require:

for domestic ruminants, equines and pigs

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 for the 6 months prior to shipment in an *establishment* where separation from wild and feral animals was maintained and where no *case* of rabies was reported for at least 12 months prior to shipment.

Article 2.2.5.7.

When importing from countries considered infected with rabies, *Veterinary Authorities* should require:

for laboratory reared rodents and lagomorphs, and lagomorphs or wild mammals (other than non-human primates) reared under confined conditions

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, or for the 12 months prior to shipment, in an *establishment* where no *case* of rabies was reported for at least 12 months prior to shipment.

Article 2.2.5.8.

When importing from countries considered infected with rabies, *Veterinary Authorities* should require:

for wild mammals not belonging to the orders of primates or carnivores and not reared under confined conditions

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 in a *quarantine station* for the 6 months prior to shipment.

Article 2.2.5.9.

When importing from countries considered infected with rabies, *Veterinary Authorities* should require:

for frozen semen of dogs

the presentation of an *international veterinary certificate* attesting that the donor animals showed no clinical sign of rabies during the 15 days following collection of the semen.

1 *[Note: For non-human primates, reference should be made to Chapter 2.10.1.]*

CHAPTER 2.2.6.

PARATUBERCULOSIS

Article 2.2.6.1.

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

CHAPTER 2.2.7.

HEARTWATER

Article 2.2.7.1.

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

Article 2.2.7.2.

Veterinary Authorities of countries free from heartwater may prohibit importation or transit through their territory, from countries considered infected with heartwater, of domestic and wild ruminants.

Article 2.2.7.3.

When importing from countries considered infected with heartwater, *Veterinary Authorities* should require:

for domestic and wild ruminants

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of heartwater on the day of shipment;
2. were subjected to a diagnostic test for heartwater with negative results during the 15 days prior to shipment;
3. were treated with acaricides prior to shipment and were completely free of ticks.

CHAPTER 2.2.8.

NEW WORLD SCREWWORM
(*Cochliomyia hominivorax*)
AND OLD WORLD SCREWWORM
(*Chrysomya bezziana*)

Article 2.2.8.1.

When importing from countries considered infested with new world or old world screwworm, *Veterinary Authorities* should require:

for domestic and wild mammals

the presentation of an *international veterinary certificate* attesting that:

1. immediately prior to loading, the animals to be exported have been inspected, on the premises of origin, by an *Official Veterinarian*. After inspection for wounds with egg masses or larvae of new world or old world screwworm, any infested animal has been rejected for export;
2. immediately prior to entering the quarantine pens in the *exporting country*:
   a) each animal has been thoroughly examined for infested wounds, under the direct supervision of an *Official Veterinarian*, and that no infestation has been found in any animal; and
   b) any wounds have been treated prophylactically with an officially approved oily larvicide at the recommended dose; and
   c) all animals have been dipped, sprayed, or otherwise treated, immediately after inspection, with a product officially approved by the *importing* and *exporting countries* for the control of new world or old world screwworm, under the supervision of an *Official Veterinarian* and in conformity with the manufacturer's recommendations;
3. at the end of the quarantine and immediately prior to shipment for export:
   a) all animals have been re-examined for the presence of infestation and all animals have been found free of infestation;
   b) all wounds have been prophylactically treated with an approved oily larvicide under the supervision of an *Official Veterinarian*;
   c) all animals have been prophylactically treated again by dipping or spraying as in point 2 above.

Article 2.2.8.2.

Quarantine and transportation recommendations

1. The floor of the quarantine area and the *vehicles* must be thoroughly sprayed with an officially approved larvicide before and after each use.
2. The transit route must be the most direct, with no stopover without prior permission of the *importing country*.

Article 2.2.8.3.

Post importation inspection

1. On arrival at the importation point, all animals must be thoroughly inspected for wounds and possible new world or old world screwworm infestation under the supervision of an *Official Veterinarian*.

2. The bedding material of the *vehicle* and the quarantine area should immediately be gathered and burned following each consignment.

Article 2.2.8.4.

Import/export of animal products

The larval stage of the new world or old world screwworm fly is dependent on live animals and cannot survive for any length of time in dead tissue or animal products; therefore, restrictions on these products are not considered necessary.

CHAPTER 2.2.9.

TRICHINELLOSIS
(*Trichinella spiralis*)

Article 2.2.9.1.

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

Article 2.2.9.2.

Veterinary Authorities of *importing countries* should require:

for *fresh meat* of swine (domestic and wild)

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat:

1. comes from domestic swine which have been slaughtered and inspected in an *approved abattoir* or wild swine which have been inspected;

AND

2. were subjected to a testing procedure for trichinellosis with negative results; or
3. comes from domestic swine which were born and bred in a country or *zone* free from trichinellosis in domestic swine; or
4. has been processed to ensure the destruction of all the larvae of the parasite.

Article 2.2.9.3.

A country or *zone* may be considered free from trichinellosis in domestic swine when:

1. trichinellosis is notifiable in the country;
2. there is in force an effective disease reporting system shown to be capable of capturing the occurrence of *cases*;

AND EITHER:

3. it has been ascertained that *Trichinella* infection does not exist in the domestic swine population of the country or *zone* under consideration; this is established by the regular surveillance of the swine population using an approved testing procedure, which provided negative results when:

   a) within a five-year period, a serological survey was conducted on a statistically based sample size from within the slaughter sow population sufficient to provide at least 95% confidence of detecting trichinellosis if it was present at a prevalence exceeding 0.02%, and

      during this five-year period, continuous testing was conducted on a statistically based sample size from within the annual slaughter swine population sufficient to provide at least 95% confidence of detecting trichinellosis if it is present at a prevalence exceeding 0.01%, following which:

   b) a serological survey is carried out every third year on the slaughter sow population sufficient to provide at least 95% confidence of detecting trichinellosis if it is present at a prevalence exceeding 0.2%; during this time the number of samples in the slaughter swine population could be reduced to detect at the 0.5% level on an annual basis;

OR

4. in the country or *zone* under consideration, the following conditions are met:

   a) trichinellosis has not been reported in the domestic swine population for at least 5 years;

b) wild susceptible species are subjected to a regular surveillance programme, and no clinical, serological or epidemiological evidence of trichinellosis has been found;

5. the regular surveillance described in point 3 above is carried out and should be concentrated where infestation was last identified, and/or where the feeding of swill to swine occurs;
6. any suspicion of disease is followed at the field level by traceback, quarantine and laboratory testing;
7. if trichinellosis is confirmed, the infected premises remains under *official control programme* and is subjected to disease control measures using a *stamping-out policy* and rodent control;
8. all feeding of swill is officially regulated;
9. any human outbreaks of trichinellosis are investigated to determine the animal source.

Article 2.2.9.4.

Free herd (under study).

Article 2.2.9.5.

Veterinary Authorities of *importing countries* may require:

for *fresh meat* of equines (domestic and wild)

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat:

1. comes from equines slaughtered and/or inspected in an *approved abattoir*;

AND

2. were subjected to a testing procedure for trichinellosis with negative results; or
3. has been processed to ensure the destruction of all the larvae of the parasite.

CHAPTER 2.2.10.

FOOT AND MOUTH DISEASE

Article 2.2.10.1.

For the purposes of the *Terrestrial Code*, the *incubation period* for foot and mouth disease (FMD) shall be 14 days.

For the purposes of this Chapter, ruminants include animals of the family of Camelidae.

For the purposes of this Chapter, a *case* includes an animal infected with FMD virus (FMDV).

For the purposes of *international trade*, this Chapter deals not only with the occurrence of clinical signs caused by FMDV, but also with the presence of infection with FMDV in the absence of clinical signs.

The following defines the occurrence of FMDV infection:

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

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

Article 2.2.10.2.

FMD free country where vaccination is not practised

Susceptible animals in the FMD free country where vaccination is not practised should be separated from neighbouring infected countries by a *buffer zone*, or physical or geographical barriers, and animal health measures that effectively prevent the entry of the virus should be implemented.

To qualify for inclusion in the existing list of FMD free countries where vaccination is not practised, a country should:

1. have a record of regular and prompt animal disease reporting;
2. send a declaration to the OIE stating that:
   a) there has been no *outbreak* of FMD during the past 12 months;
   b) no evidence of FMDV infection has been found during the past 12 months;
   c) no vaccination against FMD has been carried out during the past 12 months;
   d) no vaccinated animal has been introduced since the cessation of vaccination;
3. supply documented evidence that:
   a) surveillance for both FMD and FMDV infection in accordance with Appendix 3.8.7. is in operation;
   b) regulatory measures for the prevention and control of FMD have been implemented.

The country will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information in points 2 and 3a) above be submitted annually to the OIE.

Article 2.2.10.3.

FMD free country where vaccination is practised

Susceptible animals in the FMD free country where vaccination is practised should be separated from neighbouring infected countries by a *buffer zone* or by physical/geographical barriers, and animal health measures that effectively prevent the entry of the virus should be implemented.

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

1. have a record of regular and prompt animal disease reporting;
2. send a declaration to the OIE that there has been no *outbreak* of FMD for the past 2 years and no evidence of FMDV circulation for the past 12 months, with documented evidence that:
   a) surveillance for FMD and FMDV circulation in accordance with Appendix 3.8.7. is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;
   b) routine vaccination is carried out for the purpose of the prevention of FMD;
   c) the vaccine used complies with the standards described in the *Terrestrial Manual*.

The country will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information in point 2 above be submitted annually to the OIE.

If an FMD free country where vaccination is practised wishes to change its status to FMD free country where vaccination is not practised, the country should wait for 12 months after vaccination has ceased then notify the OIE and provide evidence showing that FMDV circulation has not occurred during that period.

Article 2.2.10.4.

FMD free zone where vaccination is not practised

An FMD free zone where vaccination is not practised can be established in either an FMD free country where vaccination is practised or in a country of which parts are infected. In defining such zones the principles of Chapter 1.3.5. should be followed. Susceptible animals in the FMD free zone should be separated by a *buffer zone* or by physical/geographical barriers from the rest of the country and from neighbouring countries if they are of a different *animal health status*, and animal health measures that effectively prevent the entry of the virus should be implemented.

A country in which an FMD free zone where vaccination is not practised is to be established should:

1. have a record of regular and prompt animal disease reporting;
2. send a declaration to the OIE stating that it wishes to establish an FMD free zone where vaccination is not practised, and that within the proposed FMD free zone:
   a) there has been no *outbreak* of FMD during the past 12 months;
   b) no evidence of FMDV infection has been found during the past 12 months;
   c) no vaccination against FMD has been carried out during the past 12 months;
   d) no vaccinated animal has been introduced into the zone since the cessation of vaccination, except in accordance with Article 2.2.10.9.;
   e) documented evidence shows that surveillance in accordance with Appendix 3.8.7. is in operation for both FMD and FMDV infection;
3. describe in detail:
   a) regulatory measures for the prevention and control of both FMD and FMDV infection,
   b) the boundaries of the proposed FMD free zone and, if applicable, the *buffer zone* or physical or geographical barriers,

c) the system for preventing the entry of the virus (including the control of the movement of susceptible animals) into the proposed FMDV free zone (in particular if the procedure described in Article 2.2.10.9. is implemented),

and supply documented evidence that these are properly implemented and supervised.

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

The information required in points 2 and 3c) above should be submitted annually as well as any relevant changes under points 3a) and 3b).

Article 2.2.10.5.

FMD free zone where vaccination is practised

An FMD free zone where vaccination is practised can be established in either an FMD free country where vaccination is not practised or in a country of which parts are infected. In defining such zones the principles of Chapter 1.3.5. should be followed. Susceptible animals in the FMD free zone where vaccination is practised should be separated by a *buffer zone* or by physical/geographical barriers from the rest of the country and from neighbouring countries if they are of a different *animal health status*, and animal health measures that effectively prevent the entry of the virus should be implemented.

A country in which an FMD free zone where vaccination is practised is to be established should:

1. have a record of regular and prompt animal disease reporting;

2. send a declaration to the OIE that it wishes to establish an FMD free zone where vaccination is practised and that within the proposed FMD free zone;

   a) there has been no *outbreak* of FMD for the past 2 years;

   b) no evidence of FMDV circulation for the past 12 months;

   c) documented evidence shows that surveillance in accordance with Appendix 3.8.7. is in operation for FMD and FMDV circulation;

3. supply documented evidence that the vaccine used complies with the standards described in the *Terrestrial Manual*;

4. describe in detail:

   a) regulatory measures for the prevention and control of both FMD and FMDV circulation,

   b) the boundaries of the proposed FMD free zone where vaccination is practised and, if applicable, the *buffer zone* or physical or geographical barriers,

   c) the system for preventing the entry of the virus into the proposed FMD free zone (in particular if the procedure described in Article 2.2.10.9. is implemented),

   and supply evidence that these are properly implemented and supervised.

The proposed free zone will be included in the list of FMD free zones where vaccination is practised only after the submitted evidence has been accepted by the OIE. The information required in points 2, 3 and 4c) above should be submitted annually as well as any relevant changes under points 4a) and 4b).

If a country that has an FMD free zone where vaccination is practised wishes to change the status of the zone to FMD free zone where vaccination is not practised, a waiting period of 12 months after vaccination has ceased is required and evidence must be provided showing that FMDV infection has not occurred in the said zone during that period.

Article 2.2.10.6.

FMD infected country or zone

An FMD infected country is a country that does not fulfil the requirements to qualify as either an FMD free country where vaccination is not practised or an FMD free country where vaccination is practised.

An FMD infected zone is a zone that does not fulfil the requirements to qualify as either an FMD free zone where vaccination is not practised or an FMD free zone where vaccination is practised.

Article 2.2.10.7.

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

In the event of a limited *outbreak* within an FMD free country or zone with or without vaccination, a single *containment zone*, which includes all *cases*, 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 *outbreak* is limited based on the following factors:
   a) immediately on suspicion, a rapid response including notification has been made;
   b) standstill of animal movements has been imposed, and effective controls on the movement of other *commodities* mentioned in this chapter are in place;
   c) epidemiological investigation (trace-back, trace-forward) has been completed;
   d) the infection has been confirmed;
   e) the source of the *outbreak* has been identified;
   f) all *cases* have been shown to be epidemiologically linked;
2. surveillance in accordance with Appendix 3.8.7. demonstrates that there are no undetected *cases* in the *containment zone*;
3. a *stamping-out policy* has been applied;
4. increased passive and targeted surveillance in accordance with Appendix 3.8.7. in the rest of the country or zone has been carried out and has not detected any evidence of infection;
5. measures to prevent spread of the infection from the *containment zone* to the rest of the country or zone, including ongoing surveillance in the *containment zone*, are in place.

The free status of the areas outside the *containment zone* would be suspended pending the establishment of the *containment zone*. The suspension of free status of these areas could be lifted irrespective of the provisions of Article 2.2.10.8., once the *containment zone* is clearly established, by complying with points 1 to 5 above.

The recovery of the FMD free status of the *containment zone* should follow the provisions of Article 2.2.10.8.

Article 2.2.10.8.

Recovery of free status

1. When an FMD *outbreak* or FMDV infection occurs in an FMD free country or zone where vaccination is not practised, one of the following waiting periods is required to regain the status of FMD free country or zone where vaccination is not practised:
   a) 3 months after the last *case* where a *stamping-out policy* and serological surveillance are applied in accordance with Appendix 3.8.7.; or
   b) 3 months after the slaughter of all vaccinated animals where a *stamping-out policy*, emergency vaccination and serological surveillance are applied in accordance with Appendix 3.8.7.; or

c) 6 months after the last *case* or the last vaccination (according to the event that occurs the latest), where a *stamping-out policy*, emergency vaccination not followed by the slaughtering of all vaccinated animals, and serological surveillance are applied in accordance with Appendix 3.8.7., provided that a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of infection in the remaining vaccinated population.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 2.2.10.2. or 2.2.10.4. applies.

2. When an FMD *outbreak* or FMDV infection occurs in an FMD free country or zone where vaccination is practised, one of the following waiting periods is required to regain the status of FMD free country or zone where vaccination is practised:

a) 6 months after the last *case* where a *stamping-out policy*, emergency vaccination and serological surveillance in accordance with Appendix 3.8.7. are applied, provided that the serological surveillance based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation; or

b) 18 months after the last *case* where a *stamping-out policy* is not applied, but emergency vaccination and serological surveillance in accordance with Appendix 3.8.7. are applied, provided that the serological surveillance based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation.

Article 2.2.10.9.

Transfer directly to slaughter of FMD susceptible animals from an infected zone to a free zone within a country

FMD susceptible animals should only leave the infected zone if moved by mechanised transport to the nearest designated *abattoir* located in the *buffer zone* directly to slaughter.

In the absence of an *abattoir* in the *buffer zone*, live FMD susceptible animals can be transported to the nearest *abattoir* in a free zone directly to slaughter only under the following conditions:

1. no FMD susceptible animal has been introduced into the *establishment* of origin and no animal in the *establishment* of origin has shown clinical signs of FMD for at least 30 days prior to movement;

2. the animals were kept in the *establishment* of origin for at least 3 months prior to movement;

3. FMD has not occurred within a 10-kilometre radius of the *establishment* of origin for at least 3 months prior to movement;

4. the animals must be transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *abattoir* without coming into contact with other susceptible animals;

5. such an *abattoir* is not approved for the export of *fresh meat* during the time it is handling the meat of animals from the infected zone;

6. *vehicles* and the *abattoir* must be subjected to thorough cleansing and *disinfection* immediately after use.

All products obtained from the animals and any products coming into contact with them must be considered infected, and treated in such a way as to destroy any residual virus in accordance with Appendix 3.6.2.

Animals moved into a free zone for other purposes must be moved under the supervision of the *Veterinary Authority* and comply with the conditions in Article 2.2.10.12.

Article 2.2.10.10.

When importing from FMD free countries where vaccination is not practised or FMD free zones where vaccination is not practised, *Veterinary Authorities* should require:

for FMD susceptible animals

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of FMD on the day of shipment;
2. were kept in an FMD free country or zone where vaccination is not practised since birth or for at least the past 3 months;
3. have not been vaccinated.

Article 2.2.10.11.

When importing from FMD free countries where vaccination is practised or from FMD free zones where vaccination is practised, *Veterinary Authorities* should require:

for domestic ruminants and pigs

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of FMD on the day of shipment;
2. were kept in an FMD free country or zone since birth or for at least the past 3 months; and
3. have not been vaccinated and were subjected, with negative results, to tests for antibodies against FMD virus, when destined to an FMD free country or zone where vaccination is not practised.

Article 2.2.10.12.

When importing from FMD infected countries or zones, *Veterinary Authorities* should require:

for domestic ruminants and pigs

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of FMD on the day of shipment;
2. were kept in the *establishment* of origin since birth, or

   a) for the past 30 days, if a *stamping-out policy* is in force in the *exporting country*, or

   b) for the past 3 months, if a *stamping-out policy* is not in force in the *exporting country*,

   and that FMD has not occurred within a ten-kilometre radius of the *establishment* of origin for the relevant period as defined in points a) and b) above; and
3. were isolated in an *establishment* for the 30 days prior to shipment, and all animals in isolation were subjected to diagnostic tests (probang and serology) for evidence of FMDV infection with negative results at the end of that period, and that FMD did not occur within a ten-kilometre radius of the *establishment* during that period; or
4. were kept in a *quarantine station* for the 30 days prior to shipment, all animals in quarantine were subjected to diagnostic tests (probang and serology) for evidence of FMDV infection with negative results at the end of that period, and that FMD did not occur within a ten-kilometre radius of the *quarantine station* during that period;
5. were not exposed to any source of FMD infection during their transportation from the *quarantine station* to the *place of shipment*.

Article 2.2.10.13.

When importing from FMD free countries where vaccination is not practised or FMD free zones where vaccination is not practised, *Veterinary Authorities* should require:

for fresh semen of domestic ruminants and pigs

the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:
   a) showed no clinical sign of FMD on the day of collection of the semen;
   b) were kept in an FMD free country or zone where vaccination is not practised for at least 3 months prior to collection;
2. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.1. or Appendix 3.2.2., as relevant.

Article 2.2.10.14.

When importing from FMD free countries where vaccination is not practised or FMD free zones where vaccination is not practised, *Veterinary Authorities* should require:

for frozen semen of domestic ruminants and pigs

the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:
   a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
   b) were kept in an FMD free country or zone where vaccination is not practised for at least 3 months prior to collection;
2. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.1. or Appendix 3.2.2., as relevant.

Article 2.2.10.15.

When importing from FMD free countries where vaccination is practised or from FMD free zones where vaccination is practised, *Veterinary Authorities* should require:

for semen of domestic ruminants and pigs

the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:
   a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
   b) were kept in a country or zone free from FMD for at least 3 months prior to collection;
   c) if destined to an FMD free country or zone where vaccination is not practised:
      i) have not been vaccinated and were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMD virus, with negative results; or
      ii) had been vaccinated at least twice, with the last vaccination not more than 12 and not less than one month prior to collection;
2. no other animal present in the *artificial insemination centre* has been vaccinated within the month prior to collection;
3. the semen:
   a) was collected, processed and stored in conformity with the provisions of Appendix 3.2.1. or Appendix 3.2.2., as relevant;
   b) was stored in the country of origin for a period of at least one month following collection, and during this period no animal on the *establishment* where the donor animals were kept showed any sign of FMD.

Article 2.2.10.16.

When importing from FMD infected countries or zones, *Veterinary Authorities* should require:

for semen of domestic ruminants and pigs

the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:
   a) showed no clinical sign of FMD on the day of collection of the semen;
   b) were kept in an *establishment* where no animal had been added in the 30 days before collection, and that FMD has not occurred within 10 kilometres for the 30 days before and after collection;
   c) have not been vaccinated and were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMD virus, with negative results; or
   d) had been vaccinated at least twice, with the last vaccination not more than 12 and not less than one month prior to collection;
2. no other animal present in the *artificial insemination centre* has been vaccinated within the month prior to collection;
3. the semen:
   a) was collected, processed and stored in conformity with the provisions of Appendix 3.2.1. or Appendix 3.2.2., as relevant;
   b) was subjected, with negative results, to a test for FMDV infection if the donor animal has been vaccinated within the 12 months prior to collection;
   c) was stored in the country of origin for a period of at least one month following collection, and during this period no animal on the *establishment* where the donor animals were kept showed any sign of FMD.

Article 2.2.10.17.

Irrespective of the FMD status of the *exporting country* or *zone*, *Veterinary Authorities* should authorise without restriction on account of FMD the import or transit through their territory of *in vivo* derived embryos of cattle subject to the presentation of an *international veterinary certificate* attesting that the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1. or Appendix 3.3.3., as relevant.

Article 2.2.10.18.

When importing from FMD free countries where vaccination is not practised or FMD free zones where vaccination is not practised, *Veterinary Authorities* should require:

for *in vitro* produced embryos of cattle

the presentation of an *international veterinary certificate* attesting that:

1. the donor females:
   a) showed no clinical sign of FMD at the time of collection of the oocytes;
   b) were kept in a country or zone free from FMD at the time of collection;
2. fertilisation was achieved with semen meeting the conditions referred to in Articles 2.2.10.13., 2.2.10.14., 2.2.10.15. or 2.2.10.16., as relevant;
3. the oocytes were collected, and the embryos were processed and stored in conformity with the provisions of Appendix 3.3.2. or Appendix 3.3.3., as relevant.

Article 2.2.10.19.

When importing from FMD free countries where vaccination is practised or from FMD free zones where vaccination is practised, *Veterinary Authorities* should require:

for *in vitro* produced embryos of cattle

the presentation of an *international veterinary certificate* attesting that:

1. the donor females:
   a) showed no clinical sign of FMD at the time of collection of the oocytes;
   b) were kept in a country or zone free from FMD for at least 3 months prior to collection;
   c) if destined for an FMD free country or zone where vaccination is not practised:
      i) have not been vaccinated and were subjected, with negative results, to tests for antibodies against FMD virus; or
      ii) had been vaccinated at least twice, with the last vaccination not less than one month and not more than 12 months prior to collection;
2. no other animal present in the *establishment* has been vaccinated within the month prior to collection;
3. fertilization was achieved with semen meeting the conditions referred to in Articles 2.2.10.13., 2.2.10.14., 2.2.10.15. or 2.2.10.16., as relevant;
4. the oocytes were collected, and the embryos were processed and stored in conformity with the provisions of Appendix 3.3.2. or Appendix 3.3.3., as relevant.

Article 2.2.10.20.

When importing from FMD free countries where vaccination is not practised or FMD free zones where vaccination is not practised, *Veterinary Authorities* should require:

for *fresh meat* of FMD susceptible animals

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

1. have been kept in the FMD free country or zone where vaccination is not practised since birth, or which have been imported in accordance with Article 2.2.10.10., Article 2.2.10.11. or Article 2.2.10.12.;
2. have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results.

Article 2.2.10.21.

When importing from FMD free countries where vaccination is practised or from FMD free zones where vaccination is practised, *Veterinary Authorities* should require:

for *fresh meat* of cattle and buffaloes (*Bubalus bubalis*) (excluding feet, head and viscera)

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

1. have been kept in the FMD free country or zone where vaccination is practised since birth, or which have been imported in accordance with Article 2.2.10.10., Article 2.2.10.11. or Article 2.2.10.12.;
2. have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results.

Article 2.2.10.22.

When importing from FMD free countries where vaccination is practised or from FMD free zones where vaccination is practised, *Veterinary Authorities* should require:

for *fresh meat* or *meat products* of pigs and ruminants other than cattle and buffaloes

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

1. have been kept in the FMD free country or zone where vaccination is practised since birth, or which have been imported in accordance with Article 2.2.10.10., Article 2.2.10.11. or Article 2.2.10.12.;
2. have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results.

Article 2.2.10.23.

When importing from FMD infected countries or zones, where an official control programme exists, involving compulsory systematic vaccination of cattle, *Veterinary Authorities* should require:

for *fresh meat* of cattle and buffaloes (*Bubalus bubalis*) (excluding feet, head and viscera)

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat:

1. comes from animals which:
   a) have remained in the *exporting country* for at least 3 months prior to slaughter;
   b) have remained, during this period, in a part of the country where cattle are regularly vaccinated against FMD and where official controls are in operation;
   c) have been vaccinated at least twice with the last vaccination not more than 12 months and not less than one month prior to slaughter;
   d) were kept for the past 30 days in an *establishment*, and that FMD has not occurred within a ten-kilometre radius of the *establishment* during that period;
   e) have been transported, in a *vehicle* which was cleansed and disinfected before the cattle 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;
   f) have been slaughtered in an *approved abattoir*:
      i) which is officially designated for export;
      ii) in which no FMD has been detected during the period between the last *disinfection* carried out before slaughter and the shipment for export has been dispatched;
   g) have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results within 24 hours before and after slaughter;
2. comes from deboned carcasses:
   a) from which the major lymphatic nodes have been removed;
   b) which, prior to deboning, have been submitted to maturation at a temperature above + 2°C for a minimum period of 24 hours following slaughter and in which the pH value was below 6.0 when tested in the middle of both the longissimus dorsi.

Article 2.2.10.24.

When importing from FMD infected countries or zones, *Veterinary Authorities* should require:

for *meat products* of domestic ruminants and pigs

the presentation of an *international veterinary certificate* attesting that:

1. the entire consignment of *meat* comes from animals which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results;

2. the *meat* has been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Article 3.6.2.1.;

3. the necessary precautions were taken after processing to avoid contact of the *meat products* with any potential source of FMD virus.

Article 2.2.10.25.

When importing from FMD free countries or zones (where vaccination either is or is not practised), *Veterinary Authorities* should require:

for *milk* and *milk products* intended for human consumption and for products of animal origin (from FMD susceptible animals) intended for use in animal feeding or for agricultural or industrial use

the presentation of an *international veterinary certificate* attesting that these products come from animals which have been kept in the country or zone since birth, or which have been imported in accordance with Article 2.2.10.10., Article 2.2.10.11. or Article 2.2.10.12.

Article 2.2.10.26.

When importing from FMD infected countries or zones where an official control programme exists, *Veterinary Authorities* should require:

for *milk*, cream, milk powder and *milk products*

the presentation of an *international veterinary certificate* attesting that:

1. these products:

   a) originate from herds or flocks which were not infected or suspected of being infected with FMD at the time of *milk* collection;

   b) have been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Article 3.6.2.5. and in Article 3.6.2.6.;

2. the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMD virus.

Article 2.2.10.27.

When importing from FMD infected countries, *Veterinary Authorities* should require:

for blood and meat-meals (from domestic or wild ruminants and pigs)

the presentation of an *international veterinary certificate* attesting that the manufacturing method for these products included heating to a minimum core temperature of 70°C for at least 30 minutes.

Article 2.2.10.28.

When importing from FMD infected countries, *Veterinary Authorities* should require:

for wool, hair, bristles, raw hides and skins (from domestic or wild ruminants and pigs)

the presentation of an *international veterinary certificate* attesting that:

1. these products have been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Article 3.6.2.2., Article 3.6.2.3. and Article 3.6.2.4.;
2. the necessary precautions were taken after collection or processing to avoid contact of the products with any potential source of FMD virus.

Veterinary Authorities can authorise, without restriction, the import or transit through their territory of semi-processed hides and skins (limed hides, pickled pelts, and semi-processed leather - e.g. wet blue and crust leather), provided that these products have been submitted to the usual chemical and mechanical processes in use in the tanning industry.

Article 2.2.10.29.

When importing from FMD infected countries or zones, *Veterinary Authorities* should require:

for straw and forage

the presentation of an *international veterinary certificate* attesting that these *commodities*:

1. are free of grossly identifiable contamination with material of animal origin;
2. have been subjected to one of the following treatments, which, in the case of material sent in bales, has been shown to penetrate to the centre of the bale:
   a) either to the action of steam in a closed chamber such that the centre of the bales has reached a minimum temperature of 80°C for at least 10 minutes,
   b) or to the action of formalin fumes (formaldehyde gas) produced by its commercial solution at 35-40% in a chamber kept closed for at least 8 hours and at a minimum temperature of 19°C;

OR

3. have been kept in bond for at least 3 months (under study) before being released for export.

Article 2.2.10.30.

When importing from FMD free countries or zones (where vaccination either is or is not practised), *Veterinary Authorities* should require:

for skins and trophies derived from FMD susceptible wild animals

the presentation of an *international veterinary certificate* attesting that these products are derived from animals that have been killed in such a country or zone, or which have been imported from a country or zone free of FMD (where vaccination either is or is not practised).

Article 2.2.10.31.

When importing from FMD infected countries or zones, *Veterinary Authorities* should require:

for skins and trophies derived from FMD susceptible wild animals

the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of the FMD virus in conformity with the procedures referred to in Article 3.6.2.7.

CHAPTER 2.2.11.

VESICULAR STOMATITIS

Article 2.2.11.1.

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.*

Article 2.2.11.2.

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 2 years.

Article 2.2.11.3.

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 2.2.11.4.

When importing from VS free countries, *Veterinary Authorities* should require:

<u>for domestic cattle, sheep, goats, pigs and horses</u>

the presentation of an *international veterinary certificate* attesting that the animals:

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

Article 2.2.11.5.

When importing from VS free countries, *Veterinary Authorities* should require:

<u>for wild bovine, ovine, caprine, porcine and equine animals and deer</u>

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 2.2.11.6.

When importing from countries considered infected with VS, *Veterinary Authorities* should require:

for domestic cattle, sheep, goats, pigs and horses

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; or
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 2.2.11.7.

When importing from countries considered infected with VS, *Veterinary Authorities* should require:

for wild bovine, ovine, caprine, porcine and equine animals and deer

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 2.2.11.8.

When importing from VS free countries or zones, *Veterinary Authorities* should require:

for *in vivo* derived embryos of ruminants, swine and horses

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 Appendix 3.3.1. or Appendix 3.3.3., as relevant.

Article 2.2.11.9.

When importing from countries or zones considered infected with VS, *Veterinary Authorities* should require:

for *in vivo* derived embryos of ruminants, swine and horses

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 Appendix 3.3.1. or Appendix 3.3.3., as relevant.

CHAPTER 2.2.12.

RINDERPEST

Article 2.2.12.1.

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* includes an animal infected with rinderpest virus (RPV).

For the purpose of this chapter, susceptible animals apply to both domestic and wild artiodactyls.

For the purposes of *international trade*, this chapter deals not only with the occurrence of clinical signs caused by RPV, but also with the presence of infection with RPV in the absence of clinical signs.

Ban on vaccination against rinderpest means a ban on administering a RP vaccine to any susceptible animal and a heterologous vaccine against RP to any large ruminants or pigs.

1. Animal not vaccinated against RP means:
   a) for large ruminants and pigs: an animal that has received neither a RP vaccine nor a heterologous vaccine against RP;
   b) for small ruminants: an animal that has not received a RP vaccine.
2. The following defines the occurrence of RPV infection:
   a) RPV 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 RP has been identified in samples from one or more animals showing one or more clinical signs consistent with RP, or epidemiologically linked to an *outbreak* of RP, or giving cause for suspicion of association or contact with RP; or
   c) antibodies to RPV 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 RP in susceptible animals, or showing clinical signs consistent with recent infection with RP.

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

Article 2.2.12.2.

RP free country

To qualify for inclusion in the existing list of RP free countries, a country should:

1. have a record of regular and prompt animal disease reporting;
2. send a declaration to the OIE stating that:
   a) there has been no *outbreak* of RP during the past 24 months,
   b) no evidence of RPV infection has been found during the past 24 months,
   c) no vaccination against RP has been carried out during the past 24 months,

   and supply documented evidence that surveillance for both RP and RPV infection in accordance with Appendix 3.8.2. is in operation and that regulatory measures for the prevention and control of RP have been implemented;
3. not have imported since the cessation of vaccination any animals vaccinated against RP.

The country will be included in the list only after the submitted evidence has been accepted by the OIE.

Article 2.2.12.3.

Recovery of free status

When a RP *outbreak* or RPV infection occurs in a RP free country, one of the following waiting periods is required to regain the status of RP free country:

1. 3 months after the last *case* where a *stamping-out policy* and serological surveillance are applied in accordance with Appendix 3.8.2.; or
2. 3 months after the slaughter of all vaccinated animals where a *stamping-out policy*, emergency vaccination and serological surveillance are applied in accordance with Appendix 3.8.2.; or
3. 6 months after the last *case* or the last vaccination (according to the event that occurs the latest), where a *stamping-out policy*, emergency vaccination not followed by the slaughter of all vaccinated animals, and serological surveillance are applied in accordance with Appendix 3.8.2.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply but Article 2.2.12.2. applies.

Article 2.2.12.4.

Infected country

When the requirements for acceptance as a RP free country are not fulfilled, a country shall be considered as RP infected.

Article 2.2.12.5.

When importing from RP free countries, *Veterinary Authorities* should require:

<u>for RP susceptible animals</u>

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of RP on the day of shipment;
2. remained in a RP free country since birth or for at least 30 days prior to shipment.

Article 2.2.12.6.

When importing from RP infected countries, *Veterinary Authorities* should require:

<u>for RP susceptible animals</u>

the presentation of an *international veterinary certificate* attesting that:

1. RP is the subject of a national surveillance programme according to Appendix 3.8.2.;
2. RP has not occurred within a 10-kilometre radius of the *establishment* of origin of the animals destined for export for at least 21 days prior to their shipment to the *quarantine station* referred to in point 3b) below;
3. the animals:
   a) showed no clinical sign of RP on the day of shipment;
   b) were kept in the *establishment* of origin since birth or for at least 21 days before introduction into the *quarantine station* referred to in point c) below;
   c) have not been vaccinated against RP, were isolated in a *quarantine station* for the 30 days prior to shipment, and were subjected to a diagnostic test for RP on two occasions with negative results, at an interval of not less than 21 days;
   d) were not exposed to any source of infection during their transportation from the *quarantine station* to the place of shipment;

4. RP has not occurred within a ten-kilometre radius of the *quarantine station* for 30 days prior to shipment.

Article 2.2.12.7.

When importing from RP free countries, *Veterinary Authorities* should require:

for semen of RP susceptible animals

the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:
   a) showed no clinical sign of RP on the day of collection of the semen;
   b) were kept in a RP free country for at least 3 months prior to collection;
2. the semen was collected, processed and stored in conformity with the provisions of either Appendix 3.2.1. or Appendix 3.2.2., as relevant

Article 2.2.12.8.

When importing from RP infected countries, *Veterinary Authorities* should require:

for semen of RP susceptible animals

the presentation of an *international veterinary certificate* attesting that:

1. RP is the subject of a national surveillance programme according to Appendix 3.8.2.;
2. the donor animals:
   a) showed no clinical sign of RP on the day of collection of the semen;
   b) were kept in an *establishment* where no RP susceptible animals had been added in the 21 days before collection, and that RP has not occurred within 10 kilometres of the *establishment* for the 21 days before and after collection;
   c) were vaccinated against RP at least 3 months prior to collection; or
   d) have not been vaccinated against RP, and were subjected to a diagnostic test on two occasions with negative results, at an interval of not less than 21 days within the 30 days prior to collection;
3. the semen was collected, processed and stored in conformity with the provisions of either Appendix 3.2.1. or Appendix 3.2.2., as relevant.

Article 2.2.12.9.

When importing from RP free countries, *Veterinary Authorities* should require:

for *in vivo* derived embryos of RP susceptible animals

the presentation of an *international veterinary certificate* attesting that:

1. the donor females were kept in an *establishment* located in a RP free country at the time of collection;
2. the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1. or Appendix 3.3.3., as relevant.

Article 2.2.12.10.

When importing from RP infected countries, *Veterinary Authorities* should require:

for *in vivo* derived embryos of RP susceptible animals

the presentation of an *international veterinary certificate* attesting that:

1. RP is the subject of a national surveillance programme according to Appendix 3.8.2.;
2. the donor females:
   a) and all other animals in the *establishment* showed no clinical sign of RP at the time of collection and for the following 21 days;
   b) were kept in an *establishment* where no RP susceptible animals had been added in the 21 days before collection of the embryos;
   c) were vaccinated against RP at least 3 months prior to collection; or
   d) have not been vaccinated against RP, and were subjected to a diagnostic test for RP on two occasions with negative results, at an interval of not less than 21 days within the 30 days prior to collection;
3. the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1. or Appendix 3.3.3., as relevant.

Article 2.2.12.11.

When importing from RP free countries, *Veterinary Authorities* should require:

for *fresh meat* or *meat products* of susceptible animals

the presentation of an *international veterinary certificate* attesting that the entire consignment comes from animals which have been kept in the country since birth or for at least 3 months prior to slaughter.

Article 2.2.12.12.

When importing from RP infected countries, *Veterinary Authorities* should require:

for *fresh meat* (excluding offal) of susceptible animals

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat:

1. comes from a country where RP is the subject of a national surveillance programme according to Appendix 3.8.2.;
2. comes from animals which:
   a) showed no clinical sign of RP within 24 hours before slaughter;
   b) have remained in the country for at least 3 months prior to slaughter;
   c) were kept in the *establishment* of origin since birth or for at least 30 days prior to shipment to the *approved abattoir*, and that RP has not occurred within a ten-kilometre radius of the *establishment* during that period;
   d) were vaccinated against RP at least 3 months prior to shipment to the *approved abattoir*;
   e) 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;
   f) were slaughtered in an *approved abattoir* in which no RP has been detected during the period between the last *disinfection* carried out before slaughter and the date on which the shipment has been dispatched.

Article 2.2.12.13.

When importing from RP infected countries, *Veterinary Authorities* should require:

for *meat products* of susceptible animals

the presentation of an *international veterinary certificate* attesting that:

1. only *fresh meat* complying with the provisions of Article 2.2.12.12. has been used in the preparation of the *meat products*; or
2. the *meat products* have been processed to ensure the destruction of the RPV in conformity with one of the procedures referred to in Article 3.6.2.1.;
3. the necessary precautions were taken after processing to avoid contact of the meat products with any possible source of RPV.

Article 2.2.12.14.

When importing from RP free countries, *Veterinary Authorities* should require:

for *milk* and *milk products* intended for human consumption and for products of animal origin (from RP susceptible animals) intended for use in animal feeding or for agricultural or industrial use

the presentation of an *international veterinary certificate* attesting that these products come from animals which have been kept in the country since birth or for at least 3 months.

Article 2.2.12.15.

When importing from RP infected countries, *Veterinary Authorities* should require:

for *milk* and cream

the presentation of an *international veterinary certificate* attesting that:

1. these products:
   a) originate from herds or flocks which were not subjected to any restrictions due to RP at the time of *milk* collection;
   b) have been processed to ensure the destruction of the RPV in conformity with one of the procedures referred to in Article 3.6.2.5. and in Article 3.6.2.6.;
2. the necessary precautions were taken after processing to avoid contact of the products with any potential source of RPV.

Article 2.2.12.16.

When importing from RP infected countries, *Veterinary Authorities* should require:

for *milk products*

the presentation of an *international veterinary certificate* attesting that:

1. these products are derived from *milk* complying with the above requirements;
2. the necessary precautions were taken after processing to avoid contact of the *milk products* with a potential source of RPV.

Article 2.2.12.17.

When importing from RP infected countries, *Veterinary Authorities* should require:

for blood and meat-meals (from susceptible animals)

the presentation of an *international veterinary certificate* attesting that the manufacturing method for these products included heating to a minimum internal temperature of 70°C for at least 30 minutes.

Article 2.2.12.18.

When importing from RP infected countries, *Veterinary Authorities* should require:

for wool, hair, bristles, raw hides and skins (from susceptible animals)

the presentation of an *international veterinary certificate* attesting that:

1. these products have been processed to ensure the destruction of the RPV in conformity with one of the procedures referred to in Article 3.6.2.2., Article 3.6.2.3. and Article 3.6.2.4.;
2. the necessary precautions were taken after processing to avoid contact of the products with any potential source of RPV.

Veterinary Authorities can authorise, without restriction, the import or transit through their territory of semi-processed hides and skins (limed hides, pickled pelts, and semi-processed leather - e.g. wet blue and crust leather), provided that these products have been submitted to the usual chemical and mechanical processes in use in the tanning industry.

Article 2.2.12.19.

When importing from RP infected countries, *Veterinary Authorities* should require:

for hooves, claws, bones and horns, hunting trophies and preparations destined for museums (from susceptible animals)

the presentation of an *international veterinary certificate* attesting that these products:

1. were completely dried and had no trace on them of skin, flesh or tendon; and/or
2. have been adequately disinfected

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1 *[Note:* International veterinary certificates *for animal products coming from RP infected countries, may not be required if the products are transported in an approved manner to premises controlled and approved by the* Veterinary Authority *of the* importing country *for processing to ensure the destruction of the RPV as described in Article 3.6.2.2., Article 3.6.2.3. and Article 3.6.2.4.]*

CHAPTER 2.2.13.

BLUETONGUE

Article 2.2.13.1.

For the purposes of the *Terrestrial Code*, the *infective period* for bluetongue virus (BTV) shall be 60 days.

The global BTV distribution is currently between latitudes of approximately 53°N and 34°S but is known to be expanding in the northern hemisphere.

In the absence of clinical disease in a country or *zone* within this part of the world, its BTV status should be determined by an ongoing surveillance programme (in accordance with Appendix 3.8.10.). 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 Appendix 3.8.10.

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 Appendix 3.8.10.) 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*.

Article 2.2.13.2.

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) the country or *zone* lies wholly north of 53°N or south of 34°S, and is not adjacent to a country or *zone* not having a free status; or

   b) a surveillance programme in accordance with Appendix 3.8.10. has demonstrated no evidence of BTV in the country or *zone* during the past 2 years; or

   c) a surveillance programme has demonstrated no evidence of *Culicoides* likely to be competent BTV vectors in the country or *zone*.

2. A BTV free country or zone in which surveillance has found no evidence that *Culicoides* likely to be competent BTV vectors 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 zones.

3. A BTV free country or zone in which surveillance has found evidence that *Culicoides* likely to be competent BTV vectors are present will not lose its free status through the importation of vaccinated or seropositive animals from infected countries or zones, provided:

   a) the animals have been vaccinated in accordance with the *Terrestrial Manual* at least 60 days prior to dispatch with a vaccine which covers all serotypes whose presence in the source population has been demonstrated through a surveillance programme in accordance with Appendix 3.8.10., and that the animals are identified in the accompanying certification as having been vaccinated; or

   b) the animals are not vaccinated, and a surveillance programme in accordance with Appendix 3.8.10. has been in place in the source population for a period of 60 days immediately prior to dispatch, and no evidence of BTV transmission has been detected.

4. A BTV free country or zone adjacent to an infected country or zone should include a zone as described in Article 2.2.13.1. in which surveillance is conducted in accordance with Appendix 3.8.10. Animals within this

zone must be subjected to continuing surveillance. The boundaries of this *zone* must be clearly defined, and must take account of geographical and epidemiological factors that are relevant to BTV transmission

Article 2.2.13.3.

BTV seasonally free zone

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

For the application of Articles 2.2.13.6., 2.2.13.9. and 2.2.13.13., 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* likely to be competent BTV vectors.

For the application of Articles 2.2.13.6., 2.2.13.9. and 2.2.13.13., 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* likely to be competent BTV vectors.

A BTV seasonally free zone in which surveillance has found no evidence that *Culicoides* likely to be competent BTV vectors 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 zones.

Article 2.2.13.4.

BTV infected country or zone

A BTV infected country or zone is a clearly defined area where evidence of BTV has been reported during the past 2 years.

Article 2.2.13.5.

When importing from BTV free countries or zones, *Veterinary Authorities* should require:

<u>for ruminants and other BTV susceptible herbivores</u>

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 7 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 7 days;
   b) were vaccinated in accordance with the *Terrestrial Manual* 60 days before the introduction into the free country or zone against all serotypes whose presence in the source population has been demonstrated through a surveillance programme as described in Appendix 3.8.10.;
   c) were identified as having been vaccinated; and
   d) remained in the BTV free country or zone until shipment;

AND

5. if the animals were exported from a free zone, either:
   a) did not transit through an infected zone during transportation to the *place of shipment*; or
   b) were protected from attack from *Culicoides* likely to be competent BTV vectors at all times when transiting through an infected zone; or
   c) had been vaccinated in accordance with point 4 above.

Article 2.2.13.6.

When importing from BTV seasonally free zones, *Veterinary Authorities* should require:

for ruminants and other BTV susceptible herbivores

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 in accordance with the *Terrestrial Manual* 60 days before the introduction into the free country or zone against all serotypes whose presence in the source population has been demonstrated through a surveillance programme in accordance with Appendix 3.8.10. and were identified as having been vaccinated and remained in the BTV free country or zone until shipment;

AND

5. if the animals were exported from a free zone, either:
   a) did not transit through an infected zone during transportation to the *place of shipment*; or
   b) were protected from attack from *Culicoides* likely to be competent BTV vectors at all times when transiting through an infected zone; or
   c) were vaccinated in accordance with point 4 above.

Article 2.2.13.7.

When importing from BTV infected countries or zones, *Veterinary Authorities* should require:

for ruminants and other BTV susceptible herbivores

the presentation of an *international veterinary certificate* attesting that the animals:

1. were protected from attack from *Culicoides* likely to be competent BTV vectors since birth or for at least 60 days prior to shipment; or
2. were protected from attack from *Culicoides* likely to be competent BTV vectors for at least 28 days prior to 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 *quarantine station*; or

3. were protected from attack from *Culicoides* likely to be competent BTV vectors for at least 14 days prior to 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 *quarantine station*; or

4. were vaccinated in accordance with the *Terrestrial Manual* at least 60 days before shipment, against all serotypes whose presence in the source population has been demonstrated through a surveillance programme in accordance with Appendix 3.8.10., and were identified in the accompanying certification as having been vaccinated; or

5. are not vaccinated, a surveillance programme in accordance with Appendix 3.8.10. has been in place in the source population for a period of 60 days immediately prior to shipment, and no evidence of BTV transmission has been detected;

AND

6. were protected from attack from *Culicoides* likely to be competent BTV vectors during transportation to the *place of shipment*; or

7. were vaccinated in accordance with the *Terrestrial Manual* 60 days before shipment or had antibodies against all serotypes whose presence in the zones of transit has been demonstrated through a surveillance programme in accordance with Appendix 3.8.10.

Article 2.2.13.8.

When importing from BTV free countries or zones, *Veterinary Authorities* should require:

<u>for semen of ruminants and other BTV susceptible herbivores</u>

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;

2. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.1.

Article 2.2.13.9.

When importing from BTV seasonally free zones, *Veterinary Authorities* should require:

<u>for semen of ruminants and other BTV susceptible herbivores</u>

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 Appendix 3.2.1.

Article 2.2.13.10.

When importing from BTV infected countries or zones, *Veterinary Authorities* should require:

for semen of ruminants and other BTV susceptible herbivores

the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:

   a) were protected from attack from *Culicoides* likely to be competent BTV vectors 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 Appendix 3.2.1.

Article 2.2.13.11.

Regardless of the bluetongue status of the *exporting country*, *Veterinary Authorities* of *importing countries* should require:

for *in vivo* derived bovine embryos/oocytes

the presentation of an *international veterinary certificate* attesting that the embryos/oocytes were collected, processed and stored in conformity with the provisions of Appendix 3.3.1. or Appendix 3.3.3., as relevant.

Article 2.2.13.12.

When importing from BTV free countries or zones, *Veterinary Authorities* should require:

for *in vivo* derived embryos of ruminants (other than bovines) and other BTV susceptible herbivores

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 Appendix 3.3.1.

Article 2.2.13.13.

When importing from BTV seasonally free zones, *Veterinary Authorities* should require:

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

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 Appendix 3.3.1.

Article 2.2.13.14.

When importing from BTV infected countries or zones, *Veterinary Authorities* should require:

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

the presentation of an *international veterinary certificate* attesting that:

1. the donor females:
   a) were protected from attack from *Culicoides* likely to be competent BTV vectors 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 Appendix 3.3.1.

Article 2.2.13.15.

Protecting animals from *Culicoides* attack

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

Potential risk management strategies include:

1. treating animals with chemical repellents prior to and during transportation;
2. *loading*, transporting and *unloading* animals at times of low vector activity (i.e. bright sunshine, low temperature);
3. ensuring *vehicles* do not stop en route during dawn or dusk, or overnight, unless the animals are held behind insect proof netting;
4. darkening the interior of the *vehicle*, for example by covering the roof and/or sides of *vehicles* with shadecloth;
5. surveillance for vectors at common stopping and offloading points to gain information on seasonal variations;
6. using historical, ongoing and/or BTV modelling information to identify low risk ports and transport routes.

CHAPTER 2.2.14.

RIFT VALLEY FEVER

Article 2.2.14.1.

For the purposes of the *Terrestrial Code*, the *infective period* for Rift Valley fever (RVF) shall be 30 days.

For the purposes of this Chapter, ruminants include camels.

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

The historic distribution of RVF is the sub-Saharian African continent, Madagascar and the Arabian Peninsula.

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

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

In the absence of clinical disease, the RVF status of a country or zone within the historically infected regions of the world should be determined by a surveillance programme (carried out in accordance with Appendix 3.8.1.) focusing on mosquitoes and serology of susceptible mammals. The programme should concentrate on parts of the country or *zone* at high risk because of historical, geographic and climatic factors, ruminant and mosquito population distribution, and proximity to areas where epidemics have recently occurred.

Article 2.2.14.2.

RVF infection free country or zone

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

1. the country or *zone* lies outside the historically infected regions, and not adjacent to historically infections; or

2. a surveillance programme as described in Article 2.2.14.1. has demonstrated no evidence of RVF infection in humans, animals or mosquitoes in the country or *zone* during the past 4 years following a RVF epidemic.

The provisions of the last paragraph of Article 2.2.14.1. may need to be complied with on a continuous basis in order to maintain freedom from infection, depending on the geographical location of the country or *zone*.

A RVF infection free country or zone in which surveillance and monitoring has found no evidence that RVF infection is present will not lose its free status through the importation of permanently marked seropositive animals or those destined for direct slaughter.

Article 2.2.14.3.

RVF infected country or zone without disease

A RVF disease free country or zone is a country or zone that is not infection free (see Article 2.2.14.2.) but in which disease has not occurred in humans or animals in the past 6 months provided that climatic changes predisposing to *outbreaks* of RVF have not occurred during this time.

Article 2.2.14.4.

RVF infected country or zone with disease

A RVF infected country or zone with disease is one in which clinical disease in humans or animals has occurred within the past 6 months.

Article 2.2.14.5.

Veterinary Authorities of countries shall consider whether there is a risk with regard to RVF infection in accepting importation or transit through their territory from other countries of the following commodities:

1. live ruminants;
2. *meat* and *meat products* of domestic and wild ruminants.

Other *commodities* should be considered as not having the potential to spread RVF when they are the subject of *international trade*.

Article 2.2.14.6.

When importing from RVF infection free countries or zones, *Veterinary Authorities* should require:

for ruminants

the presentation of an *international veterinary certificate* attesting that the animals:

1. were kept in a RVF free country or zone since birth or for at least 30 days prior to shipment; and
2. if the animals were exported from a free zone, either:
   a) did not transit through an infected zone during transportation to the *place of shipment*; or
   b) were protected from mosquito attack at all times when transiting through an infected zone.

Article 2.2.14.7.

When importing from RVF infection free countries or zones, *Veterinary Authorities* should require:

for *meat* and *meat products* of domestic and wild ruminants

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

Article 2.2.14.8.

When importing from RVF infected countries/zones without disease, *Veterinary Authorities* should require:

for ruminants

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no evidence of RFV on the day of shipment;
2. were kept in a RVF infected country/zone free of disease since birth or for the last 6 months providing that climatic changes predisposing to *outbreaks* of RVF have not occurred during this time;

OR

3. were vaccinated against RVF at least 21 days prior to shipment with a modified live virus vaccine;

OR

4. were held in a mosquito-proof *quarantine station* for at least 30 days prior to shipment during which the animals showed no clinical signs of RVF and were protected from mosquitoes between quarantine and the *place of shipment* as well as at the *place of shipment*;

AND

5. did not transit through an infected zone with disease during transportation of the *place of shipment*.

Article 2.2.14.9.

When importing from RVF infected countries or zones without disease, *Veterinary Authorities* should require:

for *meat* and *meat products* of domestic and wild ruminants

the presentation of an *international veterinary certificate* attesting that:

1. the products are derived from animals which:
   a) remained in the RVF disease free country/zone since birth or for the last 30 days;
   b) were slaughtered in an *approved abattoir* and were subjected to ante-mortem and post-mortem inspections for RVF with favourable results;
2. the carcasses from which the products were derived were submitted to maturation at a temperature above +2°C for a minimum period of 24 hours following slaughter.

Article 2.2.14.10.

When importing from RVF infected countries or zones with disease, *Veterinary Authorities* should require:

for ruminants

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no evidence of RVF on the day of shipment;
2. were vaccinated against RVF at least 21 days prior to shipment with a modified live virus vaccine;

OR

3. were held in a mosquito-proof *quarantine station* for at least 30 days prior to shipment during which the animals showed no clinical signs of RVF and were protected from mosquito attack between quarantine and the *place of shipment* as well as at the *place of shipment*.

Article 2.2.14.11.

When importing from RVF infected countries or zones with disease, *Veterinary Authorities* should require:

for *meat* and *meat products* of domestic and wild ruminants

the presentation of an *international veterinary certificate* attesting that the carcasses:

1. are from animals which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for RVF with favourable results; and
2. have been fully eviscerated and submitted to maturation at a temperature above +2°C for a minimum period of 24 hours following slaughter.

Article 2.2.14.12.

When importing from RVF infected countries or zones with disease, *Veterinary Authorities* should require:

for *in vivo* derived embryos of ruminants

the presentation of an *international veterinary certificate* attesting that the donor animals:

1. showed no evidence of RVF within the period from 28 days prior to 28 days following collection of the embryos;
2. were vaccinated against RVF at least 21 days prior to collection with a modified live virus vaccine;

OR

3. were serologically tested on the day of collection and at least 14 days following collection and showed no significant rise in titre.

CHAPTER 2.2.15.

JAPANESE ENCEPHALITIS

Article 2.2.15.1.

For the purposes of the *Terrestrial Code*, the *incubation period* for Japanese encephalitis shall be 21 days.

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

Article 2.2.15.2.

When importing from countries or zones infected with Japanese encephalitis, *Veterinary Authorities* should require:

for horses

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of Japanese encephalitis on the day of shipment; and

EITHER

2. were kept for the 21 days prior to shipment, in an insect-proof *quarantine station* and were protected from insect vector attack during their transportation from the *quarantine station* to the *place of shipment*;

OR

3. were vaccinated against Japanese encephalitis not less than 7 days and no more than 12 months prior to shipment.

CHAPTER 2.2.16.

TULAREMIA

Article 2.2.16.1.

For the purposes of the *Terrestrial Code*, the *incubation period* for tularemia (in hares, genus *Lepus*) shall be 15 days.

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

Article 2.2.16.2.

Tularemia free country

A country may be considered free from tularemia when it has been shown that tularemia has not been present for at least the past 2 years and when bacteriological or serological surveys in previously infected zones have given negative results.

Article 2.2.16.3.

Tularemia infected zone

A zone shall be considered as infected with tularemia:

1. until at least one year has elapsed after the last *case* has been confirmed;

AND

2. when a bacteriological survey on ticks within the infected zone has given negative results; or
3. when regular serological testing of hares and rabbits from that zone have given negative results.

Article 2.2.16.4.

Veterinary Authorities of tularemia free countries may prohibit importation or transit through their territory, from countries considered infected with tularemia, of live hares.

Article 2.2.16.5.

When importing from countries considered infected with tularemia, *Veterinary Authorities* should require:

<u>for live hares</u>

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of tularemia on the day of shipment;
2. were not kept in a tularemia infected zone;
3. have been treated against parasites (ticks); and
4. were kept in a *quarantine station* for the 15 days prior to shipment.

SECTION 2.3.

CATTLE DISEASES

CHAPTER 2.3.1.

BOVINE BRUCELLOSIS

Article 2.3.1.1.

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

Article 2.3.1.2.

Country or zone free from bovine brucellosis

To qualify as free from bovine brucellosis, a country or *zone* shall satisfy the following requirements:

1. bovine brucellosis or any suspicion thereof is notifiable in the country;
2. the entire cattle population of a country or *zone* is under *official veterinary control* and it has been ascertained that the rate of brucellosis infection does not exceed 0.2% of the cattle herds in the country or *zone* under consideration;
3. the serological tests for bovine brucellosis are periodically conducted in each herd, with or without the ring test;
4. no animal has been vaccinated against bovine brucellosis for at least the past 3 years;
5. all reactors are slaughtered;
6. animals introduced into a free country or zone shall only come from herds officially free from bovine brucellosis or from herds free from bovine brucellosis. This condition may be waived for animals which have not been vaccinated and which, prior to entry into the herd, were isolated and were subjected to the serological tests for bovine brucellosis with negative results on two occasions, with an interval of 30 days between each test. These tests are not considered valid in female animals which have calved during the past 14 days.

   In a country where all herds of cattle have qualified as officially free from bovine brucellosis and where no reactor has been found for the past 5 years, the system for further control may be decided by the country concerned.

Article 2.3.1.3.

Herd officially free from bovine brucellosis

To qualify as officially free from bovine brucellosis, a herd of cattle shall satisfy the following requirements:

1. it is under *official veterinary control*;
2. it contains no animal which has been vaccinated against bovine brucellosis during at least the past 3 years;

3. it only contains animals which have not showed evidence of bovine brucellosis infection during the past 6 months, all suspect cases (such as animals which have prematurely calved) having been subjected to the necessary laboratory investigations;
4. all cattle over the age of one year (except castrated males) were subjected to serological tests with negative results on two occasions, at an interval of 12 months between each test; this requirement is maintained even if the entire herd is normally tested every year or testing is conducted in conformity with other requirements established by the *Veterinary Authority* of the country concerned;
5. additions to the herd shall only come from herds officially free from bovine brucellosis. This condition may be waived for animals which have not been vaccinated, come from a herd free from bovine brucellosis, provided that negative results were shown following a buffered *Brucella* antigen test and the complement fixation test during the 30 days prior to entry into the herd. Any recently calved or calving animal should be retested after 14 days, as tests are not considered valid in female animals which have calved during the past 14 days.

Article 2.3.1.4.

Herd free from bovine brucellosis

To qualify as free from bovine brucellosis, a herd of cattle shall satisfy the following requirements:

1. it is under *official veterinary control*;
2. it is subjected to either a vaccination or a non-vaccination regime;
3. if a live vaccine is used in female cattle, vaccination must be carried out between 3 and 6 months of age, in which case these female cattle must be identified with a permanent mark;
4. all cattle over the age of one year are controlled as provided in point 4 of the definition of a herd of cattle officially free from bovine brucellosis; however, cattle under 30 months of age which have been vaccinated using a live vaccine before reaching 6 months of age, may be subjected to a buffered *Brucella* antigen test with a positive result, with the complement fixation test giving a negative result;
5. all cattle introduced into the herd come from a herd officially free from bovine brucellosis or from a herd free from bovine brucellosis, or from a country or zone free from bovine brucellosis. This condition may be waived for animals which have been isolated and which, prior to entry into the herd, were subjected to the serological tests for bovine brucellosis with negative results on two occasions, with an interval of 30 days between each test. These tests are not considered valid in female animals which have calved during the past 14 days.

Article 2.3.1.5.

Veterinary Authorities of *importing countries* should require:

<u>for cattle for breeding or rearing (except castrated males)</u>

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of bovine brucellosis on the day of shipment;
2. were kept in a herd in which no clinical sign of bovine brucellosis was officially reported during the 6 months prior to shipment;
3. were kept in a country or zone free from bovine brucellosis, or were from a herd officially free from bovine brucellosis and were subjected to a serological test for bovine brucellosis with negative results during the 30 days prior to shipment; or
4. were kept in a herd free from bovine brucellosis and were subjected to buffered *Brucella* antigen and complement fixation tests with negative results during the 30 days prior to shipment;

if the cattle come from a herd other than those mentioned above:

5. were isolated prior to shipment and were subjected to a serological test for bovine brucellosis with negative results on two occasions, with an interval of not less than 30 days between each test, the second test being

performed during the 15 days prior to shipment. These tests are not considered valid in female animals which have calved during the past 14 days.

Article 2.3.1.6.

Veterinary Authorities of *importing countries* should require:

for cattle for slaughter (except castrated males)

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of bovine brucellosis on the day of shipment;
2. are not being eliminated as part of an eradication programme against bovine brucellosis;
3. were kept in a country or zone free from bovine brucellosis; or
4. were kept in a herd officially free from bovine brucellosis; or
5. were kept in a herd free from bovine brucellosis; or
6. were subjected to a serological test for bovine brucellosis with negative results during the 30 days prior to shipment.

Article 2.3.1.7.

Veterinary Authorities of *importing countries* should require:

for bovine semen

the presentation of an *international veterinary certificate* attesting that:

1. when the semen is from an *artificial insemination centre*, the testing programme includes the buffered *Brucella* antigen and complement fixation tests;
2. when the semen is not from an *artificial insemination centre*, the donor animals:
   a) were kept in a country or zone free from bovine brucellosis; or
   b) were kept in a herd officially free from bovine brucellosis, showed no clinical sign of bovine brucellosis on the day of collection of the semen and were subjected to a buffered *Brucella* antigen test with negative results during the 30 days prior to collection; or
   c) were kept in a herd free from bovine brucellosis, showed no clinical sign of bovine brucellosis on the day of collection and were subjected to the buffered *Brucella* antigen and complement fixation tests with negative results during the 30 days prior to collection; or
3. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.1.

Article 2.3.1.8.

Veterinary Authorities of *importing countries* should require:

for *in vivo* derived bovine embryos

the presentation of an *international veterinary certificate* attesting that the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1. or Appendix 3.3.3., as relevant.

Article 2.3.1.9.

Veterinary Authorities of *importing countries* should require:

for *in vitro* produced bovine embryos/oocytes

the presentation of an *international veterinary certificate* attesting that:

1. the donor females:
   a) were kept in a country or zone free from bovine brucellosis; or
   b) were kept in a herd officially free from bovine brucellosis and were subjected to tests as prescribed in Appendix 3.1.1.;
2. the oocytes were fertilised with semen meeting the conditions referred to in Appendix 3.2.1.;
3. the embryos/oocytes were collected, processed and stored in conformity with the provisions of Appendix 3.3.1., Appendix 3.3.2. or Appendix 3.3.3., as relevant.

CHAPTER 2.3.2.

BOVINE GENITAL CAMPYLOBACTERIOSIS

Article 2.3.2.1.

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

Article 2.3.2.2.

Veterinary Authorities of *importing countries* should require:

for female bovines for breeding

the presentation of an *international veterinary certificate* attesting that:

1. the animals are virgin heifers; or
2. the animals were kept in a herd in which no *case* of bovine genital campylobacteriosis has been declared; and/or
3. for animals which have been mated, the culture of vaginal mucus for the presence of the causal agent of bovine genital campylobacteriosis proved negative.

Article 2.3.2.3.

Veterinary Authorities of *importing countries* should require:

for bulls for breeding

the presentation of an *international veterinary certificate* attesting that:

1. the animals:
   a) have never been used for natural service; or
   b) have only mated virgin heifers; or
   c) were kept in an *establishment* in which no *case* of bovine genital campylobacteriosis has been declared;
2. the semen and preputial specimen cultures and/or the associated tests for the presence of the causal agent of bovine genital campylobacteriosis were negative.

Article 2.3.2.4.

Veterinary Authorities of *importing countries* should require:

for bovine semen

the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:
   a) have never been used for natural service; or
   b) have only mated virgin heifers; or
   c) were kept in an *establishment* or *artificial insemination centre* where no *case* of bovine genital campylobacteriosis has been reported;

2. the culture of semen and preputial specimens for the presence of the causal agent of bovine genital campylobacteriosis proved negative.

CHAPTER 2.3.3.

BOVINE TUBERCULOSIS

Article 2.3.3.1.

The recommendations in this Chapter are intended to manage the human and animal health risks associated with *Mycobacterium bovis* (*M. bovis*) infection in domestic (permanently captive and owned free-range) bovines including cattle (*Bos taurus, B. indicus* and *B. grunniens*), water buffaloes (*Bubalus bubalis*) and wood bisons (*Bison bison* and *B. bonasus*).

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should comply with the requirements prescribed in this Chapter relevant to the status of bovine tuberculosis in the *exporting country*, *zone* or *compartment*:

1. live animals;

2. semen, ova and *in vivo* derived embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;

3. *meat* and *meat products*;

4. *milk* and *milk products*.

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

Article 2.3.3.2.

Country, zone or compartment free from bovine tuberculosis

To qualify as free from bovine tuberculosis, a country, *zone* or *compartment* should satisfy the following requirements:

1. *M. bovis* infection in domestic (permanently captive and owned free-range) bovines including cattle (*Bos taurus, B. indicus* and *B. grunniens*), water buffalo (*Bubalus bubalis*) and wood bison (*Bison bison* and *B. bonasus*) is a notifiable disease in the country;

2. an on-going awareness programme should be in place to encourage reporting of all cases suggestive of tuberculosis;

3. regular and periodic testing of all cattle, water buffalo and wood bison herds has shown that at least 99.8% of the herds and 99.9% of the animals in the country, *zone* or *compartment* have been found free from bovine tuberculosis and the percentage of herds confirmed infected with *M. bovis* has not exceeded 0.1% per year for 3 consecutive years;

4. a surveillance programme should be in place to detect bovine tuberculosis in the country, *zone* or *compartment*, through monitoring at slaughter based on the inspection described in Article 2.3.3.8.;

5. cattle, water buffaloes and wood bisons introduced into a country, zone or compartment free from bovine tuberculosis should be accompanied by a certificate from an *official Veterinarian* attesting that they come from a country, *zone* or compartment or herd free from bovine tuberculosis or comply with the relevant provisions in Article 2.3.3.4. or in Article 2.3.3.5.

Article 2.3.3.3.

Herd free from bovine tuberculosis

To qualify as free from bovine tuberculosis, a herd of cattle, water buffaloes or wood bisons should satisfy the following requirements:

1. the herd is in a country, zone or compartment free from bovine tuberculosis and is certified free by the *Veterinary Authority*; or

2. cattle, water buffaloes and wood bisons in the herd:

   a) showed no clinical sign of bovine tuberculosis;

   b) over 6 weeks of age, have shown a negative result to at least two tuberculin tests carried out at an interval of 6 months, the first test being performed at 6 months following the slaughter of the last affected animal;

   c) showed a negative result to an annual tuberculin test to ensure the continuing absence of bovine tuberculosis; or

      i) showed a negative result to a tuberculin test every 2 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of herds confirmed as infected with tuberculosis is not more than 1% of all herds in the country or zone during the last 2 years; or

      ii) showed a negative result to a tuberculin test every 3 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of herds confirmed as infected with tuberculosis is not more than 0.2% of all herds in the country or zone during the last 4 years; or

      iii) showed a negative result to a tuberculin test every 4 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of herds confirmed as infected with tuberculosis is not more than 0.1% of all herds in the country or zone during the last 6 years;

3. cattle, water buffaloes and wood bisons introduced into the herd come from a herd free from bovine tuberculosis. This condition may be waived for animals which have been isolated and which, prior to entry into the herd, were subjected to at least two tuberculin tests carried out at a 6-month interval with negative results.

Article 2.3.3.4.

Veterinary Authorities of *importing countries* should require:

<u>for cattle, water buffaloes and wood bisons for breeding or rearing</u>

the presentation of an *international veterinary certificate* attesting that the animals:

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

2. originate from a herd free from bovine tuberculosis that is in a country, zone or compartment free from bovine tuberculosis; or

3. were subjected to the tuberculin test for bovine tuberculosis with negative results during the 30 days prior to shipment and come from a herd free from bovine tuberculosis; or

4. have been isolated and prior to entry into the herd were subjected to at least two tuberculin tests carried out at a 6-month interval with negative results.

Article 2.3.3.5.

Veterinary Authorities of *importing countries* should require:

for cattle, water buffaloes and wood bisons for slaughter

the presentation of an *international veterinary certificate* attesting that the animals:

1. originated from a herd free from bovine tuberculosis or were subjected to a tuberculin test for bovine tuberculosis with negative results during the 30 days prior to shipment;
2. were not being eliminated as part of an eradication programme against bovine tuberculosis.

Article 2.3.3.6.

Veterinary Authorities of *importing countries* should require:

for semen of cattle, water buffaloes and wood bisons

the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:
   a) showed no clinical sign of bovine tuberculosis on the day of collection of the semen;
   b) were kept in an *artificial insemination centre* free from bovine tuberculosis in a country, zone or compartment free from bovine tuberculosis and which only accepts animals from free herds in a free country, zone or compartment; or
   c) showed negative results to tuberculin tests carried out annually and were kept in a herd free from bovine tuberculosis;
2. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.1.

Article 2.3.3.7.

Veterinary Authorities of *importing countries* should require:

for embryos/ova of cattle, water buffaloes and wood bisons

the presentation of an *international veterinary certificate* attesting that:

1. the donor females:
   a) and all other susceptible animals in the herd of origin showed no clinical sign of bovine tuberculosis during the 24 hours prior to embryo collection;
   b) originated from a herd free from bovine tuberculosis in a country, zone or compartment free from bovine tuberculosis; or
   c) were kept in a herd free from bovine tuberculosis, and were subjected to a tuberculin test for bovine tuberculosis with negative results during an isolation period of 30 days in the *establishment* of origin prior to departure to the collection centre;
2. the embryos/ova were collected, processed and stored in conformity with the provisions of Appendix 3.3.1., Appendix 3.3.2. or Appendix 3.3.3., as relevant.

Article 2.3.3.8.

Veterinary Authorities of *importing countries* should require:

for *fresh meat* and *meat products* of cattle, water buffaloes and wood bisons

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from animals which have been subjected to *ante-mortem* and *post-mortem* inspections as described in Appendix 3.10.1.

Article 2.3.3.9.

Veterinary Authorities of *importing countries* should require:

for *milk* and *milk products* of cattle, water buffaloes and wood bisons

the presentation of an *international veterinary certificate* attesting that the consignment:

1. has been derived from animals in a herd free from bovine tuberculosis; or
2. was subjected to pasteurization; or
3. was subjected to a combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.

CHAPTER 2.3.4.

ENZOOTIC BOVINE LEUKOSIS

Article 2.3.4.1.

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

Article 2.3.4.2.

Country or zone free from enzootic bovine leukosis

1. Qualification

   To qualify as free from enzootic bovine leukosis (EBL), a country or zone must satisfy the following requirements for at least 3 years:

   a) all tumours, suspected to be lymphosarcoma, are reported to the *Veterinary Authority*, and are examined at a laboratory by appropriate diagnostic techniques;

   b) all animals with tumours in which EBL has been confirmed or cannot be ruled out are traced back to the herds in which they have been kept since birth; all cattle over 24 months of age in these herds are subjected to an individual diagnostic test for EBL;

   c) at least 99.8% of the herds are qualified as EBL free.

2. Maintenance of free status

   For a country or zone to maintain its EBL free status:

   a) a serological survey must be carried out annually on a random sample of the cattle population of the country or zone sufficient to provide a 99% level of confidence of detecting EBL if it is present at a prevalence rate exceeding 0.2% of the herds;

   b) all imported bovines (except for slaughter) comply with the provisions of Article 2.3.4.4.;

   c) all imported bovine semen and embryos/ova fulfil the requirements referred to in Article 2.3.4.5. and in Article 2.3.4.6., respectively.

Article 2.3.4.3.

Herd free from enzootic bovine leukosis

1. Qualification

   To qualify as free from EBL, a herd must satisfy the following requirements:

   a) there has been no evidence of EBL either clinical, post-mortem, or as a result of a diagnostic test for EBL within the previous 2 years;

   b) all animals over 24 months of age have been subjected to a diagnostic test for EBL on two occasions with negative results, at an interval of not less than 4 months during the preceding 12 months;

   c) animals introduced into the herd after the first test have fulfilled the conditions of Article 2.3.4.4.;

   d) all bovine semen and embryos/ova introduced into the herd after the first test have fulfilled the conditions referred to in Article 2.3.4.5. and in Article 2.3.4.6., respectively.

2. Maintenance of free status

   For a herd to maintain its EBL free status, the animals in the herd over 24 months of age on the day of sampling must be subjected to a diagnostic test for EBL with negative results at intervals of no more than 36 months and the conditions referred to in points 1a), 1c) and 1d) above continue to be fulfilled.

3. Suspension and restoration of free status

   If in an EBL free herd any animals react positively to a diagnostic test for EBL or a virological test (under study) for bovine leukosis virus, the status of the herd shall be suspended until the following measures have been taken:

   a) the animals which have reacted positively, and their progeny since the last negative test, must be removed from the herd immediately; however, any animal within the progeny which has been subjected to a PCR test with negative results (under study) may be retained in the herd;

   b) the remaining animals must have been subjected to a diagnostic test for EBL carried out as described in point 1b) above with negative results at least 4 months after removal of the positive animals and their progeny.

Article 2.3.4.4.

Veterinary Authorities of *importing countries* should require:

for cattle for breeding or rearing

the presentation of an *international veterinary certificate* attesting that the animals:

1. come from a country or zone free from EBL; or
2. come from an EBL free herd; or
3. meet the following three conditions:

   a) the animals were kept in a herd in which:

      i) there has been no evidence of EBL either clinical, post-mortem, or as a result of a diagnostic test for EBL within the previous 2 years;

      ii) all animals over 24 months of age have been subjected to a diagnostic test for EBL on a blood sample on two occasions with negative results during the preceding 12 months, at an interval of at least 4 months, or were tested on two occasions while segregated from the herd in an isolation unit approved by the *Veterinary Authority* at an interval of at least 4 months;

   b) the animals were subjected to a diagnostic test for EBL within 30 days prior to shipment with negative results;

   c) if less than 2 years of age, the animals come from 'uterine' dams which have been subjected to a diagnostic test for EBL on a blood sample on two occasions at intervals of at least 4 months within the preceding 12 months, with negative results.

Article 2.3.4.5.

Veterinary Authorities of *importing countries* should require:

for bovine semen

the presentation of an *international veterinary certificate* attesting that:

1. the donor bull was resident at the time of semen collection in an EBL free herd; and
2. if less than 2 years of age, the bull came from a serologically negative ‘uterine’ dam; or
3. the bull was subjected to diagnostic tests for EBL on blood samples on two occasions with negative results, the first test being carried out at least 30 days before and the second test at least 90 days after collection of the semen;

4. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.1.

Article 2.3.4.6.

Veterinary Authorities of *importing countries* should require:

for bovine embryos/ova

the presentation of an *international veterinary certificate* attesting that the embryos/ova have been collected, processed and stored in conformity with the provisions of Appendix 3.3.1., Appendix 3.3.2. or Appendix 3.3.3., as relevant.

CHAPTER 2.3.5.

INFECTIOUS BOVINE RHINOTRACHEITIS/ INFECTIOUS PUSTULAR VULVOVAGINITIS

Article 2.3.5.1.

For the purposes of the *Terrestrial Code*, the *incubation period* for infectious bovine rhinotracheitis/infectious pustular vulvovaginitis (IBR/IPV) shall be 21 days.

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

Article 2.3.5.2.

Country or zone free from infectious bovine rhinotracheitis/infectious pustular vulvovaginitis

1. Qualification

   To qualify as free from IBR/IPV, a country or zone must satisfy the following requirements:

   a) the disease or suspicion of the disease is notifiable;

   b) no animal has been vaccinated against IBR/IPV for at least 3 years;

   c) at least 99.8% of the herds are qualified as free from IBR/IPV.

2. Maintenance of free status

   For a country or zone to maintain its status free from IBR/IPV:

   a) a serological survey should be carried out annually on a random sample of the cattle population of the country or zone sufficient to provide a 99% level of confidence of detecting IBR/IPV if it is present at a prevalence rate exceeding 0.2% of the herds;

   b) all imported bovines comply with the provisions of Article 2.3.5.4.;

   c) all imported bovine semen and embryos/ova fulfil the requirements referred to in Articles 2.3.5.6. or 2.3.5.7., and in Article 2.3.5.8., respectively.

Article 2.3.5.3.

Herd free from infectious bovine rhinotracheitis/infectious pustular vulvovaginitis

1. Qualification

   To qualify as free from IBR/IPV, a herd of cattle must satisfy the following requirements:

   a) all the animals in the herd have been subjected to a diagnostic test for IBR/IPV on a blood sample on two occasions with negative results, at an interval of not less than 2 months and not more than 12 months; or

   b) if the herd contains only dairy cattle of which at least a quarter are lactating cows, each of the latter has been subjected to a diagnostic test on individual milk samples carried out on three occasions at intervals of 2 months with negative results;

   c) animals introduced into the herd after the first tests referred to in point a) or point b) as relevant have been:

      i) kept in an IBR/IPV free herd; or

ii) placed in isolation for a period of 30 days, and during this period have been subjected to a diagnostic test for IBR/IPV on a blood sample on two occasions with negative results, at an interval of not less than 21 days;

d) all bovine semen and embryos/ova introduced into the herd after the first tests referred to in point a) or point b) as relevant have fulfilled the conditions provided in Articles 2.3.5.6. or 2.3.5.7. and in Article 2.3.5.8., respectively.

2. Maintenance of free status

For a herd to maintain its status free from IBR/IPV, it must be subjected to the following tests with negative results:

EITHER

a) diagnostic tests for IBR/IPV on blood samples for all the animals repeated at maximum intervals of 12 months; in herds composed entirely of fattening animals, blood sampling may be limited to animals sent for slaughter;

OR

b) diagnostic tests on individual milk samples from all lactating cows repeated at intervals of 6 months; *Veterinary Authorities* applying an IBR/IPV eradication programme may extend these intervals (under study) if more than 98% of herds have been free from the disease for at least 3 years; and

c) diagnostic tests on blood samples for IBR/IPV of all breeding bulls repeated at maximum intervals of 12 months;

AND

d) diagnostic tests on blood samples for IBR/IPV of all cattle having aborted after more than 3 months of gestation.

Animals introduced into the herd must satisfy the conditions provided in point 1c) above, and semen and embryos/ova used in the herd must satisfy the conditions provided in Articles 2.3.5.6. or 2.3.5.7. and in Article 2.3.5.8., respectively.

Article 2.3.5.4.

Veterinary Authorities of *importing countries* should require:

for cattle destined for IBR/IPV free herds

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of IBR/IPV on the day of shipment;
2. come from an IBR/IPV free herd; or
3. were kept in a *quarantine station* for the 30 days prior to shipment and were subjected to a diagnostic test for IBR/IPV on a blood sample on two occasions with negative results, at an interval of not less than 21 days.

Article 2.3.5.5.

Veterinary Authorities of *importing countries* should require:

for cattle intended for herds not qualified as free from IBR/IPV

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of IBR/IPV on the day of shipment;
2. were vaccinated with an inactivated virus vaccine not less than one month and not more than 6 months prior to shipment.

Article 2.3.5.6.

Veterinary Authorities of *importing countries* should require:

for fresh semen

the presentation of an *international veterinary certificate* attesting that:

1. the donor animals were kept in an IBR/IPV free herd at the time of collection of the semen;

2. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.1.

Article 2.3.5.7.

Veterinary Authorities of *importing countries* should require:

for frozen semen

the presentation of an *international veterinary certificate* attesting that:

1. the donor animals were kept in an IBR/IPV free herd at the time of collection of the semen; or

2. the donor animals were held in isolation during the period of collection and for the 30 days following collection and were subjected to a diagnostic test for IBR/IPV on a blood sample taken at least 21 days after collection of the semen, with negative results; or

3. if the serological status of the bull is unknown or if the bull is serologically positive, an aliquot of each semen collection was subjected to a virus isolation test, with negative results; and

4. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.1.

Article 2.3.5.8.

Veterinary Authorities of *importing countries* should require:

for embryos/ova

the presentation of an *international veterinary certificate* attesting that the embryos/ova were collected, processed and stored in conformity with the provisions of Appendix 3.3.1., Appendix 3.3.2. or Appendix 3.3.3., as relevant.

CHAPTER 2.3.6.

TRICHOMONOSIS

Article 2.3.6.1.

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

Article 2.3.6.2.

Veterinary Authorities of *importing countries* should require:

for cattle for breeding

the presentation of an *international veterinary certificate* attesting that:

1. the animals showed no clinical sign of trichomonosis on the day of shipment;
2. the animals were kept in a herd in which no *case* of trichomonosis has been reported; and/or
3. for females which have been mated, direct microscopic examination and culture of vaginal mucus were negative.

Article 2.3.6.3.

Veterinary Authorities of *importing countries* should require:

for bulls for breeding (natural service or artificial insemination)

the presentation of an *international veterinary certificate* attesting that:

1. the animals showed no clinical sign of trichomonosis on the day of shipment;
2. the animals were kept in a herd in which no *case* of trichomonosis has been reported; and/or
3. the animals have never been used for natural service; or
4. the animals have only mated virgin heifers; or
5. the animals were subjected to a direct microscopic and cultural examination of preputial specimens with negative results.

Article 2.3.6.4.

Veterinary Authorities of *importing countries* should require:

for bovine semen

the presentation of an *international veterinary certificate* attesting that:

1. the donor animals have never been used for natural service; or
2. the donor animals have only mated virgin heifers; or
3. the donor animals were kept in an *establishment* or *artificial insemination centre* where no *case* of trichomonosis has been reported;
4. the donor animals were subjected to a direct microscopic and cultural examination of preputial specimens with negative results;

5. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.1.

CHAPTER 2.3.7.

BOVINE ANAPLASMOSIS

Article 2.3.7.1.

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

Article 2.3.7.2.

When importing from countries considered infected with bovine anaplasmosis, *Veterinary Authorities* of free countries should require:

for cattle

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of bovine anaplasmosis on the day of shipment; and

2. were, since birth, kept in a zone known to be free of bovine anaplasmosis for the previous 2 years;

OR

3. showed no clinical sign of bovine anaplasmosis on the day of shipment; and

4. were subjected to a diagnostic test for bovine anaplasmosis with negative results during 30 days prior to shipment; and

5. were treated with an effective drug such as oxytetracycline for 5 consecutive days at a dose of 22 mg/kg (under study);

AND

in either of the above cases:

6. were treated with an acaricide and, if necessary, a repellant against biting insects prior to shipment and were completely free of ticks.

CHAPTER 2.3.8.

BOVINE BABESIOSIS

Article 2.3.8.1.

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

Article 2.3.8.2.

When importing from countries considered infected with bovine babesiosis, *Veterinary Authorities* of free countries should require:

for cattle

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of bovine babesiosis on the day of shipment; and

2. were, since birth, resident in a zone known to be free of bovine babesiosis for the previous 2 years;

OR

3. showed no clinical sign of bovine babesiosis on the day of shipment; and

4. were subjected to a diagnostic test for bovine babesiosis with negative results during 30 days prior to shipment; and

5. were treated with an effective drug such as imidocarb as a single dose injection at 2 mg/kg or amicarbalide at 10 mg/kg (under study);

AND

in either of the above cases:

6. were treated with an acaricide prior to shipment and were completely free of ticks.

CHAPTER 2.3.9.

BOVINE CYSTICERCOSIS

Article 2.3.9.1.

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

Article 2.3.9.2.

Veterinary Authorities of *importing countries* should require:

for *fresh meat* of cattle

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat:

1. comes from animals which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for bovine cysticercosis with favourable results;
2. has been recognised as being free from bovine cysticercosis; or
3. in cases of moderate infestation, has been processed using one of the methods provided in the "Recommended International Code of Practice for *ante-mortem* and *post-mortem* judgement of slaughter animals and meat", namely: freezing or heat treatment at 60°C (140°F) (FAO/WHO - Codex Alimentarius Commission CAC/RCP 34-1985).

CHAPTER 2.3.10.

DERMATOPHILOSIS

Article 2.3.10.1.

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

Article 2.3.10.2.

When importing from countries considered infected with dermatophilosis, *Veterinary Authorities* should require:

for ruminants and equines

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of dermatophilosis on the day of shipment;
2. were treated with acaricides prior to shipment and were completely free of ticks.

CHAPTER 2.3.11.

THEILERIOSIS

Article 2.3.11.1.

For the purposes of the *Terrestrial Code*, theileriosis is defined as a highly fatal disease in cattle and buffaloes caused by *Theileria parva* and *T. annulata*.

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

Article 2.3.11.2.

When importing from countries considered infected with theileriosis, *Veterinary Authorities* of free countries should require:

for cattle

the presentation of an *international veterinary certificate* attesting that the animals:

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

2. were, since birth, kept in a zone known to be free of theileriosis for the previous 2 years;

OR

3. showed no clinical sign of theileriosis on the day of shipment; and

4. were subjected to a diagnostic test for theileriosis with negative results during the 30 days prior to shipment (under study); and

5. showed negative results from microscopic examination of blood smears;

AND

in either of the above cases:

6. were treated with an acaricide prior to shipment and were completely free of ticks.

CHAPTER 2.3.12.

HAEMORRHAGIC SEPTICAEMIA

(*Pasteurella multocida* serotypes 6:b and 6:e)

Article 2.3.12.1.

For the purposes of this *Terrestrial Code*, haemorrhagic septicaemia (HS) is defined as a highly fatal disease in cattle and buffaloes caused by specific serotypes of *Pasteurella multocida* designated as 6:B and 6:E. The *incubation period* for the disease shall be 90 days (active and latent carriers occur).

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

Article 2.3.12.2.

Country free from haemorrhagic septicaemia

A country may be considered free from HS when:

1. the disease is notifiable in the country;
2. no *case* of HS has occurred during the past 3 years.

This period shall be 6 months after the slaughter of the last affected animal for countries in which a *stamping-out policy* is practised with or without vaccination against HS.

Article 2.3.12.3.

Zone free from haemorrhagic septicaemia

A zone may be considered free of the disease if it can be established that HS has not been present for at least the past 3 years and if the following conditions are met:

1. the disease is notifiable in the whole country;
2. the zone shall be delineated by natural or artificial barriers;
3. the introduction of animals into the zone shall be carried out in conformity with the provisions of Articles 2.3.12.6. or 2.3.12.7.

Article 2.3.12.4.

Zone infected with haemorrhagic septicaemia

A zone shall be considered as infected with HS until at least 6 months have elapsed after the confirmation of the last *case* and the completion of a *stamping-out policy* and *disinfection* procedures.

Article 2.3.12.5.

Veterinary Authorities of HS free countries may prohibit importation or transit through their territory, from countries considered infected with HS, of cattle and buffaloes.

Article 2.3.12.6.

When importing from HS free countries or zones, *Veterinary Authorities* should require:

for cattle and buffaloes

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of HS on the day of shipment; and
2. were kept in a country or zone free from HS since birth or for at least 6 months.

Article 2.3.12.7.

When importing from countries considered infected with HS, *Veterinary Authorities* should require:

for cattle and buffaloes

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of HS on the day of shipment; and
2. were kept in a *quarantine station* for 3 months prior to shipment; and
3. were examined for the presence of the causative organism in the naso-pharynx, in conformity with the procedures described in the *Terrestrial Manual*, on four occasions, at weekly intervals during the last month in quarantine with negative results; and
4. were vaccinated not less than 30 days prior to shipment (under study); or
5. showed a positive reaction to the passive mouse protection test (under study) conducted during pre-shipment quarantine.

CHAPTER 2.3.13.

BOVINE SPONGIFORM ENCEPHALOPATHY

Article 2.3.13.1.

The recommendations in this Chapter are intended to manage the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agent in cattle (*Bos taurus* and *B. indicus*) only.

1. When authorising import or transit of the following *commodities* and any products made from these *commodities* and containing no other tissues from cattle, *Veterinary Authorities* should not require any BSE related conditions, regardless of the BSE risk status of the cattle population of the *exporting country*, *zone* or *compartment*:

   a) *milk* and *milk products*;

   b) semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;

   c) hides and skins;

   d) gelatine and collagen prepared exclusively from hides and skins;

   e) protein-free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;

   f) dicalcium phosphate (with no trace of protein or fat);

   g) deboned skeletal muscle meat (excluding mechanically separated meat) from cattle 30 months of age or less, which were not subjected to a stunning process prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process, and which passed ante-mortem and post-mortem inspections and which has been prepared in a manner to avoid contamination with tissues listed in Article 2.3.13.14.;

   h) blood and blood by-products, from cattle which were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process.

2. When authorising import or transit of other *commodities* listed in this Chapter, *Veterinary Authorities* should require the conditions prescribed in this Chapter relevant to the BSE risk status of the cattle population of the *exporting country*, *zone* or *compartment*.

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

Article 2.3.13.2.

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

1. the outcome of a *risk assessment*, based on Section 1.3., identifying all potential factors for BSE occurrence and their historic perspective. Countries should review the risk assessment annually to determine whether the situation has changed.

   a) <u>Release assessment</u>

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

      i) the presence or absence of the BSE agent in the indigenous ruminant population of the country, *zone* or *compartment* and, if present, evidence regarding its prevalence;

      ii) production of *meat-and-bone meal* or *greaves* from the indigenous ruminant population;

iii) imported *meat-and-bone meal* or *greaves*;

iv) imported cattle, sheep and goats;

v) imported animal feed and feed ingredients;

vi) imported products of ruminant origin for human consumption, which may have contained tissues listed in Article 2.3.13.13. and may have been fed to cattle;

vii) imported products of ruminant origin intended for *in vivo* use in cattle.

The results of any epidemiological investigation into the disposition of the *commodities* identified above should be taken into account in carrying out the assessment.

b) Exposure assessment

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

i) recycling and amplification of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;

ii) the use of ruminant carcasses (including from fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;

iii) the feeding or not of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants, including measures to prevent cross-contamination of animal feed;

iv) the level of surveillance for BSE conducted on the cattle population up to that time and the results of that surveillance;

2. on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of cattle to encourage reporting of all *cases* showing clinical signs consistent with BSE in target sub-populations as defined in Appendix 3.8.4.;

3. the compulsory notification and investigation of all cattle showing clinical signs consistent with BSE;

4. the examination carried out in accordance with the *Terrestrial Manual* in an *approved laboratory* of brain or other tissues collected within the framework of the aforementioned surveillance and monitoring system.

When the *risk assessment* demonstrates negligible risk, the country should conduct Type B surveillance in accordance with Appendix 3.8.4.

When the *risk assessment* fails to demonstrate negligible risk, the country should conduct Type A surveillance in accordance with Appendix 3.8.4.

Article 2.3.13.3.

Negligible BSE risk

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

1. a *risk assessment*, as described in point 1 of Article 2.3.13.2., has been conducted in order to identify the historical and existing risk factors, and the country has demonstrated that appropriate specific measures have been taken for the relevant period of time defined below to manage each identified risk;

2. the country has demonstrated that Type B surveillance in accordance with Appendix 3.8.4. is in place and the relevant points target, in accordance with Table 1, has been met;

3. EITHER:

a) there has been no *case* of BSE or, if there has been a *case*, every *case* of BSE has been demonstrated to have been imported and has been completely destroyed, and

i) the criteria in points 2 to 4 of Article 2.3.13.2. have been complied with for at least 7 years; and

ii) it has been demonstrated through an appropriate level of control and audit that for at least 8 years neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants;

OR

b) if there has been an indigenous *case*, every indigenous *case* was born more than 11 years ago; and

i) the criteria in points 2 to 4 of Article 2.3.13.2. have been complied with for at least 7 years; and

ii) it has been demonstrated through an appropriate level of control and audit that for at least 8 years neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants; and

iii) all BSE *cases*, as well as:

- all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or
- if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases*,

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

Article 2.3.13.4.

Controlled BSE risk

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

1. a *risk assessment*, as described in point 1 of Article 2.3.13.2., has been conducted in order to identify the historical and existing risk factors, and the country has demonstrated that appropriate measures are being taken to manage all identified risks, but these measures have not been taken for the relevant period of time;

2. the country has demonstrated that Type A surveillance in accordance with Appendix 3.8.4. has been carried out and the relevant points target, in accordance with Table 1, has been met; Type B surveillance may replace Type A surveillance once the relevant points target is met;

3. EITHER:

a) there has been no *case* of BSE or, if there has been a *case*, every *case* of BSE has been demonstrated to have been imported and has been completely destroyed, the criteria in points 2 to 4 of Article 2.3.13.2. are complied with, and it can be demonstrated through an appropriate level of control and audit that neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants, but at least one of the following two conditions applies:

i) the criteria in points 2 to 4 of Article 2.3.13.2. have not been complied with for 7 years;

ii) it cannot be demonstrated that controls over the feeding of *meat-and-bone meal* or *greaves* derived from ruminants to ruminants have been in place for 8 years;

OR

b) there has been an indigenous *case* of BSE, the criteria in points 2 to 4 of Article 2.3.13.2. are complied with, and it can be demonstrated through an appropriate level of control and audit that neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants, but at least one of the following two conditions applies:

i) the criteria in points 2 to 4 of Article 2.3.13.2. have not been complied with for 7 years;

ii) it cannot be demonstrated that controls over the feeding of *meat-and-bone meal* and *greaves* derived from ruminants to ruminants have been in place for 8 years;

AND

iii) all BSE *cases*, as well as:

- all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or
- if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases*,

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

Article 2.3.13.5.

Undetermined BSE risk

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

Article 2.3.13.6.

When importing from a country, zone or compartment posing a negligible BSE risk, *Veterinary Authorities* should require:

for all *commodities* from cattle not listed in point 1 of Article 2.3.13.1.

the presentation of an *international veterinary certificate* attesting that the country, *zone* or *compartment* complies with the conditions in Article 2.3.13.3.

Article 2.3.13.7.

When importing from a country, zone or compartment posing a negligible BSE risk, *Veterinary Authorities* should require:

for cattle selected for export

the presentation of an *international veterinary certificate* attesting that the animals:

1. are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as described in point 3)b)iii) of Article 2.3.13.3.;
2. were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants had been effectively enforced.

Article 2.3.13.8.

When importing from a country, zone or compartment posing a controlled BSE risk, *Veterinary Authorities* should require:

for cattle

the presentation of an *international veterinary certificate* attesting that:

1. the country, *zone* or *compartment* complies with the conditions referred to in Article 2.3.13.4.;
2. cattle selected for export are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as described in point 3b)iii) of Article 2.3.13.4.;
3. cattle selected for export were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants was effectively enforced.

Article 2.3.13.9.

When importing from a country, zone or compartment with an undetermined BSE risk, *Veterinary Authorities* should require:

for cattle

the presentation of an *international veterinary certificate* attesting that:

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

   if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed;
3. cattle selected for export:
   a) are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as demonstrated in point 2 above;
   b) were born at least 2 years after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants was effectively enforced.

Article 2.3.13.10.

When importing from a country, zone or compartment posing a negligible BSE risk, *Veterinary Authorities* should require:

for *fresh meat* and *meat products* from cattle (other than those listed in point 1 of Article 2.3.13.1.)

the presentation of an *international veterinary certificate* attesting that:

1. the country, *zone* or *compartment* complies with the conditions in Article 2.3.13.3.;
2. the cattle from which the *fresh meat* and *meat products* were derived passed ante-mortem and post-mortem inspections;
3. in countries with negligible BSE risk where there have been indigenous *cases*, the cattle from which the *fresh meat* and *meat products* were derived were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants had been effectively enforced.

Article 2.3.13.11.

When importing from a country, zone or compartment with an controlled BSE risk, *Veterinary Authorities* should require:

for *fresh meat* and *meat products* from cattle (other than those listed in point 1 of Article 2.3.13.1.)

the presentation of an *international veterinary certificate* attesting that:

1. the country, *zone* or *compartment* complies with the conditions referred to in Article 2.3.13.4.;
2. the cattle from which the *fresh meat* and *meat products* were derived passed ante-mortem and post-mortem inspections;
3. cattle from which the *fresh meat* and *meat products* destined for export were derived were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;

4. the *fresh meat* and *meat products* were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:
   a) the tissues listed in points 1 and 2 of Article 2.3.13.14.,
   b) mechanically separated meat from the skull and vertebral column from cattle over 30 months of age.

Article 2.3.13.12.

When importing from a country, zone or compartment with an undetermined BSE risk, *Veterinary Authorities* should require:

for *fresh meat* and *meat products* from cattle (other than those listed in point 1 of Article 2.3.13.1.)

the presentation of an *international veterinary certificate* attesting that:

1. the cattle from which the *fresh meat* and *meat products* originate:
   a) have not been fed *meat-and-bone meal* or *greaves* derived from ruminants;
   b) passed ante-mortem and post-mortem inspections;
   c) were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;
2. the *fresh meat* and *meat products* were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:
   a) the tissues listed in points 1 and 3 of Article 2.3.13.14.,
   b) nervous and lymphatic tissues exposed during the deboning process,
   c) mechanically separated meat from the skull and vertebral column from cattle over 12 months of age.

Article 2.3.13.13.

1. Ruminant-derived *meat-and-bone meal* or *greaves*, or any commodities containing such products, which originate from a country, *zone* or *compartment* defined in Article 2.3.13.3., but where there has been an indigenous *case* of BSE, should not be traded if such products were derived from cattle born before the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants had been effectively enforced.
2. Ruminant-derived *meat-and-bone meal* or *greaves*, or any commodities containing such products, which originate from a country, *zone* or *compartment* defined in Articles 2.3.13.4. and 2.3.13.5. should not be traded between countries.

Article 2.3.13.14.

1. From cattle of any age originating from a country, *zone* or *compartment* defined in Articles 2.3.13.4. and 2.3.13.5., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: tonsils and distal ileum. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this Chapter) should also not be traded.
2. From cattle that were at the time of slaughter over 30 months of age originating from a country, *zone* or *compartment* defined in Article 2.3.13.4., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull and vertebral column. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this Chapter) should also not be traded.
3. From cattle that were at the time of slaughter over 12 months of age originating from a country, *zone* or *compartment* defined in Article 2.3.13.5., the following commodities, and any commodity contaminated by

them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull and vertebral column. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this Chapter) should also not be traded.

Article 2.3.13.15.

Veterinary Authorities of *importing countries* should require:

for gelatine and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that:

1. the *commodities* came from a country, zone or compartment posing a negligible BSE risk;

OR

2. they originate from a country, zone or compartment posing a controlled BSE risk and are derived from cattle which have passed ante-mortem and post-mortem inspections; and that
   a) skulls from cattle over 30 months of age at the time of slaughter have been excluded;
   b) the bones have been subjected to a process which includes all of the following steps:
      i) degreasing,
      ii) acid demineralisation,
      iii) acid or alkaline treatment,
      iv) filtration,
      v) sterilisation at ≥138°C for a minimum of 4 seconds,

      or to an equivalent or better process in terms of infectivity reduction (such as high pressure heating);

OR

3. they originate from a country, zone or compartment posing an undetermined BSE risk and are derived from cattle which have passed ante-mortem and post-mortem inspections; and that
   a) skulls and vertebrae (except tail vertebrae) from cattle over 12 months of age at the time of slaughter have been excluded;
   b) the bones have been subjected to a process which includes all of the following steps:
      i) degreasing,
      ii) acid demineralisation,
      iii) acid or alkaline treatment,
      iv) filtration,
      v) sterilisation at ≥138°C for a minimum of 4 seconds,

      or to an equivalent or better process in terms of infectivity reduction (such as high pressure heating).

Article 2.3.13.16.

Veterinary Authorities of *importing countries* should require:

for tallow and dicalcium phosphate (other than as defined in Article 2.3.13.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that:

1. the *commodities* came from a country, zone or compartment posing a negligible BSE risk; or

2. they originate from a country, zone or compartment posing a controlled BSE risk, are derived from cattle which have passed ante-mortem and post-mortem inspections, and have not been prepared using the tissues listed in points 1 and 2 of Article 2.3.13.14.

Article 2.3.13.17.

Veterinary Authorities of *importing countries* should require:

for tallow derivatives (other than those made from protein-free tallow as defined in Article 2.3.13.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that:

1. they originate from a country, zone or compartment posing a negligible BSE risk; or
2. they are derived from tallow meeting the conditions referred to in Article 2.3.13.16.; or
3. they have been produced by hydrolysis, saponification or transesterification using high temperature and pressure.

CHAPTER 2.3.14.

LUMPY SKIN DISEASE

(caused by group III virus, type Neethling)

Article 2.3.14.1.

For the purposes of the *Terrestrial Code*, the *incubation period* for lumpy skin disease (LSD) shall be 28 days.

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

Article 2.3.14.2.

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 3 years.

Article 2.3.14.3.

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

1. domestic and wild animals of the bovine species;
2. semen of animals of the bovine species.

Article 2.3.14.4.

When importing from LSD free countries, *Veterinary Authorities* should require:

<u>for domestic bovines</u>

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.

Article 2.3.14.5.

When importing from LSD free countries, *Veterinary Authorities* should require:

<u>for wild bovines</u>

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 2.3.14.6.

When importing from countries considered infected with LSD, *Veterinary Authorities* should require:

for domestic bovines

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 not vaccinated against LSD during the 30 days prior to shipment; or
3. were vaccinated against LSD not more than 3 months prior to shipment;
4. 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
5. were kept in a *quarantine station* for the 28 days prior to shipment.

Article 2.3.14.7.

When importing from countries considered infected with LSD, *Veterinary Authorities* should require:

for wild bovines

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 2.3.14.8.

When importing from LSD free countries, *Veterinary Authorities* should require:

for semen of bovines

the presentation of an *international veterinary certificate* attesting that the donor animals:

1. showed no clinical sign of LSD on the day of collection of the semen and for the following 28 days;
2. were kept in an LSD free country.

Article 2.3.14.9.

When importing from countries considered infected with LSD, *Veterinary Authorities* should require:

for semen of bovines

the presentation of an *international veterinary certificate* attesting that the donor animals:

1. showed no clinical sign of LSD on the day of collection of the semen and for the following 28 days;
2. 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.

Article 2.3.14.10.

When importing from LSD free countries, *Veterinary Authorities* should require:

for products of animal origin (from bovines) intended for agricultural or industrial use

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 2.3.14.11.

When importing from countries considered infected with LSD, *Veterinary Authorities* should require:

for products of animal origin (from bovines) intended for agricultural or industrial use

the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of the LSD virus.

Article 2.3.14.12.

When importing from countries considered infected with LSD, *Veterinary Authorities* should require:

for raw hides of bovines

the presentation of an *international veterinary certificate* attesting that these products were stored for at least 40 days before shipment.

CHAPTER 2.3.15.

CONTAGIOUS BOVINE PLEUROPNEUMONIA

Article 2.3.15.1.

For the purposes of the *Terrestrial Code*, the *incubation period* for contagious bovine pleuropneumonia (CBPP) shall be 6 months.

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

Article 2.3.15.2.

CBPP free country

To be declared free from either disease or infection by the OIE, a country should meet the requirements contained in Appendix 3.8.3.

Article 2.3.15.3.

CBPP free zone

To be declared free from either disease or infection by the OIE, a zone defined according to the provisions of Chapter 1.3.5. should meet the requirements contained in Appendix 3.8.3.

Article 2.3.15.4.

CBPP infected country or zone

When the requirements for acceptance as a CBPP free country or zone are not fulfilled, a country or zone shall be considered as infected.

Article 2.3.15.5.

Veterinary Authorities of CBPP free countries may prohibit importation or transit through their territory, from countries considered infected with CBPP, of domestic and wild bovidae.

Article 2.3.15.6.

When importing from CBPP free countries, *Veterinary Authorities* should require:

<u>for domestic bovidae</u>

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of CBPP on the day of shipment;
2. were kept in a CBPP free country since birth or for at least the past 6 months.

Article 2.3.15.7.

When importing from CBPP free countries, *Veterinary Authorities* should require:

for wild bovidae

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of CBPP on the day of shipment;
2. come from a CBPP free country;

if the country of origin has a common border with a country considered infected with CBPP:

3. were kept in a *quarantine station* for the 6 months prior to shipment.

Article 2.3.15.8.

When importing from CBPP infected countries, *Veterinary Authorities* should require:

for bovidae for breeding

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of CBPP on the day of shipment;
2. were subjected to the complement fixation test for CBPP with negative results, on two occasions, with an interval of not less than 21 days and not more than 30 days between each test, the second test being performed within 14 days prior to shipment;
3. were isolated from other domestic bovidae from the day of the first complement fixation test until shipment;
4. were kept since birth, or for the past 6 months, in an *establishment* where no *case* of CBPP was officially reported during that period, and that the *establishment* was not situated in a CBPP infected zone;
5. have not been vaccinated against CBPP; or
6. were vaccinated using a vaccine complying with the standards described in the *Terrestrial Manual* not more than 4 months prior to shipment. In this case, the condition laid down in point 2 above is not required.

Article 2.3.15.9.

When importing from CBPP infected countries, *Veterinary Authorities* should require:

for bovidae for slaughter

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of CBPP on the day of shipment;
2. were kept since birth, or for the past 6 months, in an *establishment* where no *case* of CBPP was officially reported during that period, and that the *establishment* was not situated in a CBPP infected zone.

Article 2.3.15.10.

When importing from CBPP infected countries, *Veterinary Authorities* should require:

for wild bovidae

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of CBPP on the day of shipment;
2. were kept, for the 180 days prior to shipment, in a *quarantine station* where no *case* of CBPP was officially reported during that period, and that the *quarantine station* was not situated in a CBPP infected zone;
3. have not been vaccinated against CBPP; or

4. were vaccinated using a vaccine complying with the standards described in the *Terrestrial Manual* not more than 4 months prior to shipment. In this case, the condition laid down in point 2 above is not required.

Article 2.3.15.11.

When importing from CBPP infected countries, *Veterinary Authorities* should require:

for *fresh meat* of bovidae

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from animals:

1. which showed no lesion of CBPP;
2. which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for CBPP with favourable results.

Article 2.3.15.12.

When importing from CBPP free countries, *Veterinary Authorities* should require:

for *in vivo* derived or *in vitro* produced embryos/oocytes of bovidae

the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:
   a) showed no clinical sign of CBPP on the day of collection of the embryos/oocytes;
   b) were kept in a CBPP free country since birth or for at least the past 6 months;
2. the oocytes were fertilised with semen meeting the conditions referred to in points a) and b) above and in Appendix 3.2.1.;
3. the embryos/oocytes were collected, processed and stored in conformity with the provisions of Appendix 3.3.1., Appendix 3.3.2. or Appendix 3.3.3., as relevant.

Article 2.3.15.13.

When importing from CBPP infected countries, *Veterinary Authorities* should require:

for *in vivo* derived or *in vitro* produced embryos/oocytes of bovidae

the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:
   a) showed no clinical sign of CBPP on the day of collection of the embryos/oocytes;
   b) were subjected to the complement fixation test for CBPP with negative results, on two occasions, with an interval of not less than 21 days and not more than 30 days between each test, the second test being performed within 14 days prior to collection;
   c) were isolated from other domestic bovidae from the day of the first complement fixation test until collection;
   d) were kept since birth, or for the past 6 months, in an *establishment* where no *case* of CBPP was reported during that period, and that the *establishment* was not situated in a CBPP infected zone;
   e) have not been vaccinated against CBPP; or
   f) were vaccinated using a vaccine complying with the standards described in the *Terrestrial Manual* not more than 4 months prior to collection; in this case, the condition laid down in point b) above is not required;

2. the oocytes were fertilised with semen meeting the conditions referred to in points a) to f) above and in Appendix 3.2.1.;
3. the embryos/oocytes were collected, processed and stored in conformity with the provisions of Appendix 3.3.1., Appendix 3.3.2. or Appendix 3.3.3., as relevant.

SECTION 2.4.

SHEEP AND GOAT DISEASES

CHAPTER 2.4.1.

OVINE EPIDIDYMITIS
(*Brucella ovis*)

Article 2.4.1.1.

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

Article 2.4.1.2.

Sheep flock free from ovine epididymitis

To qualify as free from ovine epididymitis, a sheep flock shall satisfy the following requirements:

1. it is under *official veterinary control*;
2. all sheep in the flock showed no clinical evidence of ovine epididymitis during the past year;
3. all sheep in the flock are permanently identified.

If some or all the males in the flock are vaccinated, the flock should still be regarded as free.

Article 2.4.1.3.

Veterinary Authorities of *importing countries* should require:

<u>for sheep for breeding or rearing (except castrated males)</u>

the presentation of an *international veterinary certificate* attesting that:

1. the animals showed no clinical sign of ovine epididymitis on the day of shipment;
2. the animals come from a sheep flock free from ovine epididymitis;
3. for sheep over 6 months of age, the animals were isolated in the *establishment* of origin for the 30 days prior to shipment and were subjected to the diagnostic tests for *Brucella ovis* with negative results; or
4. for sheep from a flock other than that stated in point 2 above, the animals were isolated prior to shipment and were subjected to the diagnostic tests for *Brucella ovis* with negative results on two occasions, with an interval of 30 to 60 days between each test, the second test being performed during the 15 days prior to shipment.

Article 2.4.1.4.

Veterinary Authorities of *importing countries* should require:

for semen of sheep

the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:
   a) showed no clinical sign of ovine epididymitis on the day of collection of the semen;
   b) come from a sheep flock free from ovine epididymitis;
   c) were kept in the *exporting country* for the 60 days prior to collection, in an *establishment* or *artificial insemination centre* where all animals are free from ovine epididymitis;
   d) were subjected to the diagnostic tests for *Brucella ovis* with negative results during the 30 days prior to collection;
2. the semen does not contain *Brucella ovis* or other *Brucella* antibodies.

CHAPTER 2.4.2.

CAPRINE AND OVINE BRUCELLOSIS
(excluding *Brucella ovis*)

Article 2.4.2.1.

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

Article 2.4.2.2.

Country or zone officially free from caprine and ovine brucellosis

1. Qualification

To qualify as officially free from caprine and ovine brucellosis, a country or *zone* must satisfy the following requirements:

a) the occurrence or suspected occurrence of caprine and ovine brucellosis has been notifiable for at least 5 years; and

b) all flocks of sheep and goats in the country or *zone* are under *official veterinary control*; and either

c) 99.8% of these flocks are qualified as officially free from caprine and ovine brucellosis; or

d) no *case* of brucellosis in sheep or goats has been reported for at least 5 years, and no sheep or goat has been vaccinated against the disease for at least 3 years.

2. Maintenance of officially free status

For a country or *zone* to maintain its status as officially free from caprine and ovine brucellosis, a serological survey should be carried out every year in the *establishments* or *abattoirs* on a representative sample of the caprine and ovine flocks of the country or *zone* sufficient to provide at least a 99% level of confidence of detecting caprine and ovine brucellosis if it is present at a prevalence rate exceeding 0.2% of the flocks.

However, for a country or zone qualified as officially free under paragraph 1)d) above, maintenance testing is not required.

Article 2.4.2.3.

Sheep or goat flock officially free from caprine and ovine brucellosis

1. Qualification

To qualify as officially free from caprine and ovine brucellosis, a sheep or goat flock must satisfy the following requirements:

a) it is under *official veterinary control*;

b) no clinical, bacteriological or immunological evidence of caprine and ovine brucellosis has been found for at least one year;

c) it contains only sheep or goats not vaccinated against brucellosis or permanently identified animals which were vaccinated more than 2 years ago;

d) all sheep and goats over 6 months of age on the day of sampling have been subjected to a diagnostic test for brucellosis with negative results on two occasions, at an interval of not more than 12 months and not less than 6 months; however, for flocks situated in a country or zone qualified as officially free under point 1d) of Article 2.4.2.2., testing is not required;

e) when qualified, it contains only sheep and goats born therein or introduced in conformity with the provisions of Article 2.4.2.5.

2. Maintenance of officially free status

For a flock to maintain its status as officially free from caprine and ovine brucellosis, a sample of the animals in the flock must be subjected each year to a diagnostic test for brucellosis, with negative results.

For a flock containing up to 1,000 animals, the sample must include:

a) all non-castrated males over 6 months of age;

b) all the animals introduced into the flock since the previous test;

c) 25% of the pubescent females; the number of females included in the sample should not be less than 50, unless the flock contains fewer than 50 females, in which case all pubescent females should be included.

For a flock containing more than 1,000 animals, a serological survey should be carried out every year on a representative sample of the animals in the flock sufficient to provide a 99% level of confidence of detecting caprine and ovine brucellosis if it is present at a prevalence rate exceeding 0.2%.

Control tests must be carried out at up to 3-year intervals if the flock is situated in a zone where 99% of flocks are officially free from caprine and ovine brucellosis and the remainder are submitted to an eradication programme.

However, for flocks situated in a country or zone qualified as officially free under point 1d) of Article 2.4.2.2., maintenance testing is not required.

Whatever the periodicity of control tests and the way the status has been obtained, sheep and goats must only be introduced into the flocks in conformity with the provisions of Article 2.4.2.5.

3. Suspension and recovery of officially free status

If a sheep or goat reacts positively to a diagnostic test for caprine and ovine brucellosis, the status of flock officially free from brucellosis shall be suspended and may not be recovered unless the following requirements have been fulfilled:

a) all infected and in-contact animals were eliminated from the flock as soon as the result of the diagnostic test was known;

b) all the remaining sheep and goats in the flock over 6 months of age on the day of sampling have been subjected to a diagnostic test for caprine and ovine brucellosis, with negative results, on two occasions, at an interval of not less than 3 months.

Article 2.4.2.4.

Sheep or goat flock free from caprine and ovine brucellosis

1. Qualification

To qualify as free from caprine and ovine brucellosis, a sheep or goat flock must satisfy the following requirements:

a) it is under *official veterinary control*;

b) no clinical, bacteriological or immunological evidence of caprine and ovine brucellosis has been found for at least one year;

c) if all or some of the sheep or goats have been vaccinated against caprine and ovine brucellosis, this was performed before 7 months of age;

d) all non-vaccinated sheep and goats over 6 months of age, and all vaccinated ones over 18 months of age on the day of sampling have been subjected to a diagnostic test for brucellosis with negative results on two occasions, at an interval of not more than 12 months and not less than 6 months;

e) when qualified, it contains only sheep and goats born therein or introduced in conformity with the provisions of Article 2.4.2.6.

2. Maintenance of free status

For a flock to maintain its status as free from caprine and ovine brucellosis, a sample of the animals in the flock must be subjected each year to a diagnostic test for brucellosis with negative results.

For a flock containing up to 1,000 animals, the sample should include:

a) all non-castrated males over 18 months of age if vaccinated, and over 6 months of age if unvaccinated;

b) all animals introduced into the flock since the previous control;

c) 25% of the pubescent females except vaccinated females less than 18 months of age; the number of females included in the sample should not be less than 50, unless the flock contains fewer than 50 females, in which case all pubescent females should be included in the sample.

For a flock containing more than 1,000 animals, a serological survey should be carried out every year on a representative sample of the animals in the flock, excluding vaccinated females less than 18 months of age, sufficient to provide a 99% level of confidence of detecting caprine and ovine brucellosis if it is present at a prevalence rate exceeding 0.2%.

Sheep and goats must only be introduced into the flock in conformity with the provisions of Article 2.4.2.6.

3. Suspension and recovery of free status

If a sheep or goat over 18 months of age, if vaccinated, or over 6 months of age, if not vaccinated, reacts positively to a diagnostic test for caprine and ovine brucellosis, the status of flock free from brucellosis shall be suspended, and may not be recovered unless the following requirements have been fulfilled:

a) all infected and in-contact animals were eliminated from the flock as soon as the result of the diagnostic test was known;

b) all the remaining sheep and goats in the flock over 18 months of age if vaccinated, and over 6 months of age if not vaccinated on the day of sampling, have been subjected to a diagnostic test for caprine and ovine brucellosis with negative results on two occasions, at an interval of not less than 3 months.

4. Change of status

For a flock free from caprine and ovine brucellosis to qualify as officially free, the flock must fulfil the following requirements for at least 2 years:

a) it has been free from caprine and ovine brucellosis;

b) vaccination against brucellosis has not been practised;

c) any sheep or goats introduced into the flock satisfied the provisions of Article 2.4.2.5.;

and at the end of the period, all sheep and goats over 6 months of age on the day of sampling have been subjected to a diagnostic test for caprine and ovine brucellosis, with negative results.

Article 2.4.2.5.

Veterinary Authorities of *importing countries* should require:

for sheep and goats for breeding or rearing (except castrated males) destined for flocks officially free from caprine and ovine brucellosis

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of caprine and ovine brucellosis on the day of shipment;

2. come from a sheep or goat flock officially free from caprine and ovine brucellosis;

OR

3. come from a sheep or goat flock free from caprine and ovine brucellosis; and

4. have not been vaccinated against brucellosis, or, if vaccinated, that the last vaccination was performed at least 2 years previously; and

5. were isolated in the *establishment* of origin, and were subjected during that period to a diagnostic test for caprine and ovine brucellosis with negative results on two occasions, at an interval of not less than 6 weeks.

Article 2.4.2.6.

Veterinary Authorities of *importing countries* should require:

for sheep and goats for breeding or rearing (except castrated males) destined for flocks not officially free from caprine and ovine brucellosis

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of caprine and ovine brucellosis on the day of shipment;
2. come from a sheep or goat flock officially free from caprine and ovine brucellosis or a sheep or goat flock free from caprine and ovine brucellosis.

Article 2.4.2.7.

Veterinary Authorities of *importing countries* should require:

for sheep and goats for slaughter (except castrated males)

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of caprine and ovine brucellosis on the day of shipment;
2. come from a sheep or goat flock where no *case* of brucellosis has occurred during the 42 days prior to shipment.

Article 2.4.2.8.

Veterinary Authorities of *importing countries* should require:

for semen of sheep and goats

the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:
   a) showed no clinical sign of caprine and ovine brucellosis on the day of collection of the semen;
   b) were kept in a sheep or goat flock officially free from caprine and ovine brucellosis; or
   c) were kept in a sheep or goat flock free from caprine and ovine brucellosis, and were subjected to two different diagnostic tests for caprine and ovine brucellosis on the same blood sample with negative results during the 30 days prior to collection;
2. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.1.

Article 2.4.2.9.

Veterinary Authorities of *importing countries* should require:

for embryos/ova of sheep and goats

the presentation of an *international veterinary certificate* attesting that:

1. the donor females:
   a) were kept in a sheep or goat flock officially free from caprine and ovine brucellosis, and showed no clinical sign of brucellosis on the day of collection of the embryos/ova; or
   b) were kept in a sheep or goat flock free from caprine and ovine brucellosis, showed no clinical sign of brucellosis on the day of collection, and were subjected to two different diagnostic tests for caprine and ovine brucellosis on the same blood sample taken within the 30 days prior to collection, with negative results;

2. the embryos/ova were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

CHAPTER 2.4.3.

CONTAGIOUS AGALACTIA

Article 2.4.3.1.

Veterinary Authorities of *importing countries* should require:

for sheep and goats

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of contagious agalactia on the day of shipment;
2. were kept since birth or for the 6 months prior to shipment in an *establishment* where no *case* of contagious agalactia was officially reported during that period;
3. were kept in a *quarantine station* for the 21 days prior to shipment.

CHAPTER 2.4.4.

CAPRINE ARTHRITIS/ENCEPHALITIS

Article 2.4.4.1.

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

Article 2.4.4.2.

Veterinary Authorities of *importing countries* should require:

for goats for breeding

the presentation of an *international veterinary certificate* attesting that:

1. the animals showed no clinical sign of caprine arthritis/encephalitis on the day of shipment;
2. animals over one year of age were subjected to a diagnostic test for caprine arthritis/encephalitis with negative results during the 30 days prior to shipment; or
3. caprine arthritis/encephalitis was neither clinically nor serologically diagnosed in the sheep and goats present in the flocks of origin during the past 3 years, and also that no sheep or goat from a flock of inferior health status was introduced into these flocks during that period.

CHAPTER 2.4.5.

MAEDI-VISNA

Article 2.4.5.1.

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

Article 2.4.5.2.

Veterinary Authorities of *importing countries* should require:

for sheep and goats for breeding

the presentation of an *international veterinary certificate* attesting that:

1. the animals showed no clinical sign of maedi-visna on the day of shipment;
2. animals over one year of age were subjected to a diagnostic test for maedi-visna with negative results during the 30 days prior to shipment;
3. maedi-visna was neither clinically nor serologically diagnosed in the sheep and goats present in the flocks of origin during the past 3 years, and also that no sheep or goat from a flock of inferior health status was introduced into these flocks during that period.

CHAPTER 2.4.6.

CONTAGIOUS CAPRINE PLEUROPNEUMONIA

Article 2.4.6.1.

For the purposes of the *Terrestrial Code*, contagious caprine pleuropneumonia (CCPP) is defined as a disease of goats caused by *Mycoplasma capricolum* subsp. *capripneumoniae*. The *incubation period* for the disease shall be 45 days (chronic carriers occur).

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

Article 2.4.6.2.

Country free from contagious caprine pleuropneumonia

A country may be considered free from CCPP when it has been shown that CCPP is not present and that one year has elapsed after the slaughter of the last affected animal for countries in which a *stamping-out policy* is practised.

Article 2.4.6.3.

Zone infected with contagious caprine pleuropneumonia

A zone shall be considered as infected with CCPP until at least 45 days have elapsed after the confirmation of the last *case* and the completion of a *stamping-out policy* and *disinfection* procedures.

Article 2.4.6.4.

Veterinary Authorities of CCPP free countries may prohibit importation or transit through their territory, from countries considered infected with CCPP, of domestic and wild goats, and may prohibit importation into their territory, from countries considered infected with CCPP, of semen of domestic and wild goats and of embryos/ova of domestic goats.

Article 2.4.6.5.

When importing from CCPP free countries, *Veterinary Authorities* should require:

<u>for domestic goats</u>

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of CCPP on the day of shipment;
2. were kept in a CCPP free country since birth or for at least 3 months.

Article 2.4.6.6.

When importing from CCPP free countries, *Veterinary Authorities* should require:

<u>for wild goats</u>

the presentation of an *international veterinary certificate* attesting that the animals:

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

2. were kept in a CCPP free country;

if the animals originated from an area adjacent to a country considered infected with CCPP:

3. were kept in a *quarantine station* for at least the 45 days prior to shipment.

Article 2.4.6.7.

When importing from countries considered infected with CCPP, *Veterinary Authorities* should require:

for domestic goats

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of CCPP on the day of shipment;
2. were subjected to a complement fixation test for CCPP with negative results, on two occasions, with an interval of not less than 21 days and not more than 30 days between each test, the second test being performed within 14 days prior to shipment (under study);
3. were isolated from other domestic goats from the day of the first complement fixation test until shipment;
4. were kept since birth, or for at least the past 45 days, in an *establishment* where no *case* of CCPP was officially reported during that period, and that the *establishment* of origin was not situated in a CCPP infected zone;
5. have not been vaccinated against CCPP; or
6. were vaccinated not more than 4 months prior to shipment. In this case, point 2 above is not required (under study).

Article 2.4.6.8.

When importing from countries considered infected with CCPP, *Veterinary Authorities* should require:

for goats for immediate slaughter

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of CCPP on the day of shipment;
2. were kept since birth, or for at least the past 45 days, in an *establishment* where no *case* of CCPP was officially reported during that period, and that the *establishment* of origin was not situated in a CCPP infected zone.

Article 2.4.6.9.

When importing from countries considered infected with CCPP, *Veterinary Authorities* should require:

for wild goats

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of CCPP on the day of shipment;
2. were kept, for at least the past 45 days prior to shipment, in a *quarantine station* where no *case* of CCPP was officially reported during that period, and that the *quarantine station* was not situated in a CCPP infected zone;
3. have not been vaccinated against CCPP; or
4. were vaccinated not more than 4 months prior to shipment (under study).

Article 2.4.6.10.

When importing from countries considered infected with CCPP, *Veterinary Authorities* should require:

for *fresh meat* of goats

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from animals:

1. which originate from *establishments* free of CCPP;
2. which have been slaughtered in an *approved abattoir* and have been subjected to an ante-mortem inspection for CCPP with favourable results; and
3. which showed no lesion of CCPP at the post-mortem inspection.

CHAPTER 2.4.7.

ENZOOTIC ABORTION OF EWES
(Ovine chlamydiosis)

Article 2.4.7.1.

For the purposes of the *Terrestrial Code*, the following information should be considered with regard to the *incubation period* for enzootic abortion of ewes (EAE).

Susceptible animals become infected through ingestion of infectious materials. In lambs and non-pregnant ewes, the infection remains latent until conception. Ewes exposed to infection late in pregnancy may not exhibit signs of infection until the subsequent pregnancy. Countries should take account of these risk factors.

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

Article 2.4.7.2.

Veterinary Authorities of *importing countries* should require:

for sheep and/or goats for breeding

the presentation of an *international veterinary certificate* attesting that the animals:

1. have remained since birth, or for the previous 2 years, in *establishments* where no EAE has been diagnosed during the past 2 years;
2. showed no clinical sign of EAE on the day of shipment;
3. were subjected to a diagnostic test for EAE with negative results within the 30 days prior to shipment.

Article 2.4.7.3.

Sheep flocks and/or goat herds free from EAE infection

To qualify as free from EAE infection, a sheep flock or goat herd shall satisfy the following requirements:

1. it is under official veterinary surveillance;
2. all sheep and goats showed no clinical evidence of EAE infection during the past 2 years;
3. a statistically valid number of sheep and goats over 6 months of age were subjected to a diagnostic test for EAE with negative results within the past 6 months;
4. all sheep or goats are permanently identified;
5. no sheep or goat has been added to the flock or herd since 30 days prior to the flock or herd test referred to in point 3 above unless:
   a) either the additions were isolated from other members of the flock or herd in the *establishment* of origin for a minimum period of 30 days and then were subjected to a diagnostic test for EAE with negative results, before entry into the new flock or herd; or
   b) they originated from an *establishment* of equal health status.

Article 2.4.7.4.

Veterinary Authorities of *importing countries* should require:

for semen of sheep

the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:
   a) have been kept in *establishments* or *artificial insemination centres* free from EAE during the past 2 years, and have not been in contact with animals of a lower health status;
   b) were subjected to a diagnostic test for EAE with negative results 2 to 3 weeks after collection of the semen;
2. an aliquot of the semen to be exported was shown to be free of *Chlamydia psittaci*, by culture techniques.

CHAPTER 2.4.8.

SCRAPIE

Article 2.4.8.1.

Scrapie is a neurodegenerative disease of sheep and goats. The main mode of transmission is from mother to offspring immediately after birth and to other susceptible neonates exposed to the birth fluids and tissues of an infected animal. Transmission occurs at a much lower frequency to adults exposed to the birth fluids and tissues of an infected animal. A variation in genetic susceptibility of sheep has been recognised. The *incubation period* of the disease is variable, however it is usually measured in years. The duration in *incubation period* can be influenced by a number of factors including host genetics and strain of agent.

The recommendations in the present chapter are not intended, or sufficient, to manage the risks associated with the potential presence of the bovine spongiform encephalopathy agent in small ruminants.

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

Article 2.4.8.2.

The scrapie status of a country, a *zone* or an *establishment* can be determined on the basis of the following criteria:

1. the outcome of a *risk assessment* identifying all potential factors for scrapie occurrence and their historic perspective, in particular the:
   a) epidemiological situation concerning all animal transmissible spongiform encephalopathies (TSE) in the country, *zone* or *establishment*;
   b) importation or introduction of small ruminants or their embryos/oocytes potentially infected with scrapie;
   c) extent of knowledge of the population structure and husbandry practices of sheep and goats in the country or *zone*;
   d) feeding practices, including consumption of *meat-and-bone meal* or *greaves* derived from ruminants;
   e) importation of *meat-and-bone meal* or *greaves* potentially contaminated with an animal TSE or feedstuffs containing either;
   f) the origin and use of ruminant carcasses (including fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;
2. an on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of sheep and goats to facilitate recognition and encourage reporting of all animals with clinical signs compatible with scrapie;
3. a surveillance and monitoring system including the following:
   a) official veterinary surveillance, reporting and regulatory control in accordance with the provisions of Appendix 3.8.1.;
   b) a *Veterinary Authority* with current knowledge of, and authority over, all *establishments* which contain sheep and goats in the whole country;
   c) compulsory notification and clinical investigation of all sheep and goats showing clinical signs compatible with scrapie;
   d) examination in an *approved laboratory* of appropriate material from sheep and goats older than 18 months displaying clinical signs compatible with scrapie taking into account the guidelines in Appendix X.X.X. (under study);
   e) maintenance of records including the number and results of all investigations for at least 7 years.

Article 2.4.8.3.

Scrapie free country or zone

Countries or zones may be considered free from scrapie if within the said territory:

1. a *risk assessment*, as described in point 1 of Article 2.4.8.2., has been conducted, and it has been demonstrated that appropriate measures have been taken for the relevant period of time to manage any risk identified;

AND EITHER

2. the country or the zone have demonstrated historical freedom taking into account the guidelines in Appendix 3.8.6.;

OR

3. for at least 7 years, a surveillance and monitoring system as referred to in Article 2.4.8.2. has been in place, and no *case* of scrapie has been reported during this period;

OR

4. for at least 7 years, a sufficient number of investigations has been carried out annually, to provide a 95% level of confidence of detecting scrapie if it is present at a prevalence rate exceeding 0.1% out of the total number of all chronic wasting conditions in the population of sheep and goats older than 18 months of age (under study) and no *case* of scrapie has been reported during this period; it is assumed that the occurrence rate of chronic wasting conditions within the population of sheep and goats older than 18 months of age is at least 1%;

OR

5. all *establishments* containing sheep or goats have been accredited free as described in Article 2.4.8.4.;

AND

6. the feeding to sheep and goats of *meat-and-bone meal* or *greaves* potentially contaminated with an animal TSE has been banned and effectively enforced in the whole country for at least 7 years;

AND

7. introductions of sheep and goats, semen and embryos/oocytes from countries or zones not free from scrapie are carried out in accordance with Articles 2.4.8.6., 2.4.8.7., 2.4.8.8. or 2.4.8.9., as relevant.

For maintenance of country or zone free status, the investigations referred to in point 4 above should be repeated every 7 years.

Article 2.4.8.4.

Scrapie free establishment

An *establishment* may be considered eligible for accreditation as a scrapie free *establishment* if:

1. in the country or zone where the *establishment* is situated, the following conditions are fulfilled:
   a) the disease is compulsorily notifiable;
   b) a surveillance and monitoring system as referred to in Article 2.4.8.2. is in place;
   c) affected sheep and goats are slaughtered and completely destroyed;
   d) the feeding to sheep and goats of *meat-and-bone meal* or *greaves* potentially contaminated with an animal TSE has been banned and effectively enforced in the whole country;
   e) an official accreditation scheme is in operation under the supervision of the *Veterinary Authority*, including the measures described in point 2 below;
2. in the *establishment* the following conditions have been complied with for at least 7 years:
   a) sheep and goats should be permanently identified and records maintained, to enable trace back to their *establishment* of birth;

b) records of movements of sheep and goats in and out of the *establishment* are established and maintained;

c) introductions of animals are allowed only from *establishments* of an equal or higher stage in the process of accreditation; however, rams and bucks complying with the provisions in point 2 of Article 2.4.8.8. may also be introduced;

d) an *Official Veterinarian* inspects sheep and goats in the *establishment* and audits the records at least once a year;

e) no *case* of scrapie has been reported;

f) sheep and goats of the *establishment* should have no direct or indirect contact with sheep or goats from *establishments* of a lower status;

g) all culled animals over 18 months of age are inspected by an *Official Veterinarian*, and a proportion of those exhibiting neurological or wasting signs are tested in a laboratory for scrapie. The selection of the animals to be tested should be made by the *Official Veterinarian*. Animals over 18 months of age that have died or have been killed for reasons other than routine slaughter should also be tested (including 'fallen' stock and emergency slaughter).

Article 2.4.8.5.

Regardless of the scrapie status of the *exporting country*, *Veterinary Authorities* should authorise without restriction the import or transit through their territory of *meat* (excluding materials as referred to in Article 2.4.8.11.), *milk*, *milk products*, wool and its derivatives, hides and skins, tallow, derivatives made from this tallow and dicalcium phosphate originating from sheep and goats.

Article 2.4.8.6.

When importing from countries not considered free from scrapie, *Veterinary Authorities* should require:

<u>for sheep and goats for breeding or rearing</u>

the presentation of an *international veterinary certificate* attesting that the animals come from a zone or an *establishment* free from scrapie as described in Article 2.4.8.3. and in Article 2.4.8.4.

Article 2.4.8.7.

When importing from countries or zones not considered free from scrapie, *Veterinary Authorities* should require:

<u>for sheep and goats for slaughter</u>

the presentation of an *international veterinary certificate* attesting that:

1. in the country or *zone*:

   a) the disease is compulsorily notifiable;

   b) a surveillance and monitoring system as referred to in Article 2.4.8.2. is in place;

   c) affected sheep and goats are slaughtered and completely destroyed;

2. the sheep and goats selected for export showed no clinical sign of scrapie on the day of shipment.

Article 2.4.8.8.

When importing from countries or zones not considered free from scrapie, *Veterinary Authorities* should require:

for semen of sheep and goats

the presentation of an *international veterinary certificate* attesting that:

1. in the country or *zone*:
   a) the disease is compulsorily notifiable;
   b) a surveillance and monitoring system as referred to in Article 2.4.8.2. is in place;
   c) affected sheep and goats are slaughtered and completely destroyed;
   d) the feeding of sheep and goats with *meat-and-bone meal* or *greaves* potentially contaminated with an animal TSE has been banned and effectively enforced in the whole country;
2. the donor animals:
   a) are permanently identified, to enable trace back to their *establishment* of origin;
   b) have been kept since birth in *establishments* in which no *case* of scrapie had been confirmed during their residency;
   c) showed no clinical sign of scrapie at the time of semen collection;
3. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.1.

Article 2.4.8.9.

When importing from countries or zones not considered free from scrapie, *Veterinary Authorities* should require:

for embryos/oocytes of sheep and goats

the presentation of an *international veterinary certificate* attesting that:

1. in the country or *zone*:
   a) the disease is compulsorily notifiable;
   b) a surveillance and monitoring system as referred to in Article 2.4.8.2. is in place;
   c) affected sheep and goats are slaughtered and completely destroyed;
   d) the feeding to sheep and goats of *meat-and-bone meal* or *greaves* potentially contaminated with animal TSE has been banned and effectively enforced in the whole country;
2. the donor animals:
   a) are permanently identified, to enable trace back to their *establishment* of origin;
   b) have been kept since birth in *establishments* in which no *case* of scrapie had been confirmed during their residency;
   c) showed no clinical sign of scrapie at the time of embryo/oocyte collection;
3. the embryos/oocytes were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.4.8.10.

Meat-and-bone meal containing any sheep or goat protein, or any feedstuffs containing that type of *meat-and-bone meal*, which originate from countries not considered free of scrapie should not be traded between countries for ruminant feeding.

Article 2.4.8.11.

When importing from countries or zones not considered free from scrapie, *Veterinary Authorities* should require:

for skulls including brains, ganglia and eyes, vertebral column including ganglia and spinal cord, tonsils, thymus, spleen, intestine, adrenal gland, pancreas, or liver, and protein products derived therefrom, from sheep and goats

the presentation of an *international veterinary certificate* attesting that:

1. in the country or *zone*:
   a) the disease is compulsorily notifiable;
   b) a surveillance and monitoring system as referred to in Article 2.4.8.2. is in place;
   c) affected sheep and goats are slaughtered and completely destroyed;
2. the materials come from sheep and goats that showed no clinical sign of scrapie on the day of slaughter.

Article 2.4.8.12.

Veterinary Authorities of *importing countries* should require:

for ovine and caprine materials destined for the preparation of biologicals

the presentation of an *international veterinary certificate* attesting that the products originate from sheep and goats born and raised in a scrapie free country, zone or *establishment*.

CHAPTER 2.4.9.

PESTE DES PETITS RUMINANTS

Article 2.4.9.1.

For the purposes of the *Terrestrial Code*, the *incubation period* for the peste des petits ruminants (PPR) shall be 21 days.

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

Article 2.4.9.2.

PPR free country

A country may be considered free from PPR when it has been shown that PPR has not been present for at least the past 3 years.

This period shall be 6 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 2.4.9.3.

PPR infected zone

A zone shall be considered as infected with PPR until:

1. at least 21 days have elapsed after the confirmation of the last *case* and the completion of a *stamping-out policy* and *disinfection* procedures, or
2. 6 months have elapsed after the clinical recovery or death of the last affected animal if a *stamping-out policy* was not practised.

Article 2.4.9.4.

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

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

Article 2.4.9.5.

When importing from PPR free countries, *Veterinary Authorities* should require:

for domestic small ruminants

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 since birth or for at least the past 21 days.

Article 2.4.9.6.

When importing from PPR free countries, *Veterinary Authorities* should require:

for wild ruminants

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of PPR on the day of shipment;
2. come from a PPR free country;

if the country of origin has a common border with a country considered infected with PPR:

3. were kept in a *quarantine station* for the 21 days prior to shipment.

Article 2.4.9.7.

When importing from countries considered infected with PPR, *Veterinary Authorities* should require:

for domestic small ruminants

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 since birth, or for the past 21 days, in an *establishment* where no *case* of PPR was officially 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; or
5. were vaccinated against PPR:
   a) not less than 15 days and not more than 4 months prior to shipment in the case of *animals for breeding or rearing*; or
   b) not less than 15 days and not more than 12 months prior to shipment in the case of *animals for slaughter*.

Article 2.4.9.8.

When importing from countries considered infected with PPR, *Veterinary Authorities* should require:

for wild ruminants

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 *quarantine station* for the 21 days prior to shipment.

Article 2.4.9.9.

When importing from PPR free countries, *Veterinary Authorities* should require:

for semen of domestic small ruminants

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 for not less than 21 days prior to collection.

Article 2.4.9.10.

When importing from countries considered infected with PPR, *Veterinary Authorities* should require:

for semen of domestic small ruminants

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 the *exporting country* for the 21 days prior to collection, in an *establishment* or *artificial insemination centre* where no *case* of PPR was officially reported during that period, and that the *establishment* or *artificial insemination centre* was not situated in a PPR infected zone;
3. have not been vaccinated against PPR; or
4. were vaccinated against PPR.

Article 2.4.9.11.

When importing from PPR free countries, *Veterinary Authorities* should require:

for embryos of domestic small ruminants and cervids

the presentation of an *international veterinary certificate* attesting that:

1. the donor females were kept in an *establishment* located in a PPR free country at the time of collection of the embryos;
2. the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.4.9.12.

When importing from countries considered infected with PPR, *Veterinary Authorities* should require:

for embryos of domestic small ruminants and cervids

the presentation of an *international veterinary certificate* attesting that:

1. the donor females:
   a) were kept in an *establishment* to which no animals had been added for the 21 days prior to collection;
   b) and all other animals in the *establishment* showed no clinical sign of PPR at the time of collection of the embryos and during the following 21 days;
   c) have been vaccinated against PPR not less than 21 days and not more than 4 months prior to collection; or
   d) have not been vaccinated against PPR and were subjected to a diagnostic test for PPR with negative results at least 21 days after collection;
2. the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.4.9.13.

When importing from PPR free countries, *Veterinary Authorities* should require:

for *fresh meat* or *meat products* of domestic small ruminants

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from animals:

1. which have been kept in the country since birth, or have been imported from a PPR free country;
2. which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for PPR with favourable results.

Article 2.4.9.14.

When importing from countries considered infected with PPR, *Veterinary Authorities* should require:

for *meat products* of domestic small ruminants

the presentation of an *international veterinary certificate* attesting that:

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

Article 2.4.9.15.

When importing from PPR free countries, *Veterinary Authorities* should require:

for products of animal origin (from small ruminants) intended for use in animal feeding or for agricultural or industrial use

the presentation of an *international veterinary certificate* attesting that these products come from animals which have been kept in a PPR free country since birth or for at least the past 21 days.

Article 2.4.9.16.

When importing from PPR free countries, *Veterinary Authorities* should require:

for products of animal origin (from small ruminants) intended for pharmaceutical or surgical use

the presentation of an *international veterinary certificate* attesting that these products come from animals:

1. which have been kept in a PPR free country 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 for PPR with favourable results.

Article 2.4.9.17.

When importing from countries considered infected with PPR, *Veterinary Authorities* should require:

for meal and flour from blood, meat, defatted bones, hooves, claws and horns (from small ruminants)

the presentation of an *international veterinary certificate* attesting that these products have been processed using heat treatment to ensure the destruction of the PPR virus.

Article 2.4.9.18.

When importing from countries considered infected with PPR, *Veterinary Authorities* should require:

for hooves, claws, bones and horns, hunting trophies and preparations destined for museums (from small ruminants)

the presentation of an *international veterinary certificate* attesting that these products:

1. were completely dried and had no trace on them of skin, flesh or tendon; and/or
2. have been adequately disinfected.

Article 2.4.9.19.

When importing from countries considered infected with PPR, *Veterinary Authorities* should require:

for wool, coarse hair and other hair (from small ruminants)

the presentation of an *international veterinary certificate* attesting that these products:

1. come from animals which have not been kept in a PPR infected zone; or
2. have been processed to ensure the destruction of the PPR virus, in premises controlled and approved by the *Veterinary Authority* of the *exporting country*.

Article 2.4.9.20.

When importing from countries considered infected with PPR, *Veterinary Authorities* should require:

for raw hides and skins (from small ruminants)

the presentation of an *international veterinary certificate* attesting that these products:

1. come from animals which have not been kept in a PPR infected zone; or
2. have been adequately disinfected.

Article 2.4.9.21.

When importing from countries considered infected with PPR, *Veterinary Authorities* should require:

for products of animal origin (from small ruminants) intended for pharmaceutical or surgical use

the presentation of an *international veterinary certificate* attesting that these products:

1. have been processed to ensure the destruction of the PPR virus; or
2. come from animals which did not come from a PPR infected zone;
3. come from animals which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for PPR with favourable results.

CHAPTER 2.4.10.

SHEEP POX AND GOAT POX

Article 2.4.10.1.

For the purposes of the *Terrestrial Code*, the *incubation period* for sheep pox and goat pox shall be 21 days.

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

Article 2.4.10.2.

Sheep pox and goat pox free country

A country may be considered free from sheep pox and goat pox when it has been shown that sheep pox and goat pox has not been present for at least the past 3 years.

This period shall be 6 months after the slaughter of the last affected animal for countries in which a *stamping-out policy* is practised with or without vaccination against sheep pox and goat pox.

Article 2.4.10.3.

Sheep pox and goat pox infected zone

A zone shall be considered as infected with sheep pox and/or goat pox until:

1. at least 21 days have elapsed after the confirmation of the last *case* and the completion of a *stamping-out policy* and *disinfection* procedures, or
2. 6 months have elapsed after the clinical recovery or death of the last affected animal if a *stamping-out policy* was not practised.

Article 2.4.10.4.

Veterinary Authorities of sheep pox and goat pox free countries may prohibit importation or transit through their territory, from countries considered infected with sheep pox and goat pox, of domestic sheep and goats.

Article 2.4.10.5.

When importing from sheep pox and goat pox free countries, *Veterinary Authorities* should require:

<u>for domestic sheep and goats</u>

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of sheep pox or goat pox on the day of shipment;
2. were kept in a sheep pox and goat pox free country since birth or for at least the past 21 days.

Article 2.4.10.6.

When importing from countries considered infected with sheep pox and goat pox, *Veterinary Authorities* should require:

for domestic sheep and goats

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of sheep pox or goat pox on the day of shipment;
2. were kept since birth, or for the past 21 days, in an *establishment* where no *case* of sheep pox and goat pox was officially reported during that period, and that the *establishment* was not situated in a sheep pox and goat pox infected zone; or
3. were kept in a *quarantine station* for the 21 days prior to shipment;
4. have not been vaccinated against sheep pox and goat pox; or
5. were vaccinated using a vaccine complying with the standards described in the *Terrestrial Manual* not less than 15 days and not more than 4 months prior to shipment (the nature of the vaccine used, whether inactivated or modified live virus, and the virus types and strains included in the vaccine shall also be stated in the certificate).

Article 2.4.10.7.

When importing from sheep pox and goat pox free countries, *Veterinary Authorities* should require:

for semen of sheep and goats

the presentation of an *international veterinary certificate* attesting that the donor animals:

1. showed no clinical sign of sheep pox or goat pox on the day of collection of the semen and for the following 21 days;
2. were kept in a sheep pox and goat pox free country.

Article 2.4.10.8.

When importing from countries considered infected with sheep pox and goat pox, *Veterinary Authorities* should require:

for semen of sheep and goats

the presentation of an *international veterinary certificate* attesting that the donor animals:

1. showed no clinical sign of sheep pox or goat pox on the day of collection of the semen and for the following 21 days;
2. were kept in the *exporting country* for the 21 days prior to collection, in an *establishment* or *artificial insemination centre* where no *case* of sheep pox and goat pox was officially reported during that period, and that the *establishment* or *artificial insemination centre* was not situated in a sheep pox and goat pox infected zone;
3. have not been vaccinated against sheep pox and goat pox; or
4. were vaccinated using a vaccine complying with the standards described in the *Terrestrial Manual* (the nature of the vaccine used, whether inactivated or modified live virus, and the virus types and strains included in the vaccine shall also be stated in the certificate).

Article 2.4.10.9.

When importing from countries considered infected with sheep pox and goat pox, *Veterinary Authorities* should require:

for skins, fur, wool and hair (from sheep or goats)

the presentation of an *international veterinary certificate* attesting that these products:

1. come from animals which have not been kept in a sheep pox and goat pox infected zone; or

2. have been processed to ensure the destruction of the sheep pox and goat pox virus, in premises controlled and approved by the *Veterinary Authority* of the *exporting country*.

SECTION 2.5.

EQUINE DISEASES

CHAPTER 2.5.1.

CONTAGIOUS EQUINE METRITIS

Article 2.5.1.1.

For the purposes of this Chapter, 'infected *establishment*' means premises in which equines infected with contagious equine metritis (CEM) are kept. The *establishment* shall be considered infected until 2 months have elapsed since the confirmation of the last *case* and after the premises have been adequately cleansed and disinfected.

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

Article 2.5.1.2.

Veterinary Authorities of *importing countries* should require:

<u>for stallions and mares considered free from CEM (for countries where an official control organisation is present)</u>

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of CEM on the day of shipment;
2. have had no contact with CEM:
   a) directly, through coitus with an infected animal; or
   b) indirectly, by passing through an infected *establishment*;
3. were subjected to the laboratory test for CEM with negative results during the 30 days prior to shipment.

Article 2.5.1.3.

Veterinary Authorities of *importing countries* should require:

<u>for stallions and mares which have previously shown signs of CEM or which have been in contact with CEM (for countries where an official control organisation is present)</u>

the presentation of an *international veterinary certificate* attesting that the animals which have been in direct contact through coitus with an infected animal, or indirect contact by passing through an infected *establishment*:

1. have been recognised as not being contagious through laboratory tests for CEM;
2. have been protected against any possibility of contagion since the beginning of the tests.

CHAPTER 2.5.2.

DOURINE

Article 2.5.2.1.

For the purposes of the *Terrestrial Code*, the *incubation period* for dourine shall be 6 months.

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

Article 2.5.2.2.

Dourine free country

A country formerly infected with dourine may be considered free again when:

1. a *stamping-out policy* has been practised for affected animals;
2. no clinical *case* of dourine has been observed during the past 2 years;
3. breeding horses have been subjected to a diagnostic test for dourine with negative results performed annually over a 2-year period.

Article 2.5.2.3.

When importing from dourine free countries for the past 6 months, *Veterinary Authorities* should require:

<u>for equines</u>

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of dourine on the day of shipment;
2. were kept since birth, or for the 6 months prior to shipment, in a country which has been free from dourine for not less than the past 6 months.

Article 2.5.2.4.

When importing from countries considered infected with dourine, *Veterinary Authorities* should require:

<u>for equines</u>

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of dourine on the day of shipment;
2. were kept for the 6 months prior to shipment in an *establishment* where no *case* of dourine was officially reported during that period;
3. were subjected to a diagnostic test for dourine with negative results during the 15 days prior to shipment.

Article 2.5.2.5.

When importing from dourine free countries for the past 6 months, *Veterinary Authorities* should require:

for semen of equines

the presentation of an *international veterinary certificate* attesting that the donor animals were kept since birth, or for the 6 months prior to collection of the semen, in a country which has been free from dourine for not less than the past 6 months.

Article 2.5.2.6.

When importing from countries considered infected with dourine, *Veterinary Authorities* should require:

for semen of equines

the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:
   a) were kept for the 6 months prior to collection of the semen in an *establishment* or *artificial insemination centre* where no *case* of dourine was reported during that period;
   b) were subjected to a diagnostic test for dourine with negative results;
2. the microscopic examination of the semen for dourine was negative.

CHAPTER 2.5.3.

EQUINE ENCEPHALOMYELITIS
(Eastern and Western)

Article 2.5.3.1.

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

Article 2.5.3.2.

Veterinary Authorities of *importing countries* should require:

for equines

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of equine encephalomyelitis on the day of shipment and during the 3 months prior to shipment;
2. were kept for the 3 months prior to shipment in an *establishment* where no *case* of equine encephalomyelitis was officially reported during that period; or
3. were kept in a *quarantine station* for the 21 days prior to shipment and were protected from insect vectors during quarantine and transportation to the *place of shipment*; or
4. were vaccinated not less than 15 days and not more than one year prior to shipment.

CHAPTER 2.5.4.

EQUINE INFECTIOUS ANAEMIA

Article 2.5.4.1.

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

Article 2.5.4.2.

Veterinary Authorities of *importing countries* should require:

for equines

the presentation of an *international veterinary certificate* attesting that:

1. the animals showed no clinical sign of equine infectious anaemia (EIA) on the day of shipment and during the 48 hours prior to shipment; and
2. no *case* of EIA has been associated with any premises where the animals were kept during the 3 months prior to shipment; and
3. if imported on a permanent basis, the animals were subjected to a diagnostic test for EIA with negative results on blood samples collected during the 30 days prior to shipment; or
4. if imported on a temporary basis, the animals were subjected to a diagnostic test for EIA with negative results on blood samples collected during the 90 days prior to shipment

CHAPTER 2.5.5.

EQUINE INFLUENZA

Article 2.5.5.1.

For the purposes of the *Terrestrial Code*, equine influenza (EI) is defined as an infection of domestic horses, donkeys and mules.

For the purposes of *international trade*, 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 horses from horses 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 equine influenza is 21 days.

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

Article 2.5.5.2.

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 potential factors for EI occurrence and their historic perspective;
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 horses.

Article 2.5.5.3.

Equine influenza free country, zone or compartment

A country or a *zone* or a *compartment* may be considered free from EI provided the disease is notifiable in the whole country and it shows evidence of an effective surveillance programme, planned and implemented according to the general principles in Appendix 3.8.1. 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 into the country, *zone* or *compartment*, wild equid populations or proximity to recent outbreaks.

A country, a *zone* or a *compartment* seeking freedom from EI, in which vaccination is practised, should also demonstrate that EIV has not been circulating in the domestic horse population during the past 12 months, through surveillance, in accordance with Appendix 3.8.1., at a level sufficient to provide at least a 95% level of confidence of detecting infection if it is present at a prevalence rate exceeding 1%. In a country in which vaccination is not practised, surveillance could be conducted using serological testing. In countries where vaccination is practised, the surveillance should include methods of virus detection.

If an outbreak of clinical equine influenza 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 12-month period at a level sufficient to provide at least a 95% level of confidence of detecting infection if it is present at a prevalence rate exceeding 1%.

Article 2.5.5.4.

(Under study) Regardless of the EI status of the exporting country, *zone* or *compartment*, the *Veterinary Authority* of a country, *zone* or *compartment* should authorise without restriction on account of EI the importation into their territory of the following commodities:

1. semen;
2. *in vivo* derived equine embryos collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.5.5.5.

When importing horses for immediate slaughter, the *Veterinary Authorities* should require:

the presentation of an *international veterinary certificate* attesting that the horses showed no clinical sign of EI on the day of shipment.

Article 2.5.5.6.

When importing horses for unrestricted movement, *Veterinary Authorities* should require:

the presentation of an *international veterinary certificate* attesting that the horses:

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 horse, 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 vaccinated according to the manufacturer's instructions between 21 and 90 days before shipment either with a primary course or a booster.

Article 2.5.5.7.

When importing horses which will be kept in isolation (see Article 2.5.5.1.), *Veterinary Authorities* should require:

the presentation of an *international veterinary certificate* attesting that the horses:

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 horse, 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 horses had been resident for the 21 days prior to shipment nor on the day of shipment; and
3. were vaccinated according to the manufacturer's instructions.

Article 2.5.5.8.

When importing *fresh meat* of horses, mules or donkeys, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the *fresh meat* came from horses, mules or donkeys which had been subjected to ante-mortem and post-mortem inspections as described in Appendix 3.10.1..

CHAPTER 2.5.6.

EQUINE PIROPLASMOSIS

Article 2.5.6.1.

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

Article 2.5.6.2.

Veterinary Authorities of *importing countries* should require:

for equines

the presentation of an *international veterinary certificate* attesting that the animals:

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

2. were subjected to diagnostic tests for equine piroplasmosis (*Theileria equi* and *Babesia caballi*) with negative results during the 30 days prior to shipment;

3. were maintained free from ticks, by preventive treatment when necessary, during the 30 days prior to shipment.

Article 2.5.6.3.

Veterinary Authorities of *importing countries* should consider the possibility of importing competition horses on a temporary basis and which are positive to the testing procedure referred to in point 2 of Article 2.5.6.2. under the following safeguards:

1. the horses are accompanied by a passport in conformity with the model contained in Appendix 4.1.5.;

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

   a) showed no clinical sign of equine piroplasmosis on the day of shipment;

   b) were treated against ticks within the 7 days prior to shipment;

3. the horses are kept in an area where necessary precautions are taken to control ticks and that is under the direct supervision of the *Veterinary Authority*;

4. the horses are regularly examined for the presence of ticks under the direct supervision of the *Veterinary Authority*.

CHAPTER 2.5.7.

EQUINE RHINOPNEUMONITIS

(Equine herpes virus type 1 infection)

Article 2.5.7.1.

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

Article 2.5.7.2.

Veterinary Authorities of *importing countries* should require:

for equines

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of equine herpes virus type 1 infection, on the day of shipment and during the 21 days prior to shipment;
2. were kept for the 21 days prior to shipment in an *establishment* where no *case* of equine herpes virus type 1 infection was reported during that period.

CHAPTER 2.5.8.

GLANDERS

Article 2.5.8.1.

For the purposes of the *Terrestrial Code*, the *incubation period* for glanders shall be 6 months.

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

Article 2.5.8.2.

Glanders free country

A country may be considered free from glanders when:

1. glanders is notifiable in the country;
2. no *case* of glanders has been reported during the past 3 years, or no *case* has been reported for a period of at least 6 months and a surveillance programme is in place demonstrating the absence of the disease in accordance with general guidelines on animal health surveillance (Appendix 3.8.1.).

Article 2.5.8.3.

When importing from glanders free countries, *Veterinary Authorities* should require:

<u>for equines</u>

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical signs of glanders on the day of shipment;
2. were kept for the 6 months prior to shipment, or since birth if less than 6 months of age, in the *exporting country*.

Article 2.5.8.4.

When importing from countries considered infected with glanders, *Veterinary Authorities* should require:

<u>for equines</u>

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of glanders on the day of shipment;
2. were kept for the 6 months prior to shipment in an *establishment* where no *case* of glanders was reported during that period;
3. were subjected to a test as prescribed in the *Terrestrial Manual* for glanders with negative results, during the 30 days prior to shipment.

CHAPTER 2.5.9.

HORSE POX

Article 2.5.9.1.

Veterinary Authorities of *importing countries* should require:

for equines

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of horse pox on the day of shipment;
2. were kept for the 3 months prior to shipment in an *establishment* where no *case* of horse pox was officially reported during that period.

CHAPTER 2.5.10.

EQUINE VIRAL ARTERITIS

Article 2.5.10.1.

The *infective period* for equine viral arteritis (EVA) shall be 28 days for all categories of 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 2.5.10.2.

Veterinary Authorities of *importing countries* should require:

<u>for uncastrated male equines imported on a temporary basis for breeding or on a permanent basis</u>

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of EVA on the day of shipment and during the 28 days prior to shipment;
2. were subjected, to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out either:
   a) on a single blood sample collected during the 28 days prior to shipment with negative result, or
   b) on blood samples taken on two occasions at least 14 days apart within 28 days prior to shipment, which demonstrated stable or declining antibody titres; or
3. were subjected between 6 and 9 months of age to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out on two blood samples collected at least 14 days apart with stable or decreasing titre, immediately vaccinated for EVA and regularly revaccinated according to the manufacturer's instructions; or
4. 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 equidae and regularly revaccinated according to the manufacturer's instructions; or
5. 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 12 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 28 days prior to shipment.

Article 2.5.10.3.

Veterinary Authorities of *importing countries* should require:

<u>for uncastrated male equines imported on a temporary basis other than for breeding, and for equines other than uncastrated males</u>

the presentation of an *international veterinary certificate* attesting that the animals:

1. 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;

2. were subjected to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out either:

   a) on a single blood sample collected during the 28 days prior to shipment with negative results, or

   b) on blood samples collected on two occasions at least 14 days apart within 28 days prior to shipment, which demonstrated stable or declining antibody titres;

OR

3. were subjected, between 6 and 9 months of age, to a diagnostic test for EVA, as prescribed in the *Terrestrial Manual*, carried out on two blood samples collected at least 14 days apart, with negative results or stable or declining titre, and immediately vaccinated for EVA and regularly revaccinated.

Article 2.5.10.4.

Veterinary Authorities of *importing countries* should require:

<u>for semen</u>

the presentation of an *international veterinary certificate* attesting that the animal donors:

1. were kept for the 28 days prior to semen collection in an *establishment* where no equine has shown any clinical sign of EVA during that period;

2. showed no clinical sign of EVA on the day of semen collection;

3. were subjected between 6 and 9 months of age to a test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with stable or decreasing titre, immediately vaccinated for EVA and regularly revaccinated according to the manufacturer's instructions; or

4. 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 equidae and regularly revaccinated according to the manufacturer's instructions; or

5. 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 equidae from the time of the taking of the blood sample to the time of semen collection; or

6. have been subjected to a test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with positive results and then: either

   a) were subsequently test mated to two mares within 12 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 one year prior to collection of the semen to be exported.

CHAPTER 2.5.11.

HORSE MANGE

Article 2.5.11.1.

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

Article 2.5.11.2.

Veterinary Authorities of *importing countries* should require:

for equines

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of horse mange on the day of shipment;
2. were kept for the 3 months prior to shipment in an *establishment* where no *case* of horse mange was officially reported during that period.

CHAPTER 2.5.12.

VENEZUELAN EQUINE ENCEPHALOMYELITIS

Article 2.5.12.1.

For the purposes of the *Terrestrial Code*, the *infective period* for Venezuelan equine encephalomyelitis (VEE) shall be 14 days, and the *incubation period* 5 days.

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

Article 2.5.12.2.

VEE free country

A country formerly infected with VEE may be considered free when:

1. VEE is notifiable and a surveillance system is in place and provides that all VEE suspected animals are investigated promptly; specimens are collected, and all specimens are submitted for laboratory examination, including virus isolation;
2. no *case* of VEE has been confirmed for the past 2 years;
3. no equine animal has been imported from any country where VEE has been confirmed during the past 2 years.

If a country considered free from VEE imports horses from an infected country, the *importing country* will not be considered infected, provided that the importation has been carried out in conformity with the provisions of Article 2.5.12.5.

Article 2.5.12.3.

Veterinary Authorities of VEE free countries may prohibit importation or transit through their territory, from countries considered infected with VEE, of domestic and wild equines, and may prohibit the importation into their territory, from countries considered infected with VEE, of semen and embryos/ova of domestic and wild equines.

Article 2.5.12.4.

When importing from VEE free countries, the *Veterinary Authorities* of *importing countries* should require:

<u>for domestic and wild equines</u>

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of VEE on the day of shipment;
2. have not, during the past 6 months, been in any country in which VEE has occurred in the last 2 years;
3. have not been vaccinated against VEE within 60 days prior to shipment.

Article 2.5.12.5.

When importing from countries considered infected with VEE, the *Veterinary Authorities* of *importing countries* should require:

for domestic and wild equines

the presentation of an *international veterinary certificate* attesting that:

1. vaccinated animals:
   a) were vaccinated against VEE not less than 60 days prior to shipment and were clearly identified with a permanent mark at the time of vaccination;
   b) were kept in a *quarantine station* in the country of origin under official veterinary supervision for 3 weeks prior to shipment and remained clinically healthy during that period; any animal which showed a rise in temperature (taken daily) was subjected to a blood test for virus isolation, with negative results;
   c) were protected from insect vectors during transportation to and from the *quarantine station* and during the quarantine period;
   d) showed no clinical sign of VEE on the day of shipment;
2. unvaccinated animals:
   a) were kept in a *quarantine station* in the country of origin under official veterinary supervision for 3 weeks prior to shipment and remained clinically healthy during that period; any animal which showed a rise in temperature (taken daily) was subjected to a blood test for virus isolation, with negative results;
   b) were subjected to a diagnostic test for VEE with negative results conducted not less than 14 days after the commencement of quarantine;
   c) were protected from insect vectors during transportation to and from the *quarantine station* and during the quarantine period;
   d) showed no clinical sign of VEE on the day of shipment.

In addition, animals may be isolated in the *importing country* for 7 days under official veterinary supervision. Any animal which shows a rise in temperature (taken daily) shall be subjected to a blood test for virus isolation.

CHAPTER 2.5.13.

EPIZOOTIC LYMPHANGITIS

Article 2.5.13.1.

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

Article 2.5.13.2.

Veterinary Authorities of *importing countries* should require:

for domestic horses

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of epizootic lymphangitis on the day of shipment;
2. were kept in *establishments* in which no *case* of epizootic lymphangitis was officially reported during the 2 months prior to shipment.

CHAPTER 2.5.14.

AFRICAN HORSE SICKNESS

Article 2.5.14.1.

For the purposes of the *Terrestrial Code*, the *infective period* for African horse sickness (AHS) shall be 40 days for domestic horses.

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

Article 2.5.14.2.

AHS free country

A country may be considered free from AHS when the disease is notifiable in the country, and when no clinical, serological (in non-vaccinated animals) or epidemiological evidence of AHS has been found for the past 2 years. Also, when no domestic horse or other equine has been vaccinated against the disease during the past 12 months.

Article 2.5.14.3.

AHS free zone

A zone of a country may be considered free from AHS when the disease is notifiable in the whole country and when no clinical, serological (in non-vaccinated animals) or epidemiological evidence of AHS has been found in the zone during the past 2 years. Also, when no domestic horse or other equine has been vaccinated against the disease during the past 12 months. The free zone must be clearly delineated by substantial geographical barriers if possible. The animal health regulations to prevent the movement of domestic horses and other equines into the free zone from an infected country or infected zone must be published and rigorously implemented, with notification to the OIE in conformity with the provisions of Article 1.1.2.4. of Section 1.1. of the *Terrestrial Code.* Regular inspection and supervision of movement of domestic horses and other equines should be made in the free zone to ensure freedom from AHS.

If an AHS free country or zone imports domestic horses or other equines from an infected country or infected zone, the *importing country* or zone will not be considered infected, provided that the importation has been carried out in conformity with the provisions of Article 2.5.14.8.

Article 2.5.14.4.

AHS infected zone

An infected zone shall comprise two areas:

1. a protection zone of radius of approximately 100 kilometres around an *outbreak*;
2. a surveillance zone of at least a further 50 kilometres around the protection zone and within which no vaccination programme for AHS has been carried out.

The infected zone shall be maintained for 2 years after the last *outbreak*.

The boundary between the infected zone and a free country or zone shall not be limited by national frontiers, must be clearly defined and must take account of geographical and ecological factors as well as all epizootiological factors which are relevant to this disease. The area of the zone should be extended or reduced if necessary to satisfy the following factors:

a) Epizootiology of the disease

AHS is a non-contagious disease. It can be readily transmitted by the parenteral injection of infective blood or organ emulsion. The main natural mode of transmission is by female midges of the genus *Culicoides* of which *C. imicola* appears to be the most significant vector. In areas with a temperate climate, the peak incidence of disease occurs in the late summer and early autumn. Its prevalence is directly influenced by climatic conditions favouring insect breeding and *outbreaks* are abruptly curtailed by severe frost.

b) Ecological factors

A severe frost involving 3 periods of temperature of -3°C lasting a minimum of 2-3 hours each, during a 3-week period (under study) would eliminate both adult midges and hatching larvae of *Culicoides* species in the area. During an *outbreak*, the percentage of infected midges is extremely low. Although an infected midge may harbour a relatively large amount of virus, the potential for spread of disease by this means over long distances is extremely low.

c) Geographical factors

The activity of the midge vectors is significantly reduced at high altitudes. The presence of mountain ranges at the boundary of an infected zone will provide a natural barrier to the movement of vectors. Extensive areas of arid terrain would also serve as a natural barrier.

d) The factors to be taken into account in delineating the extent of an infected zone should include:

i) the presence or otherwise of the insect vector throughout the year;

ii) the presence or absence of frost severe enough to eliminate the vector;

iii) the presence of mountain ranges or areas of arid terrain acting as a natural barrier to the movement of insect vectors.

Within and at the border of the infected zone there must be effective veterinary control of domestic horses and other equines and their transportation. The regulations must be published and rigorously implemented.

No domestic horse or other equine may be moved out of the infected zone except in conformity with the provisions of Article 2.5.14.8.

All vaccinated domestic horses or other equines in the infected zone must be clearly identified with a permanent mark at the time of vaccination.

A country or zone of a country may be restored to AHS free status if:

1. the disease has been notifiable in the whole country for at least 2 years;
2. no clinical, serological (in non-vaccinated animals) and/or epidemiological evidence of AHS has been found in the country or zone during the last 2 years;
3. no equine has been vaccinated against the disease in the country or zone during the past 12 months;
4. no equine has been imported from infected countries or zones except in conformity with the provisions of Article 2.5.14.8.;
5. a system making notifiable any mortality in equines has been in force for at least 2 years, and any dead equine has been investigated so as to confirm the absence of AHS;
6. documented evidence that all the above conditions have been fulfilled should be sent to the OIE.

Article 2.5.14.5.

Veterinary Authorities of countries shall consider whether there is a risk with regard to AHS in accepting importation or transit through their territory, from other countries, of the following *commodities*:

1. animals of the family of Equidae;

2. equine semen;
3. equine embryos.

Article 2.5.14.6.

When importing from AHS free countries or zones, *Veterinary Authorities* should require:

for domestic horses

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 2 months of export;
3. were kept in an AHS free country or zone since birth or for at least the past 2 months.

Article 2.5.14.7.

When importing from AHS free countries or zones, *Veterinary Authorities* should require:

for other equines

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 2 months of export;
3. were kept in an AHS free country or zone since birth or for at least the past 2 months;

if the animal originates from a zone or country adjacent to an infected zone or a country considered infected with AHS:

4. were kept in a *quarantine station* for 60 days prior to shipment and were subjected to the diagnostic test for AHS with negative results;
5. were protected from insect vectors during quarantine and transportation to the *place of shipment*.

Article 2.5.14.8.

When importing from countries considered infected with AHS or from AHS infected zones, *Veterinary Authorities* should require:

for domestic horses

the presentation of an *international veterinary certificate* attesting that the animals:

1. have been exported only during seasons when the insect vectors are at a low level of activity;
2. showed no clinical sign of AHS on the day of shipment;
3. were kept in a *quarantine station* for a minimum period of 40 days immediately prior to shipment;
4. have been vaccinated against AHS at least 2 months prior to export and have been clearly identified with a permanent mark; or
5. were not vaccinated and were subjected to the diagnostic test for AHS within 10 days prior to shipment with negative results; and
6. were protected from insect vectors during quarantine and transportation to the *place of shipment*.

Article 2.5.14.9.

When importing from AHS free countries or zones, *Veterinary Authorities* should require:

for semen of domestic horses

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 vaccinated against AHS within 2 months of the day of collection;
3. were kept in an AHS free country or zone for at least 40 days prior to collection.

Article 2.5.14.10.

When importing from countries considered infected with AHS or from AHS infected zones, *Veterinary Authorities* should require:

for semen of domestic horses

the presentation of an *international veterinary certificate* attesting that the donor animals:

1. were kept in a *quarantine station* for at least 40 days prior to collection of the semen;
2. were protected from insect vectors during quarantine;
3. showed no clinical sign of AHS on the day of collection and for the following 40 days;
4. have been vaccinated against AHS at least 2 months prior to the day of collection; or
5. were not vaccinated and were subjected to the diagnostic test for AHS at least 10 days after collection with negative results.

Article 2.5.14.11.

When importing from AHS free countries or zones, *Veterinary Authorities* should require:

for embryos of domestic horses

the presentation of an *international veterinary certificate* attesting that:

1. the donor females:
   a) have not been vaccinated against AHS within the 2 months prior to collection;
   b) were kept in an AHS free country or zone for at least the 40 days prior to, and at the time of, embryo collection;
2. the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.5.14.12.

When importing from countries considered infected with AHS or from AHS infected zones, *Veterinary Authorities* should require:

for embryos of domestic horses

the presentation of an *international veterinary certificate* attesting that:

1. the donor females:
   a) were kept in an insect vector-proof *quarantine station* for at least the 40 days prior to collection of the embryos;
   b) showed no clinical sign of AHS on the day of collection and for the following 40 days;
   c) have been vaccinated against AHS at least 2 months prior to collection; or
   d) have not been vaccinated against AHS and were subjected to a diagnostic test for AHS between 10 and 40 days after collection, with negative results;

2. the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

SECTION 2.6.

SWINE DISEASES

CHAPTER 2.6.1.

ATROPHIC RHINITIS OF SWINE

Article 2.6.1.1.

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

Article 2.6.1.2.

Veterinary Authorities of *importing countries* should require:

for pigs for breeding or rearing

the presentation of an *international veterinary certificate* attesting that the animals:

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

2. were kept in the *exporting country*, since birth or for the 6 months prior to shipment, in an *establishment* where no *case* of atrophic rhinitis was officially reported during the past year.

CHAPTER 2.6.2.

PORCINE BRUCELLOSIS

Article 2.6.2.1.

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

Article 2.6.2.2.

Herd free from porcine brucellosis

To qualify as free from porcine brucellosis, a herd of pigs shall satisfy the following requirements:

1. it is under *official veterinary control*;
2. it contains no animal found to be infected with porcine brucellosis during the past 3 years; all suspected *cases* are subjected to laboratory investigation;
3. all cattle kept in the same *establishment* are officially free or free from brucellosis.

Article 2.6.2.3.

Veterinary Authorities of *importing countries* should require:

for pigs for breeding or rearing

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of porcine brucellosis on the day of shipment;
2. were kept in a herd free from porcine brucellosis;
3. were subjected to a diagnostic test for porcine brucellosis with negative results during the 30 days prior to shipment.

Article 2.6.2.4.

Veterinary Authorities of *importing countries* should require:

for pigs for slaughter

the presentation of an *international veterinary certificate* attesting that the animals:

1. were kept in a herd free from porcine brucellosis; or
2. are not being eliminated as part of an eradication programme against porcine brucellosis.

Article 2.6.2.5.

Veterinary Authorities of *importing countries* should require:

for semen of pigs

the presentation of an *international veterinary certificate* attesting that:

1. the donor animals showed no clinical sign of porcine brucellosis on the day of collection of the semen;
2. the donor animals were kept in a herd free from porcine brucellosis;

3. the donor animals were subjected to a diagnostic test for porcine brucellosis with negative results during the 30 days prior to collection;
4. the semen does not contain *Brucella* agglutinins;
5. the donor animals were kept in the *exporting country*, for the 60 days prior to collection, in an *establishment* or *artificial insemination centre* where the herd is free from porcine brucellosis;
6. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.2.

CHAPTER 2.6.3.

ENTEROVIRUS ENCEPHALOMYELITIS

(previously Teschen/Talfan disease)

Article 2.6.3.1.

For the purposes of the *Terrestrial Code*, the *incubation period* for enterovirus encephalomyelitis shall be 40 days.

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

Article 2.6.3.2.

Enterovirus encephalomyelitis free country

A country may be considered free from enterovirus encephalomyelitis when it has been shown that enterovirus encephalomyelitis has not been present for at least the past 3 years.

This period shall be 6 months after the slaughter of the last affected animal for countries in which a *stamping-out policy* is practised with or without vaccination against enterovirus encephalomyelitis.

Article 2.6.3.3.

Enterovirus encephalomyelitis infected zone

A zone shall be considered as infected with enterovirus encephalomyelitis until:

1. at least 40 days have elapsed after the confirmation of the last *case* and the completion of a *stamping-out policy* and *disinfection* procedures, or
2. 6 months have elapsed after the clinical recovery or death of the last affected animal if a *stamping-out policy* was not practised.

Article 2.6.3.4.

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

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

Article 2.6.3.5.

When importing from enterovirus encephalomyelitis free countries, *Veterinary Authorities* should require:

for domestic pigs

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of enterovirus encephalomyelitis on the day of shipment;
2. were kept in a country free from enterovirus encephalomyelitis since birth or for at least the past 40 days.

Article 2.6.3.6.

When importing from enterovirus encephalomyelitis free countries, *Veterinary Authorities* should require:

for wild pigs

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of enterovirus encephalomyelitis on the day of shipment;
2. come from a country free from enterovirus encephalomyelitis;

if the country of origin has a common border with a country considered infected with enterovirus encephalomyelitis:

3. were kept in a *quarantine station* for the 40 days prior to shipment.

Article 2.6.3.7.

When importing from countries considered infected with enterovirus encephalomyelitis, *Veterinary Authorities* should require:

for domestic pigs

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of enterovirus encephalomyelitis on the day of shipment;
2. were kept since birth, or for the past 40 days, in an *establishment* where no *case* of enterovirus encephalomyelitis was officially reported during that period, and that the *establishment* of origin was not situated in an enterovirus encephalomyelitis infected zone; or
3. were kept in a *quarantine station* for the 40 days prior to shipment;
4. have not been vaccinated against enterovirus encephalomyelitis; or
5. were vaccinated against enterovirus encephalomyelitis, not less than 30 days and not more than one year prior to shipment (the nature of the vaccine used, whether inactivated or modified live virus, and the virus types and strains included shall also be stated in the certificate).

Article 2.6.3.8.

When importing from countries considered infected with enterovirus encephalomyelitis, *Veterinary Authorities* should require:

for wild pigs

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of enterovirus encephalomyelitis on the day of shipment;
2. were kept in a *quarantine station* for the 40 days prior to shipment;
3. have not been vaccinated against enterovirus encephalomyelitis; or
4. were vaccinated against enterovirus encephalomyelitis, not less than 30 days and not more than one year prior to shipment (the nature of the vaccine used, whether inactivated or modified live virus, and the virus types and strains included shall also be stated in the certificate).

Article 2.6.3.9.

When importing from enterovirus encephalomyelitis free countries, *Veterinary Authorities* should require:

for semen of pigs

the presentation of an *international veterinary certificate* attesting that the donor animals:

1. showed no clinical sign of enterovirus encephalomyelitis on the day of collection of the semen;
2. were kept in a country free from enterovirus encephalomyelitis for not less than 40 days prior to collection.

Article 2.6.3.10.

When importing from countries considered infected with enterovirus encephalomyelitis, *Veterinary Authorities* should require:

for semen of pigs

the presentation of an *international veterinary certificate* attesting that the donor animals:

1. showed no clinical sign of enterovirus encephalomyelitis on the day of collection of the semen;
2. were kept in the *exporting country*, for the 40 days prior to collection, in an *establishment* or *artificial insemination centre* where no *case* of enterovirus encephalomyelitis was officially reported during that period, and that the *establishment* or *artificial insemination centre* was not situated in an enterovirus encephalomyelitis infected zone.

Article 2.6.3.11.

When importing from enterovirus encephalomyelitis free countries, *Veterinary Authorities* should require:

for *fresh meat* of pigs

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from animals:

1. which have been kept in a country free from enterovirus encephalomyelitis since birth or for at least the past 40 days;
2. which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for enterovirus encephalomyelitis with favourable results.

Article 2.6.3.12.

When importing from countries considered infected with enterovirus encephalomyelitis, *Veterinary Authorities* should require:

for *fresh meat* of pigs

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from animals:

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

Article 2.6.3.13.

When importing from countries considered infected with enterovirus encephalomyelitis, *Veterinary Authorities* should require:

for *meat products* of pigs

the presentation of an *international veterinary certificate* attesting that:

1. the entire consignment of *meat products* comes from animals which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for enterovirus encephalomyelitis with favourable results;

2. the *meat products* have been processed to ensure the destruction of the enterovirus encephalomyelitis virus;

3. the necessary precautions were taken after processing to avoid contact of the meat with any source of enterovirus encephalomyelitis virus.

Article 2.6.3.14.

When importing from enterovirus encephalomyelitis free countries, *Veterinary Authorities* should require:

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

the presentation of an *international veterinary certificate* attesting that these products come from animals which have been kept in a country free from enterovirus encephalomyelitis since birth or for at least the past 40 days.

Article 2.6.3.15.

When importing from countries considered infected with enterovirus encephalomyelitis, *Veterinary Authorities* should require:

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

the presentation of an *international veterinary certificate* attesting that these products have been processed using heat treatment to ensure the destruction of enterovirus encephalomyelitis virus.

Article 2.6.3.16.

When importing from countries considered infected with enterovirus encephalomyelitis, *Veterinary Authorities* should require:

for bristles

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

CHAPTER 2.6.4.

TRANSMISSIBLE GASTROENTERITIS

Article 2.6.4.1.

For the purposes of the *Terrestrial Code*, the *infective period* for transmissible gastroenteritis (TGE) shall be 40 days.

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

Article 2.6.4.2.

Veterinary Authorities of *importing countries* should require:

for pigs for breeding or rearing

the presentation of an *international veterinary certificate* attesting that the animals:

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

AND EITHER

2. come from an *establishment* in which no *case* of TGE was reported during the 12 months prior to shipment;

and

3. showed negative results to a diagnostic test for TGE during the 30 days prior to shipment and were kept isolated during this period;

OR

4. come from a country in which TGE is officially notifiable and no clinical *case* has been recorded in the previous 3 years.

Article 2.6.4.3.

Veterinary Authorities of *importing countries* should require:

for pigs for slaughter

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of TGE on the day of shipment;
2. come from an *establishment* in which no *case* of TGE was officially reported during the 40 days prior to shipment.

Article 2.6.4.4.

Veterinary Authorities of *importing countries* should require:

for semen of pigs

the presentation of an *international veterinary certificate* attesting that:

1. the donor animals showed no clinical sign of TGE on the day of collection of the semen;

AND EITHER

2. the donor animals have been resident for at least 40 days on an *artificial insemination centre*, and all the pigs on this *artificial insemination centre* were free from clinical signs of TGE during the 12 months prior to collection;

and

3. for fresh semen, the donor animals were subjected to a diagnostic test for TGE with negative results during the 30 days prior to collection;

4. for frozen semen, the donor animals were subjected to a diagnostic test for TGE with negative results at least 14 days after collection;

OR

5. the donor animals have been resident since birth in a country in which TGE is officially notifiable and no clinical *case* has been recorded in the previous 3 years;

and in all situations:

6. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.2.

CHAPTER 2.6.5.

SWINE VESICULAR DISEASE

Article 2.6.5.1.

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

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

Article 2.6.5.2.

SVD free country

A country may be considered free from SVD when it has been shown that SVD has not been present for at least the past 2 years.

This period may be 9 months for countries in which a *stamping-out policy* is practised.

Article 2.6.5.3.

SVD infected zone

A zone shall be considered as infected with SVD until:

1. at least 60 days have elapsed after the confirmation of the last *case* and the completion of a *stamping-out policy* and *disinfection* procedures, or
2. 12 months have elapsed after the clinical recovery or death of the last affected animal if a *stamping-out policy* was not practised.

Article 2.6.5.4.

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

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

Article 2.6.5.5.

When importing from SVD free countries, *Veterinary Authorities* should require:

for domestic pigs

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of SVD on the day of shipment;
2. were kept in an SVD free country since birth or for at least the past 6 weeks.

Article 2.6.5.6.

When importing from SVD free countries, *Veterinary Authorities* should require:

for wild pigs

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of SVD on the day of shipment;
2. come from an SVD free country;

if the country of origin has a common border with a country considered infected with SVD:

3. were kept in a *quarantine station* for the 6 weeks prior to shipment.

Article 2.6.5.7.

When importing from countries considered infected with SVD, *Veterinary Authorities* should require:

for domestic pigs

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of SVD on the day of shipment;
2. were kept since birth, or for the past 6 weeks, in an *establishment* where no *case* of SVD was officially reported during that period, and that the *establishment* was not situated in an SVD infected zone;
3. were kept in a *quarantine station* for the 28 days prior to shipment and were subjected to the virus neutralisation test for SVD with negative results during that period.

Article 2.6.5.8.

When importing from countries considered infected with SVD, *Veterinary Authorities* should require:

for wild pigs

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of SVD on the day of shipment;
2. were kept in a *quarantine station* for the 28 days prior to shipment and were subjected to the virus neutralisation test for SVD with negative results during that period.

Article 2.6.5.9.

When importing from SVD free countries, *Veterinary Authorities* should require:

for semen of pigs

the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:
   a) showed no clinical sign of SVD on the day of collection of the semen;
   b) were kept in an SVD free country for not less than 6 weeks prior to collection;
2. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.2.

Article 2.6.5.10.

When importing from countries considered infected with SVD, *Veterinary Authorities* should require:

for semen of pigs

the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:
   a) showed no clinical sign of SVD on the day of collection of the semen and were subjected to the virus neutralisation test for SVD with negative results;
   b) were kept in the *exporting country* for the 28 days prior to collection, in an *establishment* or *artificial insemination centre* where no *case* of SVD was officially reported during that period, and that the *establishment* or *artificial insemination centre* was not situated in an SVD infected zone;
2. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.2.

Article 2.6.5.11.

When importing from SVD free countries, *Veterinary Authorities* should require:

for *fresh meat* of pigs

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from animals:

1. which have been kept in an SVD free country since birth or for at least the past 28 days;
2. which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for SVD with favourable results.

Article 2.6.5.12.

When importing from countries considered infected with SVD, *Veterinary Authorities* should require:

for *fresh meat* of pigs

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from animals:

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

Article 2.6.5.13.

When importing from countries considered infected with SVD, *Veterinary Authorities* should require:

for *meat products* of pigs

the presentation of an *international veterinary certificate* attesting that:

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

Article 2.6.5.14.

When importing from SVD free countries, *Veterinary Authorities* should require:

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

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

Article 2.6.5.15.

When importing from SVD free countries, *Veterinary Authorities* should require:

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

the presentation of an *international veterinary certificate* attesting that these products come from animals:

1. which have been kept in an SVD free country since birth or for at least the past 6 weeks;
2. which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for SVD with favourable results.

Article 2.6.5.16.

When importing from countries considered infected with SVD, *Veterinary Authorities* should require:

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

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

Article 2.6.5.17.

When importing from countries considered infected with SVD, *Veterinary Authorities* should require:

for bristles (from pigs)

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

Article 2.6.5.18.

When importing from countries considered infected with SVD, *Veterinary Authorities* should require:

for fertilisers of animal origin (from pigs)

the presentation of an *international veterinary certificate* attesting that these products:

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

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

Article 2.6.5.19.

When importing from countries considered infected with SVD, *Veterinary Authorities* should require:

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

the presentation of an *international veterinary certificate* attesting that these products:

1. have been processed to ensure the destruction of the SVD virus;
2. come from animals which have not been kept in an SVD infected zone;
3. come from animals which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for SVD with favourable results.

CHAPTER 2.6.6.

AFRICAN SWINE FEVER

Article 2.6.6.1.

For the purposes of the *Terrestrial Code*, the *infective period* for African swine fever (ASF) shall be 40 days (under study). Survivors of ASF can be carriers for life and the causative virus can be present in their excretions.

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

Article 2.6.6.2.

ASF free country

A country may be considered free from ASF when it has been shown that ASF has not been present for at least the past 3 years. Any importation of live pigs, semen, embryos/ova and animal products of pig origin shall take place in conformity with the provisions of the Articles of this Chapter.

This period shall be 12 months for countries previously infected and in which a *stamping-out policy* is practised and it has been demonstrated that the disease is absent from the domestic or wild pig population.

Article 2.6.6.3.

ASF free zone

A zone of a country may be considered free from ASF when the disease is notifiable in the whole country and when no clinical, serological or epidemiological evidence of ASF has been found in the zone during the past 3 years in domestic or wild pigs.

This period shall be 12 months for a zone previously infected, in which a *stamping-out policy* is practised and it has been demonstrated that the disease is absent from any domestic or wild pig population.

The free zone must be clearly delineated and the animal health regulations to prevent the movement of domestic or wild pigs into the free zone from an infected country or infected zone must be published and rigorously implemented, with notification to the OIE in conformity with Article 1.1.2.4. of Section 1.1. of the *Terrestrial Code*. Regular inspection and supervision of movement should be made of pigs in the free zone to ensure freedom from ASF.

Article 2.6.6.4.

ASF infected zone

A zone shall be considered as infected with ASF for 3 years after the last *outbreak*. This period shall be 12 months for zones in which a *stamping-out policy* has been practised and it has been demonstrated that the disease is absent from any domestic or wild pig population.

The boundary between the infected zone and the free zone or free country shall not be limited by national frontiers.

Article 2.6.6.5.

Veterinary Authorities of countries should consider whether there is a risk regarding ASF in accepting importation or transit through their territory, from other countries, of the following *commodities*:

1. domestic and wild pigs, particularly of the *Sus*, *Potamochoerus*, *Phacochoerus* and *Hylochoerus* genera;
2. semen of domestic and wild pigs;
3. embryos/ova of domestic and wild pigs;
4. *fresh meat* of domestic and wild pigs;
5. *meat products* of domestic and wild pigs which have not been processed to ensure the destruction of the ASF virus;
6. products of animal origin (from pigs) intended for use in animal feeding or for agricultural or industrial use which have not been processed to ensure the destruction of the ASF virus;
7. products of animal origin (from pigs) intended for pharmaceutical or surgical use which have not been processed to ensure the destruction of the ASF virus;
8. *pathological material* and biological products (from pigs) which have not been processed to ensure the destruction of the ASF virus.

Article 2.6.6.6.

When importing from ASF free countries or zones, *Veterinary Authorities* should require:

<u>for domestic pigs</u>

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of ASF on the day of shipment;
2. were kept in an ASF free country or zone since birth.

Article 2.6.6.7.

When importing from ASF free countries or zones, *Veterinary Authorities* should require:

<u>for wild pigs</u>

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of ASF on the day of shipment;
2. come from an ASF free country or zone;

if the country of origin has a common border with a country or zone considered infected with ASF:

3. were kept in a *quarantine station* for the 40 days prior to shipment;
4. were subjected to diagnostic tests for ASF with negative results.

Article 2.6.6.8.

When importing from countries considered infected with ASF, *Veterinary Authorities* should require:

<u>for domestic pigs</u>

the presentation of an *international veterinary certificate* attesting that the animals:

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

2. were kept since birth, or for the past 40 days, in an *establishment* where no *case* of ASF was officially reported during that period, that the *establishment* was situated in an ASF free zone, and that the animals which were introduced into that *establishment* did not originate from a country or zone infected with ASF;
3. were subjected to diagnostic tests for ASF with negative results.

Article 2.6.6.9.

When importing from countries considered infected with ASF, *Veterinary Authorities* should require:

for wild pigs

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of ASF on the day of shipment;
2. were kept for the 40 days prior to shipment in a *quarantine station*, where no *case* of ASF was officially reported during that period, that the *quarantine station* was situated in an ASF free zone, and that the animals which were introduced into that zone originated only from ASF free countries or zones;
3. were subjected to diagnostic tests for ASF with negative results.

Article 2.6.6.10.

When importing from ASF free zones, *Veterinary Authorities* should require:

for semen, embryos or ova of pigs

the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:
   a) showed no clinical sign of ASF on the day of collection of the semen or of the embryos/ova;
   b) were kept in an ASF free country or zone for at least the 40 days prior to collection, and originated only from ASF free countries or zones;
2. the semen, embryos or ova were collected, processed and stored in conformity with the provisions of Appendix 3.2.2. and Appendix 3.3.1., respectively.

Article 2.6.6.11.

When importing from countries considered infected with ASF, *Veterinary Authorities* should require:

for semen of pigs

the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:
   a) showed no clinical sign of ASF on the day of collection of the semen;
   b) were kept in the *exporting country* for the 40 days prior to collection, in an *establishment* or *artificial insemination centre* where no *case* of ASF was officially reported during that period, and that the *establishment* or *artificial insemination centre* was situated in an ASF free zone, and that the animals did not originate from a zone infected with ASF;
   c) were subjected to diagnostic tests for ASF with negative results;
2. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.2.

Article 2.6.6.12.

When importing from ASF free zones, *Veterinary Authorities* should require:

for *fresh meat* of pigs

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from animals:

1. which have been kept in an ASF free country or zone since birth;
2. which have been slaughtered in an *approved abattoir* situated in an ASF free country or zone and which only receives animals from an ASF free country or zone;
3. which have been subjected to ante-mortem and post-mortem inspections for ASF with favourable results.

Article 2.6.6.13.

When importing from ASF free zones, *Veterinary Authorities* should require:

for *meat products* of pigs

the presentation of an *international veterinary certificate* attesting that these products:

1. have been processed from *meat* complying with the provisions referred to in Article 2.6.6.12.;
2. have been processed in meat processing plants situated in an ASF free country or zone, and in which only meat of animals from an ASF free country or zone is processed.

Article 2.6.6.14.

When importing from countries considered infected with ASF, *Veterinary Authorities* should require:

for *meat products* of pigs

the presentation of an *international veterinary certificate* attesting that:

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

Article 2.6.6.15.

When importing from ASF free zones, *Veterinary Authorities* should require:

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

the presentation of an *international veterinary certificate* attesting that these products come from animals:

1. which have been kept in an ASF free country since birth;
2. which have been slaughtered in an *approved abattoir* situated in an ASF free country or zone and which only receives animals from an ASF free country or zone;
3. which have been subjected to ante-mortem and post-mortem inspections for ASF with favourable results.

Article 2.6.6.16.

When importing from ASF free zones, *Veterinary Authorities* should require:

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

the presentation of an *international veterinary certificate* attesting that these products come from animals:

1. which have been kept in an ASF free country since birth;

2. which have been slaughtered in an *approved abattoir* situated in an ASF free country or zone and which only receives animals from an ASF free country or zone;

3. which have been subjected to ante-mortem and post-mortem inspections for ASF with favourable results.

Article 2.6.6.17.

When importing from countries considered infected with ASF, *Veterinary Authorities* should require:

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

the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of the ASF virus in approved plants, and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASF virus.

Article 2.6.6.18.

When importing from countries considered infected with ASF, *Veterinary Authorities* should require:

for bristles (from pigs)

the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of the ASF virus in premises controlled and approved by the *Veterinary Authority* of the *exporting country*, and that the necessary precautions were taken after processing to avoid contact of the products with any source of ASF virus.

Article 2.6.6.19.

When importing from countries considered infected with ASF, *Veterinary Authorities* should require:

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

the presentation of an *international veterinary certificate* attesting that:

1. these products:

   a) have been processed to ensure the destruction of the ASF virus; or

   b) come from animals which have not been kept in a country or zone infected with ASF;

   c) come from animals which have been slaughtered in an *approved abattoir* situated in an ASF free zone and have been subjected to ante-mortem and post-mortem inspections for ASF with favourable results; and

2. the necessary precautions were taken after processing to avoid contact of the products with any source of ASF virus.

CHAPTER 2.6.7.

CLASSICAL SWINE FEVER

Article 2.6.7.1.

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 breeds and wild boar. For the purposes of this chapter, a distinction is made between domestic pigs (permanently captive and owned free-range pigs) and wild pigs (including feral pigs).

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 7-10 days, and are usually infective between post-infection days 5 and 14, but up to 3 months in cases of chronic infections.

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

Article 2.6.7.2.

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. a *risk assessment* has been conducted, identifying all potential factors for CSF occurrence and their historic perspective;
2. CSF should be notifiable in the whole country, and all clinical signs suggestive of CSF should be subjected to field and/or laboratory investigations;
3. an on-going awareness programme should be in place to encourage reporting of all *cases* suggestive of CSF;
4. the *Veterinary Authority* should have current knowledge of, and authority over, all domestic pigs in the country, *zone* or *compartment*;
5. the *Veterinary Authority* should have current knowledge about the population and habitat of wild pigs in the country or *zone.*

Article 2.6.7.3.

CSF free country, zone or compartment

1. <u>CSF free status in the absence of an outbreak</u>

   a) Historically free status

   A country, *zone* or *compartment* may be considered free from the disease after conducting a *risk assessment* as referred to in Article 2.6.7.2. but without formally applying a specific surveillance programme, if the provisions of Article 3.8.1.6. are complied with.

   b) Free status as a result of a specific surveillance programme

   A country, *zone* or *compartment* which does not meet the conditions of point 1 above may be considered free from CSF when a *risk assessment* as referred to in Article 2.6.7.2. has been conducted, surveillance in accordance with Appendix 3.8.8. has been in place for at least 12 months, and when no *outbreak* has been observed for at least 12 months.

2. CSF free status following an outbreak

A country, *zone* or *compartment* which does not meet the conditions of point a) or b) above may be considered free from CSF if surveillance in accordance with Appendix 3.8.8. has been in place and after a *risk assessment* as referred to in Article 2.6.7.2. has been conducted, and

a) where a *stamping-out policy* without vaccination is practised and no *outbreak* has been observed in domestic pigs for at least 6 months;

OR

b) where a *stamping-out policy* with vaccination is practised, and either:

i) vaccinated pigs are slaughtered, and no *outbreak* has been observed in domestic pigs for at least 6 months after the last vaccinated pig was slaughtered; or

ii) where there are validated means of distinguishing between vaccinated and infected pigs, no *outbreak* has been observed in domestic pigs for at least 6 months;

OR

c) where a vaccination strategy is practised without a *stamping-out policy*:

i) vaccination has been banned in all domestic pigs in the country, *zone* or *compartment* for at least 12 months, unless there are validated means of distinguishing between vaccinated and infected pigs;

ii) if vaccination has been practised within the past 5 years, surveillance in accordance with Appendix 3.8.8. has been in place for at least 6 months to demonstrate the absence of infection within the population of domestic pigs 6 months to one year old; and

iii) no *outbreak* has been observed in domestic pigs for at least 12 months;

AND

in all cases, based on surveillance in accordance with Appendix 3.8.8., CSF infection is not known to occur in any wild pig population in the country or *zone*.

Article 2.6.7.4.

Country free of CSF in domestic pigs but with a wild pig population

Requirements in points 2a to 2c of Article 2.6.7.3., as relevant, are complied with. As CSF infection may be present in the wild pig population, the following additional conditions are complied with:

1. a programme for the management of CSF in wild pigs is in place, taking into account the measures in place to manage the disease in the wild pig population, the presence of natural boundaries, the ecology of the wild pig population, and an assessment of the risk of disease spread;

2. zoning or compartmentalisation is applied to prevent transmission of CSF from wild pigs to domestic pigs.

Article 2.6.7.5.

Recovery of free status

Should a CSF *outbreak* occur in a free country, zone or compartment, the status of the country, *zone* or *compartment* may be restored not less than 30 days after completion of a *stamping-out policy* where surveillance in accordance with Appendix 3.8.8. has been carried out with negative results.

If emergency vaccination has been practised within the CSF domestic pig control area, recovery of the free status cannot occur before all the vaccinated pigs have been slaughtered, unless there are validated means of distinguishing between vaccinated and infected pigs.

Article 2.6.7.6.

Country or zone free of CSF in wild pigs

A country or *zone* may be considered free from CSF in wild pigs when:

1. the domestic pig population in the country or *zone* is free from CSF infection;
2. surveillance in accordance with Appendix 3.8.8. has been in place to determine the CSF status of the wild pig population in the country, and in the country or *zone*:
   a) there has been no clinical evidence, nor virological evidence of CSF in wild pigs during the past 12 months;
   b) no seropositive wild pigs have been detected in the age class 6-12 months during the past 12 months;
3. there has been no vaccination in wild pigs for the past 12 months;
4. the feeding of swill to wild pigs is forbidden, unless the swill has been treated to destroy any CSF virus that may be present, in conformity with one of the procedures referred to in Article 3.6.4.1.;
5. imported wild pigs comply with the relevant requirements set forth in the present chapter.

Article 2.6.7.7.

When importing from countries, zones or compartments free of CSF, *Veterinary Authorities* should require:

for domestic pigs

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 validated means of distinguishing between vaccinated and infected pigs.

Article 2.6.7.8.

When importing from countries free of CSF in domestic pigs but with a wild pig population, *Veterinary Authorities* should require:

for domestic pigs

the presentation of an *international veterinary certificate* attesting that the animals:

1. were kept in a country or zone free of CSF in domestic pigs since birth or for at least the past 3 months;
2. have not been vaccinated against CSF, nor are they the progeny of vaccinated sows, unless there are validated means of distinguishing between vaccinated and infected pigs;
3. come from a CSF free zone or compartment;
4. showed no clinical sign of CSF on the day of shipment.

Article 2.6.7.9.

When importing from countries or zones with CSF infection in domestic pigs, *Veterinary Authorities* should require:

for domestic pigs

the presentation of an *international veterinary certificate* attesting that the animals:

1. have not been vaccinated against CSF nor are they the progeny of vaccinated sows, unless there are validated means of distinguishing between vaccinated and infected pigs;

2. were kept since birth or for the past 3 months in a CSF free compartment;
3. showed no clinical sign of CSF on the day of shipment.

Article 2.6.7.10.

When importing from countries or zones free of CSF, *Veterinary Authorities* should require:

for wild pigs

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of CSF on the day of shipment;
2. have been captured in a country or zone free from CSF;
3. have not been vaccinated against CSF, unless there are validated means of distinguishing between vaccinated and infected pigs;

and, if the *zone* where the animal has been captured is adjacent to a *zone* with infection in wild pigs:

4. 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.

Article 2.6.7.11.

When importing from countries, zones or compartments free of CSF, *Veterinary Authorities* should require:

for semen of domestic pigs

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 Appendix 3.2.2.

Article 2.6.7.12.

When importing from countries free of CSF in domestic pigs but with a wild pig population, *Veterinary Authorities* should require:

for semen of domestic pigs

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 in domestic pigs 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;
2. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.2.

Article 2.6.7.13.

When importing from countries or *zones* considered infected with CSF in domestic pigs, *Veterinary Authorities* should require:

for semen of domestic pigs

the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:
   a) were kept in a compartment free of CSF in domestic pigs 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) have not been vaccinated against CSF, and were subjected to a serological test performed at least 21 days after collection, with negative results;
2. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.2.

Article 2.6.7.14.

When importing from countries, zones or compartments free of CSF, *Veterinary Authorities* should require:

for *in vivo* derived embryos of pigs

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 Appendix 3.3.1.

Article 2.6.7.15.

When importing from countries free of CSF in domestic pigs but with a wild pig population, *Veterinary Authorities* should require:

for *in vivo* derived embryos of pigs

the presentation of an *international veterinary certificate* attesting that:

1. the donor females:
   a) were kept in a country, zone or compartment free of CSF in domestic pigs 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;
2. the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.6.7.16.

When importing from countries or *zones* considered infected with CSF in domestic pigs, *Veterinary Authorities* should require:

for *in vivo* derived embryos of pigs

the presentation of an *international veterinary certificate* attesting that:

1. the donor females:
   a) were kept in a compartment free of CSF in domestic pigs 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) have not been vaccinated against CSF and were subjected, with negative results, to a serological test performed at least 21 days after collection;
2. the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.6.7.17.

When importing from countries, zones or compartments free of CSF, *Veterinary Authorities* should require:

for *fresh meat* of domestic pigs

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

1. have been kept in a country, zone or compartment free of CSF since birth or for at least the past 3 months;
2. have been slaughtered in an *approved abattoir*, have been subjected to ante-mortem and post-mortem inspections and have been found free of any sign suggestive of CSF.

Article 2.6.7.18.

When importing from countries or zones free of CSF in domestic pigs but with a wild pig population, *Veterinary Authorities* should require:

for *fresh meat* of domestic pigs

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

1. were kept in a country, zone or compartment free of CSF in domestic pigs since birth or for at least the past 3 months;
2. have been slaughtered in an *approved abattoir*, have been subjected to ante-mortem and post-mortem inspections and have been found free of any sign suggestive of CSF.

Article 2.6.7.19.

When importing from countries or zones free of CSF, *Veterinary Authorities* should require:

for *fresh meat* of wild pigs

the presentation of an *international veterinary certificate* attesting that:

1. the entire consignment of meat comes from animals which:
   a) have been killed in a country or zone free of CSF;
   b) have been subjected to a post-mortem inspection in an approved examination centre, and have been found free of any sign suggestive of CSF;

and, if the *zone* where the animal has been killed is adjacent to a *zone* with infection in wild pigs:

2. a sample has been collected from every animal shot, and has been subjected to a virological test and a serological test for CSF, with negative results.

Article 2.6.7.20.

Veterinary Authorities of *importing countries* should require:

for *meat products* of pigs (either domestic or wild), 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, or for trophies derived from wild pigs

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 Articles 2.6.7.17., 2.6.7.18. or 2.6.7.19., as relevant;

b) in a processing establishment:

i) approved by the *Veterinary Authority* for export purposes;

ii) processing only meat meeting the conditions laid down in Articles 2.6.7.17., 2.6.7.18. or 2.6.7.19., as relevant;

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 3.6.4.2.

Article 2.6.7.21.

Veterinary Authorities of *importing countries* should require:

for products of animal origin (from pigs, but not derived from *fresh meat*) intended for use in animal feeding and for agricultural or industrial use

the presentation of an *international veterinary certificate* attesting that the products:

1. have been prepared:

a) exclusively from products meeting the conditions laid down for *fresh meat* in Articles 2.6.7.17., 2.6.7.18. or 2.6.7.19., as relevant;

b) in a processing establishment:

i) approved by the *Veterinary Authority* for export purposes;

ii) processing only products meeting the conditions laid down in point a) above;

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 3.6.4.2.

Article 2.6.7.22.

Veterinary Authorities of *importing countries* should require:

for bristles (from pigs)

the presentation of an *international veterinary certificate* attesting that the products:

1. come from a country, zone or compartment free of CSF; 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.

Article 2.6.7.23.

Veterinary Authorities of *importing countries* should require:

for litter and manure (from pigs)

the presentation of an *international veterinary certificate* attesting that the products:

1. come from a country, zone or compartment free of CSF; 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.

SECTION 2.7.

AVIAN DISEASES

CHAPTER 2.7.1.

INFECTIOUS BURSAL DISEASE
(Gumboro disease)

Article 2.7.1.1.

For the purposes of the *Terrestrial Code*, the *incubation period* for infectious bursal disease shall be 7 days.

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

Article 2.7.1.2.

Veterinary Authorities of *importing countries* should require:

for domestic birds

the presentation of an *international veterinary certificate* attesting that the birds:

1. showed no clinical sign of infectious bursal disease on the day of shipment;
2. come from an *establishment* which is regularly inspected by the *Veterinary Authority*;
3. have not been vaccinated against infectious bursal disease and come from an *establishment* free from infectious bursal disease as demonstrated by the AGP test; or
4. were vaccinated against infectious bursal disease (the nature of the vaccine used and the date of vaccination shall also be stated in the certificate).

Article 2.7.1.3.

When importing from countries considered infected with infectious bursal disease, *Veterinary Authorities* of *importing countries* should require:

for *day-old birds*

the presentation of an *international veterinary certificate* attesting that the *day-old birds*:

1. come from *establishments* which are regularly inspected by the *Veterinary Authority* and from hatcheries which comply with the standards referred to in Appendix 3.4.1.;
2. have not been vaccinated against infectious bursal disease; or
3. were vaccinated against infectious bursal disease (the nature of the vaccine used and the date of vaccination shall also be stated in the certificate);
4. are the progeny of parent flocks which come from *establishments*:
   a) which are recognised as being free from infectious bursal disease as demonstrated by the AGP test;
   b) in which vaccination against infectious bursal disease is not practised on the parent stock; or

c) in which vaccination against infectious bursal disease is practised on the parent stock;

5. were shipped in clean and unused packages.

Article 2.7.1.4.

Veterinary Authorities of *importing countries* should require:

for *hatching eggs* of domestic birds

the presentation of an *international veterinary certificate* attesting that the *hatching eggs* :

1. have been disinfected in conformity with the standards referred to in Appendix 3.4.1.;
2. come from *establishments* which are regularly inspected by the *Veterinary Authority* and from hatcheries which comply with the standards referred to in Appendix 3.4.1.;
3. were shipped in clean and unused packages.

CHAPTER 2.7.2.

MAREK'S DISEASE

Article 2.7.2.1.

For the purposes of the *Terrestrial Code*, the *incubation period* for Marek's disease (MD) shall be 4 months.

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

Article 2.7.2.2.

Veterinary Authorities of *importing countries* should require:

for chickens

the presentation of an *international veterinary certificate* attesting that the birds:

1. showed no clinical sign of Marek's disease on the day of shipment;
2. come from an *establishment* which is regularly inspected by the *Veterinary Authority*;
3. have not been vaccinated against MD and come from an *establishment* which has been free from MD for at least the past 2 years; or
4. were vaccinated against MD (the nature of the vaccine used and the date of vaccination shall also be stated in the certificate).

Article 2.7.2.3.

Veterinary Authorities of *importing countries* should require:

for *day-old birds*

the presentation of an *international veterinary certificate* attesting that the *day-old birds*:

1. come from *establishments* which are regularly inspected by the *Veterinary Authority* and from hatcheries which comply with the standards referred to in Appendix 3.4.1.;
2. were vaccinated against MD (the nature of the vaccine used and the date of vaccination shall also be stated in the certificate);
3. were shipped in clean and unused packages.

Article 2.7.2.4.

Veterinary Authorities of *importing countries* should require:

for *hatching eggs* of chickens

the presentation of an *international veterinary certificate* attesting that the *hatching eggs*:

1. have been disinfected in conformity with the standards referred to in Appendix 3.4.1.;
2. come from *establishments* which are regularly inspected by the *Veterinary Authority* and from hatcheries which comply with the standards referred to in Appendix 3.4.1.;
3. come from *establishments* in which vaccination against MD is practised (the nature of the vaccine used and the date of vaccination shall also be stated in the certificate);
4. were shipped in clean and unused packages.

Article 2.7.2.5.

Veterinary Authorities of *importing countries* should require:

for meat-meals and feather-meals

the presentation of an *international veterinary certificate* attesting that these products have been processed using heat treatment to ensure the destruction of the MD virus.

Article 2.7.2.6.

Veterinary Authorities of *importing countries* should require:

for feathers and down

the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of the MD virus.

CHAPTER 2.7.3.

AVIAN MYCOPLASMOSIS
(*Mycoplasma gallisepticum*)

Article 2.7.3.1.

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

Article 2.7.3.2.

Establishment free from avian mycoplasmosis

To qualify as free from avian mycoplasmosis, an *establishment* shall satisfy the following requirements:

1. it is under *official veterinary control*;
2. it contains no bird which has been vaccinated against avian mycoplasmosis;
3. 5% of the birds, with a maximum of 100 birds of different age groups present in the *establishment*, are subjected to the serum-agglutination test with negative results at the age of 10, 18 and 26 weeks, and thereafter at 4-week intervals (the results of at least the last two tests carried out on adult birds should be negative);
4. all birds introduced into the flocks come from an *establishment* free from avian mycoplasmosis.

Article 2.7.3.3.

Veterinary Authorities of *importing countries* should require:

for chickens and turkeys

the presentation of an *international veterinary certificate* attesting that the birds:

1. showed no clinical sign of avian mycoplasmosis on the day of shipment;
2. come from an *establishment* free from avian mycoplasmosis; and/or
3. were kept in a *quarantine station* for the 28 days prior to shipment and were subjected to a diagnostic test for avian mycoplasmosis with negative results, on two occasions, at the beginning and at the end of the 28-day period.

Article 2.7.3.4.

Veterinary Authorities of *importing countries* should require:

for *day-old birds*

the presentation of an *international veterinary certificate* attesting that the *day-old birds*:

1. come from *establishments* free from avian mycoplasmosis and from hatcheries which comply with the standards referred to in Appendix 3.4.1.;
2. were shipped in clean and unused packages.

Article 2.7.3.5.

Veterinary Authorities of *importing countries* should require:

for *hatching eggs* of chickens and turkeys

the presentation of an *international veterinary certificate* attesting that the *hatching eggs*:

1. have been disinfected in conformity with the standards referred to in Appendix 3.4.1.;
2. come from *establishments* free from avian mycoplasmosis and from hatcheries which comply with the standards referred to in Appendix 3.4.1.;
3. were shipped in clean and unused packages.

CHAPTER 2.7.4.

AVIAN CHLAMYDIOSIS

Article 2.7.4.1.

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

Article 2.7.4.2.

Veterinary Authorities of countries free from avian chlamydiosis may prohibit importation or transit through their territory, from countries considered infected with avian chlamydiosis, of birds of the *Psittacidae* family.

Article 2.7.4.3.

Veterinary Authorities of *importing countries* should require:

for birds of the *Psittacidae* family

the presentation of an *international veterinary certificate* attesting that the birds:

1. showed no clinical sign of avian chlamydiosis on the day of shipment;
2. were kept under veterinary supervision for the 45 days prior to shipment and were treated against avian chlamydiosis using chlortetracycline.

CHAPTER 2.7.5.

FOWL TYPHOID AND PULLORUM DISEASE

Article 2.7.5.1.

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

Article 2.7.5.2.

Veterinary Authorities of *importing countries* should require:

for domestic birds

the presentation of an *international veterinary certificate* attesting that the birds:

1. showed no clinical sign of fowl typhoid and pullorum disease on the day of shipment;
2. come from *establishments* which are recognised as being free from fowl typhoid and pullorum disease; and/or
3. have been subjected to a diagnostic test for fowl typhoid and pullorum disease with negative results; and/or
4. were kept in a *quarantine station* for not less than 21 days prior to shipment.

Article 2.7.5.3.

Veterinary Authorities of *importing countries* should require:

for *day-old birds*

the presentation of an *international veterinary certificate* attesting that the *day-old birds*:

1. come from *establishments* and/or hatcheries which are recognised as being free from fowl typhoid and pullorum disease and from hatcheries which comply with the standards referred to in Appendix 3.4.1.;
2. were shipped in clean and unused packages.

Article 2.7.5.4.

Veterinary Authorities of *importing countries* should require:

for *hatching eggs* of domestic birds

the presentation of an *international veterinary certificate* attesting that the *hatching eggs* :

1. have been disinfected in conformity with the standards referred to in Appendix 3.4.1.;
2. come from *establishments* and/or hatcheries which are recognised as being free from fowl typhoid and pullorum disease and from hatcheries which comply with the standards referred to in Appendix 3.4.1.;
3. were shipped in clean and unused packages.

CHAPTER 2.7.6.

AVIAN INFECTIOUS BRONCHITIS

Article 2.7.6.1.

For the purposes of the *Terrestrial Code*, the *incubation period* for avian infectious bronchitis shall be 50 days.

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

Article 2.7.6.2.

Veterinary Authorities of *importing countries* should require:

for chickens

the presentation of an *international veterinary certificate* attesting that the birds:

1. showed no clinical sign of avian infectious bronchitis on the day of shipment;
2. come from *establishments* which are recognised as being free from avian infectious bronchitis, based on the results of serological tests;
3. have not been vaccinated against avian infectious bronchitis; or
4. were vaccinated against avian infectious bronchitis (the nature of the vaccine used and the date of vaccination shall also be stated in the certificate).

Article 2.7.6.3.

Veterinary Authorities of *importing countries* should require:

for *day-old birds*

the presentation of an *international veterinary certificate* attesting that the *day-old birds*:

1. come from *establishments* which are regularly inspected by the *Veterinary Authority* and from hatcheries which comply with the standards referred to in Appendix 3.4.1.;
2. have not been vaccinated against avian infectious bronchitis; or
3. were vaccinated against avian infectious bronchitis (the nature of the vaccine used and the date of vaccination shall also be stated in the certificate);
4. are the progeny of parent flocks which:
   a) come from *establishments* and hatcheries which are recognised as being free from avian infectious bronchitis, based on the results of serological tests;
   b) come from *establishments* in which vaccination against avian infectious bronchitis is not practised on the parent stock; or
   c) come from *establishments* in which vaccination against avian infectious bronchitis is practised on the parent stock;
5. were shipped in clean and unused packages.

Article 2.7.6.4.

Veterinary Authorities of *importing countries* should require:

for *hatching eggs* of chickens

the presentation of an *international veterinary certificate* attesting that the *hatching eggs*:

1. have been disinfected in conformity with the standards referred to in Appendix 3.4.1.;
2. come from *establishments* and/or hatcheries which are recognised as being free from avian infectious bronchitis and from hatcheries which comply with the standards referred to in Appendix 3.4.1.;
3. were shipped in clean and unused packages.

CHAPTER 2.7.7.

AVIAN INFECTIOUS LARYNGOTRACHEITIS

Article 2.7.7.1.

For the purposes of the *Terrestrial Code*, the *incubation period* for avian infectious laryngotracheitis (ILT) shall be 14 days (chronic carriers occur).

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

Article 2.7.7.2.

Veterinary Authorities of *importing countries* should require:

for chickens

the presentation of an *international veterinary certificate* attesting that the birds:

1. showed no clinical sign of ILT on the day of shipment;
2. come from *establishments* which are recognised as being free from ILT, based on the results of serological tests;
3. have not been vaccinated against ILT; or
4. were vaccinated against ILT (the nature of the vaccine used and the date of vaccination shall also be stated in the certificate).

Article 2.7.7.3.

Veterinary Authorities of *importing countries* should require:

for *day-old birds*

the presentation of an *international veterinary certificate* attesting that the *day-old birds*:

1. come from *establishments* and/or hatcheries which are regularly inspected by the *Veterinary Authority* and from hatcheries which comply with the standards referred to in Appendix 3.4.1.;
2. have not been vaccinated against ILT; or
3. were vaccinated against ILT (the nature of the vaccine used and the date of vaccination shall also be stated in the certificate);
4. are the progeny of parent flocks which:
   a) come from *establishments* and/or hatcheries which are recognised as being free from ILT, based on the results of serological tests;
   b) come from *establishments* in which vaccination against ILT is not practised on the parent stock; or
   c) come from *establishments* in which vaccination against ILT is practised on the parent stock;
5. were shipped in clean and unused packages.

Article 2.7.7.4.

Veterinary Authorities of *importing countries* should require:

for *hatching eggs* of chickens

the presentation of an *international veterinary certificate* attesting that the *hatching eggs*:

1. have been disinfected in conformity with the standards referred to in Appendix 3.4.1.;
2. come from *establishments* and/or hatcheries which are recognised as being free from ILT and from hatcheries which comply with the standards referred to in Appendix 3.4.1.;
3. were shipped in clean and unused packages.

CHAPTER 2.7.8.

AVIAN TUBERCULOSIS

Article 2.7.8.1.

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

Article 2.7.8.2.

Veterinary Authorities of *importing countries* should require:

for birds for breeding or rearing

the presentation of an *international veterinary certificate* attesting that the birds:

1. showed no clinical sign of avian tuberculosis on the day of shipment;
2. come from *establishments* which are regularly inspected by the *Veterinary Authority* and which are recognised as being free from avian tuberculosis.

Article 2.7.8.3.

Veterinary Authorities of *importing countries* should require:

for birds for slaughter

the presentation of an *international veterinary certificate* attesting that the birds:

1. showed no clinical sign of avian tuberculosis on the day of shipment;
2. come from *establishments* which are regularly inspected by the *Veterinary Authority* and are recognised as being free from avian tuberculosis; or
3. come from *establishments* in which no *case* of avian tuberculosis has been reported;
4. are not being eliminated as part of an eradication programme against avian tuberculosis.

Article 2.7.8.4.

Veterinary Authorities of *importing countries* should require:

for wild avian species destined for zoological gardens

the presentation of an *international veterinary certificate* attesting that prior to shipment, the birds showed no clinical sign of avian tuberculosis and, as far as can be determined, had not been exposed to avian tuberculosis.

Article 2.7.8.5.

Veterinary Authorities of *importing countries* should require:

for *hatching eggs*

the presentation of an *international veterinary certificate* attesting that the *hatching eggs*:

1. come from *establishments* and/or hatcheries which are regularly inspected by the *Veterinary Authority*;
2. come from *establishments* and/or hatcheries which are recognised as being free from avian tuberculosis;

3. were shipped in clean and unused packages.

CHAPTER 2.7.9.

DUCK VIRUS HEPATITIS

Article 2.7.9.1.

For the purposes of the *Terrestrial Code*, the *incubation period* for duck virus hepatitis (DVH) shall be 7 days.

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

Article 2.7.9.2.

Veterinary Authorities of *importing countries* should require:

for ducks

the presentation of an *international veterinary certificate* attesting that the birds:

1. showed no clinical sign of DVH on the day of shipment;
2. come from *establishments* which are recognised as being free from DVH;
3. have not been vaccinated against DVH; or
4. were vaccinated against DVH (the nature of the vaccine used and the date of vaccination shall also be stated in the certificate).

Article 2.7.9.3.

Veterinary Authorities of *importing countries* should require:

for day-old ducks

the presentation of an *international veterinary certificate* attesting that the *day-old birds*:

1. come from *establishments* and/or hatcheries which are regularly inspected by the *Veterinary Authority* and from hatcheries which comply with the standards referred to in Appendix 3.4.1.;
2. have not been vaccinated against DVH; or
3. were vaccinated against DVH (the nature of the vaccine used and the date of vaccination shall also be stated in the certificate);
4. are the progeny of parent flocks which:
   a) come from *establishments* and/or hatcheries which are recognised as being free from DVH;
   b) come from *establishments* and/or hatcheries in which vaccination against DVH is not practised on the parent stock; or
   c) come from *establishments* and/or hatcheries in which vaccination against DVH is practised on the parent stock;
5. were shipped in clean and unused packages.

Article 2.7.9.4.

Veterinary Authorities of *importing countries* should require:

for *hatching eggs* of ducks

the presentation of an *international veterinary certificate* attesting that the *hatching eggs*:

1. have been disinfected in conformity with the standards referred to in Appendix 3.4.1.;
2. come from *establishments* and/or hatcheries which are recognised as being free from DVH and from hatcheries which comply with the standards referred to in Appendix 3.4.1.;
3. were shipped in clean and unused packages.

CHAPTER 2.7.10.

DUCK VIRUS ENTERITIS

Article 2.7.10.1.

For the purposes of the *Terrestrial Code*, the *incubation period* for duck virus enteritis (DVE) shall be 7 days (chronic carriers occur).

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

Article 2.7.10.2.

Veterinary Authorities of *importing countries* should require:

for ducks

the presentation of an *international veterinary certificate* attesting that the birds:

1. showed no clinical sign of DVE on the day of shipment;
2. come from *establishments* which are regularly inspected by the *Veterinary Authority*;
3. come from *establishments* which are recognised as being free from DVE;
4. have not been vaccinated against DVE; or
5. were vaccinated against DVE (the nature of the vaccine used and the date of vaccination shall also be stated in the certificate).

Article 2.7.10.3.

Veterinary Authorities of *importing countries* should require:

for day-old ducks

the presentation of an *international veterinary certificate* attesting that the *day-old birds*:

1. come from *establishments* and/or hatcheries which are regularly inspected by the *Veterinary Authority*;
2. have not been vaccinated against DVE; or
3. were vaccinated against DVE (the nature of the vaccine used and the date of vaccination shall also be stated in the certificate);
4. are the progeny of parent flocks which:
   a) come from *establishments* and/or hatcheries which are recognised as being free from DVE;
   b) come from *establishments* and/or hatcheries in which vaccination against DVE is not practised on the parent stock; or
   c) come from *establishments* and/or hatcheries in which vaccination against DVE is practised on the parent stock;
5. were shipped in clean and unused packages.

Article 2.7.10.4.

Veterinary Authorities of *importing countries* should require:

for *hatching eggs* of ducks

the presentation of an *international veterinary certificate* attesting that the *hatching eggs*:

1. have been disinfected in conformity with the standards referred to in Appendix 3.4.1.;
2. come from *establishments* and/or hatcheries which are regularly inspected by the *Veterinary Authority*;
3. were shipped in clean and unused packages.

CHAPTER 2.7.11.

FOWL CHOLERA

Article 2.7.11.1.

For the purposes of the *Terrestrial Code*, the *incubation period* for fowl cholera (FC) shall be 14 days (chronic carriers occur).

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

Article 2.7.11.2.

Veterinary Authorities of *importing countries* should require:

for domestic birds

the presentation of an *international veterinary certificate* attesting that the birds:

1. showed no clinical sign of FC on the day of shipment;
2. come from *establishments* which are regularly inspected by the *Veterinary Authority*;
3. come from *establishments* which are recognised as being free from FC;
4. have not been vaccinated against FC; or
5. were vaccinated against FC (the nature of the vaccine used and the date of vaccination shall also be stated in the certificate).

Article 2.7.11.3.

Veterinary Authorities of *importing countries* should require:

for *day-old birds*

the presentation of an *international veterinary certificate* attesting that the *day-old birds*:

1. come from *establishments* and/or hatcheries which are regularly inspected by the *Veterinary Authority*;
2. have not been vaccinated against FC; or
3. were vaccinated against FC (the nature of the vaccine used and the date of vaccination shall also be stated in the certificate);
4. are the progeny of parent flocks which:
   a) come from *establishments* and/or hatcheries which are recognised as being free from FC;
   b) come from *establishments* and/or hatcheries in which vaccination against FC is not practised on the parent stock; or
   c) come from *establishments* and/or hatcheries in which vaccination against FC is practised on the parent stock;
5. were shipped in clean and unused packages.

Article 2.7.11.4.

Veterinary Authorities of *importing countries* should require:

for *hatching eggs* of domestic birds

the presentation of an *international veterinary certificate* attesting that the *hatching eggs*:

1. have been disinfected in conformity with the standards referred to in Appendix 3.4.1.;
2. come from *establishments* and/or hatcheries which are regularly inspected by the *Veterinary Authority*;
3. were shipped in clean and unused packages.

CHAPTER 2.7.12.

AVIAN INFLUENZA

Article 2.7.12.1.

1. For the purposes of *international trade*, avian influenza in its notifiable form (NAI) is defined as an infection of poultry caused by any influenza A virus of the H5 or H7 subtypes or by any AI virus with an intravenous pathogenicity index (IVPI) greater than 1.2 (or as an alternative at least 75% mortality) as described below. NAI viruses can be divided into highly pathogenic notifiable avian influenza (HPNAI) and low pathogenicity notifiable avian influenza (LPNAI):

   a) HPNAI viruses have an IVPI in 6-week-old chickens greater than 1.2 or, as an alternative, cause at least 75% mortality in 4-to 8-week-old chickens infected intravenously. H5 and H7 viruses which do not have an IVPI of greater than 1.2 or cause less than 75% mortality in an intravenous lethality test should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0); if the amino acid motif is similar to that observed for other HPNAI isolates, the isolate being tested should be considered as HPNAI;

   b) LPNAI are all influenza A viruses of H5 and H7 subtype that are not HPNAI viruses.

2. Poultry is defined as 'all domesticated birds, including backyard poultry, used for the production of meat or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds, as well as fighting cocks used for any purpose'.

   Birds that are kept in captivity for any reason other than those reasons referred to in the preceding paragraph, including those that are kept for shows, races, exhibitions, competitions, breeding or selling these categories of birds as well as pet birds, are not considered to be poultry.

3. For the purposes of *international trade*, this chapter deals not only with the occurrence of clinical signs caused by NAI virus, but also with the presence of infection with NAI virus in the absence of clinical signs.

4. For the purposes of *international trade*, a country should not impose immediate trade bans in response to a notification of infection with HPAI and LPAI virus in birds other than poultry according to Article 2.1.1.3. of the *Terrestrial Code*.

5. Antibodies to H5 or H7 subtype of NAI virus, which have been detected in poultry and are not a consequence of vaccination, have to be further investigated. In the case of isolated serological positive results, NAI infection may be ruled out on the basis of a thorough epidemiological investigation that does not demonstrate further evidence of NAI infection.

6. The following defines the occurrence of infection with NAI virus:

   a) HPNAI virus has been isolated and identified as such or viral RNA specific for HPNAI has been detected in poultry or a product derived from poultry; or

   b) LPNAI virus has been isolated and identified as such or viral RNA specific for LPNAI has been detected in poultry or a product derived from poultry.

For the purposes of the *Terrestrial Code*, 'NAI free establishment' means an *establishment* in which the poultry have shown no evidence of NAI infection, based on surveillance in accordance with Appendix 3.8.9.

For the purposes of the *Terrestrial Code*, the *incubation period* for NAI shall be 21 days.

Standards for diagnostic tests, including pathogenicity testing, are described in the *Terrestrial Manual*. Any vaccine used should comply with the standards described in the *Terrestrial Manual*.

Article 2.7.12.2.

The NAI 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 potential factors for NAI occurrence and their historic perspective;
2. NAI is notifiable in the whole country, an on-going NAI awareness programme is in place, and all notified suspect occurrences of NAI 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 poultry, and the risk posed by birds other than poultry; this may be achieved through an NAI surveillance programme in accordance with Appendix 3.8.9.

Article 2.7.12.3.

NAI free country, zone or compartment

A country, *zone* or *compartment* may be considered free from NAI when it has been shown that neither HPNAI nor LPNAI infection has been present in the country, *zone* or *compartment* for the past 12 months, based on surveillance in accordance with Appendix 3.8.9. The surveillance may need to be adapted to parts of the country or existing *zones* or *compartments* depending on historical or geographical factors, industry structure, population data, or proximity to recent outbreaks.

If infection has occurred in a previously free country, zone or compartment, NAI free status can be regained:

1. In the case of HPNAI infections, 3 months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that surveillance in accordance with Appendix 3.8.9. has been carried out during that three-month period.
2. In the case of LPNAI infections, poultry may be kept for slaughter for human consumption subject to conditions specified in Article 2.7.12.18. or 2.7.12.19. or a *stamping-out policy* may be applied; in either case, 3 months after the *disinfection* of all affected *establishments*, providing that surveillance in accordance with Appendix 3.8.9. has been carried out during that three-month period.

Article 2.7.12.4.

HPNAI free country, zone or compartment

A country, *zone* or *compartment* may be considered free from HPNAI when it has been shown that HPNAI infection has not been present in the country, *zone* or *compartment* for the past 12 months, although its LPNAI status may be unknown, or when, based on surveillance in accordance with Appendix 3.8.9., it does not meet the criteria for freedom from NAI but any NAI virus detected has not been identified as HPNAI virus. The surveillance may need to be adapted to parts of the country or existing *zones* or *compartments* depending on historical or geographical factors, industry structure, population data, or proximity to recent *outbreaks*.

If infection has occurred in a previously free country, *zone* or *compartment*, HPNAI free status can be regained 3 months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that surveillance in accordance with Appendix 3.8.9. has been carried out during that three-month period.

Article 2.7.12.5.

When importing from an NAI free country, zone or compartment, *Veterinary Authorities* should require:

<u>for live poultry (other than day-old poultry)</u>

the presentation of an *international veterinary certificate* attesting that:

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

2. the poultry were kept in an NAI free country, zone or compartment since they were hatched or for at least the past 21 days;
3. the required surveillance, in accordance with Appendix 3.8.9., has been carried out on the *establishment* within at least the past 21 days;
4. if vaccinated, the poultry have been vaccinated in accordance with Appendix 3.8.9., and the relevant information is attached.

Article 2.7.12.6.

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Authorities* should require:

for live birds other than poultry

the presentation of an *international veterinary certificate* attesting that:

1. the birds showed no clinical sign of infection with a virus which would be considered NAI in poultry on the day of shipment;
2. the birds were kept in isolation approved by the *Veterinary Services* since they were hatched or for at least the 21 days prior to shipment and showed no clinical sign of infection with a virus which would be considered NAI in poultry during the isolation period;
3. the birds were subjected to a diagnostic test 7 to 14 days prior to shipment to demonstrate freedom from infection with a virus which would be considered NAI in poultry;
4. the birds are transported in new containers.

If the birds have been vaccinated, the relevant information should be attached to the certificate.

Article 2.7.12.7.

When importing from an NAI free country, zone or compartment, *Veterinary Authorities* should require:

for day-old live poultry

the presentation of an *international veterinary certificate* attesting that:

1. the poultry were kept in an NAI free country, zone or compartment since they were hatched;
2. the poultry were derived from parent flocks which had been kept in an NAI free country, zone or compartment for at least 21 days prior to and at the time of the collection of the eggs;
3. if the poultry or the parent flocks were vaccinated, vaccination was carried out in accordance with Appendix 3.8.9., and the relevant information is attached.

Article 2.7.12.8.

When importing from an HPNAI free country, zone or compartment, *Veterinary Authorities* should require:

for day-old live poultry

the presentation of an *international veterinary certificate* attesting that:

1. the poultry were kept in an HPNAI free country, zone or compartment since they were hatched;
2. the poultry were derived from parent flocks which had been kept in an NAI free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;
3. the poultry are transported in new containers;
4. if the poultry or the parent flocks were vaccinated, vaccination was carried out in accordance with Appendix 3.8.9., and the relevant information is attached.

Article 2.7.12.9.

When importing from an NAI free country, zone or compartment, *Veterinary Authorities* should require:

for *hatching eggs*

the presentation of an *international veterinary certificate* attesting that:

1. the eggs came from an NAI free country, zone or compartment;
2. the eggs were derived from parent flocks which had been kept in an NAI free country, zone or compartment for at least 21 days prior to and at the time of the collection of the eggs;
3. if the parent flocks were vaccinated, vaccination was carried out in accordance with Appendix 3.8.9., and the relevant information is attached.

Article 2.7.12.10.

When importing from an HPNAI free country, zone or compartment, *Veterinary Authorities* should require:

for *hatching eggs*

the presentation of an *international veterinary certificate* attesting that:

1. the eggs came from an HPNAI free country, zone or compartment;
2. the eggs were derived from parent flocks which had been kept in an NAI free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;
3. the eggs have had their surfaces sanitised (in accordance with Article 3.4.1.7) and are transported in new packing material;
4. if the parent flocks were vaccinated, vaccination was carried out in accordance with Appendix 3.8.9., and the relevant information is attached.

Article 2.7.12.11.

When importing from an NAI free country, zone or compartment, *Veterinary Authorities* should require:

for eggs for human consumption

the presentation of an *international veterinary certificate* attesting that the eggs come from an NAI free country, zone or compartment.

Article 2.7.12.12.

When importing from an HPNAI free country, zone or compartment, *Veterinary Authorities* should require:

for eggs for human consumption

the presentation of an *international veterinary certificate* attesting that the eggs:

1. come from an HPNAI free country, zone or compartment;
2. have had their surfaces sanitised (in accordance with Article 3.4.1.7.) and are transported in new packing material.

Article 2.7.12.13.

When importing from an NAI free country, zone or compartment, *Veterinary Authorities* should require:

for egg products

the presentation of an *international veterinary certificate* attesting that the egg products come from, and were processed in, an NAI free country, zone or compartment.

Article 2.7.12.14.

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Authorities* should require:

for egg products

the presentation of an *international veterinary certificate* attesting that:

1. the egg products are derived from eggs which meet the requirements of Articles 2.7.12.9., 2.7.12.10., 2.7.12.11. or 2.7.12.12.; or
2. the egg products were processed to ensure the destruction of NAI virus in accordance with Appendix 3.6.5.;
3. the necessary precautions were taken after processing to avoid contact of the *commodity* with any source of NAI virus.

Article 2.7.12.15.

When importing from an NAI free country, zone or compartment, *Veterinary Authorities* should require:

for poultry semen

the presentation of an *international veterinary certificate* attesting that the donor poultry:

1. showed no clinical sign of NAI on the day of semen collection;
2. were kept in an NAI free country, zone or compartment for at least the 21 days prior to and at the time of semen collection.

Article 2.7.12.16.

When importing from an HPNAI free country, zone or compartment, *Veterinary Authorities* should require:

for poultry semen

the presentation of an *international veterinary certificate* attesting that the donor poultry:

1. showed no clinical sign of HPNAI on the day of semen collection;
2. were kept in an HPNAI free country, zone or compartment for at least the 21 days prior to and at the time of semen collection.

Article 2.7.12.17.

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Authorities* should require:

for semen of birds other than poultry

the presentation of an *international veterinary certificate* attesting that the donor birds:

1. were kept in isolation approved by the *Veterinary Services* for at least the 21 days prior to semen collection;
2. showed no clinical sign of infection with a virus which would be considered NAI in poultry during the isolation period;
3. were tested between 7 and 14 days prior to semen collection and shown to be free of NAI infection.

Article 2.7.12.18.

When importing from an NAI free country, zone or compartment, *Veterinary Authorities* should require:

for *fresh meat* of poultry

the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat* comes from birds:

1. which have been kept in an NAI free country, zone or compartment since they were hatched or for at least the past 21 days;
2. which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for NAI with favourable results.

Article 2.7.12.19.

When importing from an HPNAI free country, zone or compartment, *Veterinary Authorities* should require:

for *fresh meat* of poultry

the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat* comes from birds:

1. which have been kept in an HPNAI free country, zone or compartment since they were hatched or for at least the past 21 days;
2. which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for NAI with favourable results.

Article 2.7.12.20.

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Authorities* should require:

for *meat products* of poultry

the presentation of an *international veterinary certificate* attesting that:

1. the *commodity* is derived from *fresh meat* which meet the requirements of Articles 2.7.12.18. or 2.7.12.19.; or
2. the *commodity* has been processed to ensure the destruction of avian influenza virus in accordance with Appendix 3.6.5.;
3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 2.7.12.21.

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Authorities* should require:

for products of poultry origin intended for use in animal feeding, or for agricultural or industrial use

the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* come from poultry which have been kept in an NAI free country, zone or compartment since they were hatched or for at least the past 21 days; or
2. these *commodities* have been processed to ensure the destruction of avian influenza virus (under study);
3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 2.7.12.22.

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Authorities* should require:

for feathers and down (from poultry)

the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* come from poultry which have been kept in an NAI free country, zone or compartment since they were hatched or for at least the past 21 days; or
2. these *commodities* have been processed to ensure the destruction of avian influenza virus (under study);
3. the necessary precautions were taken to avoid contact of the *commodity* with any source of avian influenza virus.

Article 2.7.12.23.

Regardless of the NAI status of the country, *zone* or *compartment*, *Veterinary Authorities* should require for the importation of:

meat or other products from birds other than poultry

the presentation of an *international veterinary certificate* attesting that:

1. the *commodity* has been processed to ensure the destruction of avian influenza virus (under study);
2. the necessary precautions were taken after processing to avoid contact of the *commodity* with any source of NAI virus.

CHAPTER 2.7.13.

NEWCASTLE DISEASE

Article 2.7.13.1.

For the purposes of the *Terrestrial Code*, the *incubation period* for Newcastle disease (ND) shall be 21 days.

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

Article 2.7.13.2.

ND free country

A country may be considered free from ND when it has been shown that ND has not been present for at least the past 3 years.

This period shall be 6 months after the slaughter of the last affected animal for countries in which a *stamping-out policy* is practised with or without vaccination against ND.

Article 2.7.13.3.

ND infected zone

A zone shall be considered as infected with ND until:

1. at least 21 days have elapsed after the confirmation of the last *case* and the completion of a *stamping-out policy* and *disinfection* procedures; or
2. 6 months have elapsed after the clinical recovery or death of the last affected bird if a *stamping-out policy* was not practised.

Article 2.7.13.4.

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

1. domestic and wild birds;
2. *day-old birds*;
3. *hatching eggs*;
4. semen of domestic and wild birds;
5. *fresh meat* of domestic and wild birds;
6. *meat products* of domestic and wild birds which have not been processed to ensure the destruction of the ND virus;
7. products of animal origin (from birds) intended for use in animal feeding or for agricultural or industrial use.

Article 2.7.13.5.

When importing from ND free countries, *Veterinary Authorities* should require:

for domestic birds

the presentation of an *international veterinary certificate* attesting that the birds:

1. showed no clinical sign of ND on the day of shipment;
2. were kept in an ND free country since they were hatched or for at least the past 21 days;
3. have not been vaccinated against ND; or
4. were vaccinated against ND using a vaccine complying with the standards described in the *Terrestrial Manual* (the nature of the vaccine used and the date of vaccination shall also be stated in the certificate).

Article 2.7.13.6.

When importing from ND free countries, *Veterinary Authorities* should require:

for wild birds

the presentation of an *international veterinary certificate* attesting that the birds:

1. showed no clinical sign of ND on the day of shipment;
2. come from an ND free country;
3. were kept in a *quarantine station* since they were hatched or for at least the 21 days prior to shipment.

Article 2.7.13.7.

When importing from countries considered infected with ND, *Veterinary Authorities* should require:

for domestic birds

the presentation of an *international veterinary certificate* attesting that the birds:

1. showed no clinical sign of ND on the day of shipment;
2. come from an *establishment* which is regularly inspected by the *Veterinary Authority*;
3. come from an *establishment* free from ND and not situated in an ND infected zone; or
4. were kept in a *quarantine station* since they were hatched or for the 21 days prior to shipment and were subjected to a diagnostic test for ND with negative results;
5. have not been vaccinated against ND; or
6. were vaccinated against ND using a vaccine complying with the standards described in the *Terrestrial Manual* (the nature of the vaccine used and the date of vaccination shall also be stated in the certificate).

Article 2.7.13.8.

When importing from countries considered infected with ND, *Veterinary Authorities* should require:

for wild birds

the presentation of an *international veterinary certificate* attesting that the birds:

1. showed no clinical sign of ND on the day of shipment;
2. were kept in a *quarantine station* since they were hatched or for at least the 21 days prior to shipment;
3. were subjected to a diagnostic test for ND with negative results before entry into quarantine.

Article 2.7.13.9.

When importing from ND free countries, *Veterinary Authorities* should require:

for *day-old birds*

the presentation of an *international veterinary certificate* attesting that:

1. the *day-old birds* come from hatcheries situated in an ND free country;
2. neither the *day-old birds* nor their parents have been vaccinated using a modified live virus vaccine.

Article 2.7.13.10.

When importing from countries considered infected with ND, *Veterinary Authorities* should require:

for *day-old birds*

the presentation of an *international veterinary certificate* attesting that the *day-old birds*:

1. come from hatcheries which are regularly inspected by the *Veterinary Authority*;
2. come from hatcheries free from ND and not situated in an ND infected zone;
3. have not been vaccinated against ND; or
4. were vaccinated against ND using a vaccine complying with the standards described in the *Terrestrial Manual* (the nature of the vaccine used and the date of vaccination shall also be stated in the certificate).

Article 2.7.13.11.

When importing from ND free countries, *Veterinary Authorities* should require:

for *hatching eggs*

the presentation of an *international veterinary certificate* attesting that the *hatching eggs* come from *establishments* or hatcheries situated in an ND free country and which are regularly inspected by the *Veterinary Authority*.

Article 2.7.13.12.

When importing from countries considered infected with ND, *Veterinary Authorities* should require:

for *hatching eggs*

the presentation of an *international veterinary certificate* attesting that the *hatching eggs*:

1. have been disinfected in conformity with the procedures referred to in Appendix 3.4.1.;
2. come from *establishments* or hatcheries which are regularly inspected by the *Veterinary Authority*;
3. come from *establishments* or hatcheries free from ND and not situated in an ND infected zone;
4. come from *establishments* or hatcheries in which birds were not vaccinated against ND; or
5. come from *establishments* or hatcheries in which birds were vaccinated against ND (the nature of the vaccine used and the date of vaccination shall also be stated in the certificate).

Article 2.7.13.13.

When importing from ND free countries, *Veterinary Authorities* should require:

for semen of domestic and wild birds

the presentation of an *international veterinary certificate* attesting that the donor birds:

1. showed no clinical sign of ND on the day of collection of the semen;
2. were kept in an ND free country for not less than 21 days prior to collection.

Article 2.7.13.14.

When importing from countries considered infected with ND, *Veterinary Authorities* should require:

for semen of domestic and wild birds

the presentation of an *international veterinary certificate* attesting that the donor birds:

1. showed no clinical sign of ND on the day of collection of the semen;
2. had not been vaccinated using ND live virus vaccine at any time before collection;
3. were kept in the *exporting country*, in an *establishment* which was regularly inspected by the *Veterinary Authority*;
4. were kept in an *establishment* free from ND and not situated in an ND infected zone.

Article 2.7.13.15.

When importing from ND free countries, *Veterinary Authorities* should require:

for *fresh meat* of poultry

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from birds:

1. which have been kept in an ND free country since they were hatched or for at least the past 21 days;
2. which have been slaughtered in an *stamping-out policy* and have been subjected to ante-mortem and post-mortem inspections for ND with favourable results.

Article 2.7.13.16.

When importing from countries considered infected with ND, *Veterinary Authorities* should require:

for *fresh meat* of poultry

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from birds:

1. which have been kept in an *establishment* free from ND and not situated in an ND infected zone;
2. which have been slaughtered in an *stamping-out policy* not situated in an ND infected zone and have been subjected to ante-mortem and post-mortem inspections for ND with favourable results.

Article 2.7.13.17.

When importing from countries considered infected with ND, *Veterinary Authorities* should require:

for *meat products* of birds

the presentation of an *international veterinary certificate* attesting that:

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

Article 2.7.13.18.

When importing from ND free countries, *Veterinary Authorities* should require:

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

the presentation of an *international veterinary certificate* attesting that these products come from birds which have been kept in an ND free country since they were hatched or for at least the past 21 days.

Article 2.7.13.19.

When importing from countries considered infected with ND, *Veterinary Authorities* should require:

for meal and flour from meat and feather (from birds)

the presentation of an *international veterinary certificate* attesting that these products have been processed using heat treatment to ensure the destruction of the ND virus.

Article 2.7.13.20.

When importing from countries considered infected with ND, *Veterinary Authorities* should require:

for feathers and down (from birds)

the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of the ND virus.

SECTION 2.8.

LAGOMORPH DISEASES

CHAPTER 2.8.1.

MYXOMATOSIS

Article 2.8.1.1.

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

Article 2.8.1.2.

Veterinary Authorities of *importing countries* should require:

for domestic rabbits

the presentation of an *international veterinary certificate* attesting that the animals:

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

2. were kept since birth, or for the 6 months prior to shipment, in an *establishment* where no *case* of myxomatosis was officially reported during that period.

Article 2.8.1.3.

Veterinary Authorities of *importing countries* should require:

for skins and fur of domestic and wild rabbits

the presentation of an *international veterinary certificate* attesting that the skins and fur were treated (dried and tanned) to ensure the destruction of the myxomatosis virus.

CHAPTER 2.8.2.

RABBIT HAEMORRHAGIC DISEASE

Article 2.8.2.1.

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 2.8.2.2.

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 6 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 2.8.2.3.

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 6 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 6 weeks;
3. the rabbitry is properly fenced to prevent the straying of wild lagomorphs into the rabbitry.

Article 2.8.2.4.

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.

Article 2.8.2.5.

When importing from RHD free countries, *Veterinary Authorities* of *importing countries* should require:

<u>for domestic rabbits destined for breeding</u>

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 2.8.2.6.

When importing from RHD free countries, *Veterinary Authorities* of *importing countries* should require:

for day-old rabbits destined for breeding

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 2.8.2.7.

When importing from countries considered infected with RHD, *Veterinary Authorities* of *importing countries* should require:

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

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% 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 2.8.2.8.

When importing from countries considered infected with RHD, *Veterinary Authorities* of *importing countries* should require:

for day-old rabbits destined for breeding

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 2.8.2.9.

When importing from countries considered infected with RHD, *Veterinary Authorities* of *importing countries* should require:

for domestic rabbits destined for immediate slaughter

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 2.8.2.10.

When importing from countries considered infected with RHD, *Veterinary Authorities* of *importing countries* should require:

for semen

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.

Article 2.8.2.11.

When importing from countries considered infected with RHD, *Veterinary Authorities* of *importing countries* should require:

for domestic rabbit *meat*

the presentation of an *international veterinary certificate* attesting that the *meat* comes from animals which:

1. were kept in *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 2.8.2.12.

When importing from RHD free countries, *Veterinary Authorities* of *importing countries* should require:

for non-treated pelts

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 2.8.2.13.

When importing from countries considered infected with RHD, *Veterinary Authorities* of *importing countries* should require:

for pelts

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 3% concentration, or by fumigation carried out in conformity with one of the methods described in Appendix 3.4.1., not more than 7 days prior to shipment.

SECTION 2.9.

BEE DISEASES

CHAPTER 2.9.1.

ACARAPISOSIS OF HONEY BEES

Article 2.9.1.1.

For the purposes of this chapter, acarapisosis, acarine disease or tracheal mite infestation is a disease of the adult honey bee *Apis mellifera L.*, and possibly of other *Apis* species (such as *Apis cerana*). It is caused by the Tarsonemid mite *Acarapis 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 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 are described in the *Terrestrial Manual.*

Article 2.9.1.2.

The acarapisosis 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 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 the health of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the whole country.

Article 2.9.1.3.

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 2.9.1.2. but without formally applying a specific surveillance programme if the country or *zone/compartment* (under study) complies with the provisions of Appendix 3.8.1.

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 2.9.1.2. and when:

a) the *Veterinary Authority* or other competent authority with responsibility for the health 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 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 *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 2.9.1.4.

Regardless of the acarapisosis status of the *exporting country*, *Veterinary Authorities* should authorise without restriction the import or transit through their territory of the following *commodities*:

1. honey bee semen and honey bee venom;

2. used equipment associated with beekeeping;

3. honey, beeswax, honey bee-collected pollen, propolis and royal jelly.

Article 2.9.1.5.

Veterinary Authorities of *importing countries* should require:

for live queen honey bees, worker bees and drones with or without associated brood combs

the presentation of an *international veterinary certificate* attesting that the bees come from a country or *zone/compartment* (under study) free from acarapisosis.

Article 2.9.1.6.

Veterinary Authorities of *importing countries* should require:

for eggs, larvae and pupae of honey bees

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*.

CHAPTER 2.9.2.

AMERICAN FOULBROOD OF HONEY BEES

Article 2.9.2.1.

For the purposes of this Chapter, American foulbrood is a disease of the larval and pupal stages of the honey bee *Apis mellifera* and other *Apis* spp., and occurs in most countries where such bees are kept. *Paenibacillus larvae subsp. larvae*, the causative organism, is a bacterium that can produce over one billion spores in each infected larva. The spores are very long-living and extremely resistant to heat and chemical agents, and only the spores are capable of inducing the disease.

Combs of infected *apiaries* may show distinctive clinical signs which can allow the disease to be diagnosed in the field. However, subclinical infections are common and require laboratory diagnosis.

For the purposes of the *Terrestrial Code*, the *incubation period* for American foulbrood shall be 15 days (not including the wintering period which may vary according to country).

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

Article 2.9.2.2.

The American foulbrood 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 American foulbrood occurrence and their historic perspective;

2. American foulbrood should be notifiable in the whole country or *zone/compartment* (under study) and all clinical signs suggestive of American foulbrood should be subjected to field and/or laboratory investigations;

3. an on-going awareness programme should be in place to encourage reporting of all cases suggestive of American foulbrood;

4. the *Veterinary Authority* or other competent authority with responsibility for the health of honey bees should have current knowledge of, and authority over, all domesticated apiaries in the country.

Article 2.9.2.3.

Country or zone/compartment (under study) free from American foulbrood

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 2.9.2.2. but without formally applying a specific surveillance programme if the country or *zone/compartment* (under study) complies with the provisions of Appendix 3.8.1.

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 American foulbrood after conducting a *risk assessment* as referred to in Article 2.9.2.2. and when:

a) the *Veterinary Authority* or other competent authority with responsibility for the health of honey bees has current knowledge of, and authority over, all domesticated *apiaries* existing in the country or *zone/compartment* (under study);

b) American foulbrood is notifiable in the whole country or *zone /compartment* (under study), and any clinical cases suggestive of American foulbrood are subjected to field and/or laboratory investigations;

c) for the 5 years following the last reported isolation of the American foulbrood agent, 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 American foulbrood 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 the last reported isolation of the American foulbrood agent;

d) to maintain free status, an annual survey supervised by the *Veterinary Authority*, with negative results, is carried out on a representative sample of hives in the country or *zone/compartment* (under study) to indicate that there has been no new isolations; such surveys may be targeted towards areas with a higher likelihood of isolation;

e) (under study) there is no self-sustaining feral population of *A. mellifera* or other possible host species in the country or *zone/compartment* (under study);

f) all equipment associated with previously infected *apiaries* has been sterilised or destroyed;

g) 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 2.9.2.4.

Regardless of the American foulbrood status of the *exporting country*, *Veterinary Authorities* should authorise without restriction the import or transit through their territory of honey bee semen and honey bee venom.

Article 2.9.2.5.

Veterinary Authorities of *importing countries* should require:

for live queen honey bees, worker bees and drones with or without associated brood combs

the presentation of an *international veterinary certificate* attesting that the bees come from a country or *zone/compartment* (under study) officially free from American foulbrood.

Article 2.9.2.6.

Veterinary Authorities of *importing countries* should require:

for eggs, larvae and pupae of honey bees

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 been isolated from queens in a *quarantine station*.

Article 2.9.2.7.

Veterinary Authorities of *importing countries* should require:

for used equipment associated with beekeeping

the presentation of an *international veterinary certificate* attesting that the equipment was sterilised under the supervision of the *Veterinary Authority* by either immersion in 1% sodium hypochlorite for at least 30 minutes (suitable only for non-porous materials such as plastic and metal), gamma irradiation using a cobalt-60 source at a dose rate of 10 kGy, or processing to ensure the destruction of both bacillary and spore forms of *P. larvae larvae*, in conformity with one of the procedures referred to in Appendix X.X.X. (under study).

Article 2.9.2.8.

Veterinary Authorities of *importing countries* officially free from American foulbrood should require:

for honey, honey bee-collected pollen, beeswax, propolis and royal jelly

the presentation of an *international veterinary certificate* attesting that the products:

1. were collected in a country or *zone/compartment* (under study) free from American foulbrood; or
2. have been processed to ensure the destruction of both bacillary and spore forms of *P. larvae larvae*, in conformity with one of the procedures referred to in Appendix X.X.X. (under study).

CHAPTER 2.9.3.

EUROPEAN FOULBROOD OF HONEY BEES

Article 2.9.3.1.

For the purposes of this Chapter, European foulbrood is a disease of the larval and pupal stages of the honey bee *Apis mellifera* and other *Apis* spp., and occurs in most countries where such bees are kept. The causative agent is the non-sporulating bacterium *Melissococcus pluton*. Subclinical infections are common and require laboratory diagnosis. Infection remains enzootic because of mechanical contamination of the honeycombs. Recurrences of disease can therefore be expected in subsequent years.

For the purposes of the *Terrestrial Code*, the *incubation period* for European foulbrood shall be 15 days (not including the wintering period which may vary according to country).

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

Article 2.9.3.2.

The European foulbrood 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 European foulbrood occurrence and their historic perspective;
2. European foulbrood should be notifiable in the whole country or *zone/compartment* (under study) and all clinical signs suggestive of European foulbrood 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 European foulbrood;
4. the *Veterinary Authority* or other competent authority with responsibility for the health of honey bees should have current knowledge of, and authority over, all apiaries in the whole country.

Article 2.9.3.3.

Country or zone/compartment (under study) free from European foulbrood

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 2.9.3.2. but without formally applying a specific surveillance programme if the country or *zone/compartment* (under study) complies with the provisions of Appendix 3.8.1.

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 European foulbrood after conducting a *risk assessment* as referred to in Article 2.9.3.2. and when:

   a) the *Veterinary Authority* or other competent authority with responsibility for the health of honey bees has current knowledge of, and authority over, all domesticated *apiaries* existing in the country or *zone/compartment* (under study);

   b) European foulbrood is notifiable in the whole country or *zone/compartment* (under study), and any clinical cases suggestive of European foulbrood are subjected to field and laboratory investigations;

   c) for the 3 years following the last reported isolation of the European foulbrood agent, 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 European foulbrood 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 the last reported isolation of the European foulbrood agent;

d) to maintain free status, an annual survey supervised by the *Veterinary Authority*, with negative results, is carried out on a representative sample of hives in the country or *zone/compartment* (under study) to indicate that there has been no new isolations; such surveys may be targeted towards areas with a higher likelihood of isolation;

e) (under study) there is no self-sustaining feral population of *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 2.9.3.4.

Regardless of the European foulbrood status of the *exporting country*, *Veterinary Authorities* should authorise without restriction the import or transit through their territory of honey bee semen and honey bee venom.

Article 2.9.3.5.

Veterinary Authorities of *importing countries* should require:

for live queen honey bees, worker bees and drones with or without associated brood combs

the presentation of an *international veterinary certificate* attesting that the bees come from a country or *zone/compartment* (under study) free from European foulbrood.

Article 2.9.3.6.

Veterinary Authorities of *importing countries* should require:

for eggs, larvae and pupae of honey bees

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 been isolated from queens in a *quarantine station*, and all workers which accompanied the queen or a representative sample of eggs or larvae were examined for the presence of *Melissococcus pluton* by bacterial culture or PCR.

Article 2.9.3.7.

Veterinary Authorities of *importing countries* should require:

for used equipment associated with beekeeping

the presentation of an *international veterinary certificate* attesting that the equipment was sterilised under the supervision of the *Veterinary Authority* by either immersion in 0.5% sodium hypochlorite for at least 20 minutes (suitable only for non-porous materials such as plastic and metal), gamma irradiation using a cobalt-60 source at a dose rate of 10 kGy, or processing to ensure the destruction of *Melissococcus pluton*, in conformity with one of the procedures referred to in Appendix X.X.X. (under study).

Article 2.9.3.8.

Veterinary Authorities of *importing countries* should require:

for honey, honey bee-collected pollen, beeswax, propolis and royal jelly

the presentation of an *international veterinary certificate* attesting that the products:

1. were collected in a country or *zone/compartment* (under study) free from European foulbrood; or
2. have been processed to ensure the destruction of *Melissococcus pluton*, in conformity with one of the procedures referred to in Appendix X.X.X. (under study).

CHAPTER 2.9.4.

VARROOSIS OF HONEY BEES

Article 2.9.4.1.

For the purposes of this Chapter, varroosis is a disease of the honey bee *Apis mellifera* L. It is caused by the Korea and Japan haplotypes of the mite *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 mellifera* L. Early signs of infection normally go unnoticed, and only when infection is heavy does it become apparent. 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.

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 the 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.*

Article 2.9.4.2.

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 the health of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the country.

Article 2.9.4.3.

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 2.9.4.2. but without formally applying a specific surveillance programme (historical freedom) if the country or *zone/compartment* (under study) complies with the provisions of Appendix 3.8.1.

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 2.9.4.2. and when:

a) the *Veterinary Authority* or other competent authority with responsibility for the health 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 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;

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 *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 2.9.4.4.

Regardless of the varroosis status of the *exporting country*, *Veterinary Authorities* should authorise without restriction the import or transit through their territory of the following *commodities*:

1. honey bee semen, honey bee eggs and honey bee venom;
2. extracted honey and beeswax (not in the form of honeycomb).

Article 2.9.4.5.

Veterinary Authorities of *importing countries* should require:

for live queen honey bees, worker bees and drones with or without associated brood combs

the presentation of an *international veterinary certificate* attesting that the bees come from a country or *zone/compartment* (under study) officially free from varroosis.

Article 2.9.4.6.

Veterinary Authorities of *importing countries* should require:

for larvae and pupae of honey bees

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 2.9.4.7.

Veterinary Authorities of *importing countries* should require:

for used equipment associated with beekeeping

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 days prior to shipment; or
3. has been treated to ensure the destruction of *Varroa destructor*, in conformity with one of the procedures referred to in Appendix X.X.X. (under study).

Article 2.9.4.8.

Veterinary Authorities of *importing countries* should require:

for honey-bee collected pollen, beeswax (in the form of honeycomb), comb honey and propolis

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 days prior to shipment; or
3. have been treated to ensure the destruction of *Varroa destructor*, in conformity with one of the procedures referred to in Appendix X.X.X. (under study).

CHAPTER 2.9.5.

TROPILAELAPS INFESTATION OF HONEY BEES

Article 2.9.5.1.

For the purposes of this Chapter, *Tropilaelaps* infestation of the honey bee *Apis mellifera* L. is caused by the mite *Tropilaelaps clareae* and *T. koenigerum*. The mite is an ectoparasite of brood of *Apis mellifera* L., *Apis laboriosa* and *Apis dorsata*, and cannot survive for periods of more than 7 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*.

Article 2.9.5.2.

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 the health of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the country.

Article 2.9.5.3.

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 2.9.5.2. but without formally applying a specific surveillance programme if the country or *zone/compartment* (under study) complies with the provisions of Appendix 3.8.1.

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 2.9.5.2. and when:

a) the *Veterinary Authority* or other competent authority with responsibility for the health 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;

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 *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 2.9.5.4.

Regardless of the status of the *exporting country* with regard to *Tropilaelaps* infestation, *Veterinary Authorities* should authorise without restriction the import or transit through their territory of the following *commodities*:

1. honey bee semen, honey bee eggs and honey bee venom;
2. extracted honey and beeswax (not in the form of honeycomb).

Article 2.9.5.5.

Veterinary Authorities of *importing countries* should require:

for live queen honey bees, worker bees and drones with associated brood combs

the presentation of an *international veterinary certificate* attesting that the bees come from a country or *zone/compartment* (under study) officially free from *Tropilaelaps* infestation.

Article 2.9.5.6.

Veterinary Authorities of *importing countries* should require:

for live queen honey bees, worker bees and drones without associated brood combs

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 7 days.

Article 2.9.5.7.

Veterinary Authorities of *importing countries* should require:

for used equipment associated with beekeeping

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 days prior to shipment; or
3. has been treated to ensure the destruction of *Tropilaelaps* spp., in conformity with one of the procedures referred to in Appendix X.X.X. (under study).

Article 2.9.5.8.

Veterinary Authorities of *importing countries* should require:

for honey-bee collected pollen, beeswax (in the form of honeycomb), comb honey and propolis

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 days prior to shipment; or
3. have been treated to ensure the destruction of *Tropilaelaps* spp., in conformity with one of the procedures referred to in Appendix X.X.X. (under study).

SECTION 2.10.

OTHER DISEASES

CHAPTER 2.10.1.

ZOONOSES TRANSMISSIBLE FROM NON-HUMAN PRIMATES

Article 2.10.1.1.

Introduction

There are about 180 different species of non-human primates belonging to 2 suborders which are split into 12 families. The tree shrew family (previously considered as belonging to the primates) has not been included in these recommendations.

All non-human primate species are included in Appendix I or Appendix II of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) and may be transported internationally only if accompanied by the permits or certificates required under CITES.

Most imported non-human primates are destined for research, educational or breeding purposes.

Public health and safety are the primary issues of concern in the importation and keeping of non-human primates. This is especially true where close contact between humans and animals, their body fluids, faeces and tissues is likely to occur. Minimising the risk requires well-trained personnel and the following of stringent personal hygiene standards.

The risk of carrying zoonotic pathogens is related to the taxonomic position and the region of origin of the species concerned. It can be considered to increase from prosimians to marmosets and tamarins, then to other New World monkeys, to Old World monkeys and apes. The risk of carrying zoonotic agents is also greater in wild-caught non-human primates than in captive-bred animals which have been maintained in a well-defined environment under veterinary supervision. For non-human primates taken from the wild, usually only very limited health related information can be given by the supplier and by the *Veterinary Authority* of the *exporting country*.

Most diseases referred to in this Chapter are not included in the OIE List, and there is, consequently, no requirement to report them on a regular basis within the OIE animal disease reporting system. However, the requirement to report exceptional epidemiological events remains in effect.

Standards for diagnostic tests are described in the *Terrestrial Manual* (under study).

Article 2.10.1.2.

General recommendations

Veterinary Authorities of *exporting countries* should issue *international veterinary certificates* only upon presentation of valid CITES documentation.

Veterinary Authorities should make sure that the animals are individually identified by approved methods that avoid transmission of disease (see Appendix 3.4.3.).

For reasons of public health, *Veterinary Authorities* of *importing countries* should not authorise the import of non-human primates for the purpose of being kept as pets.

In the case of a non-human primate being imported directly from a country within the natural range of the animal's species concerned, and where only limited health guarantees can be given, *Veterinary Authorities* of *importing countries* should place more emphasis on quarantine procedures and less on veterinary certification. As a matter of principle, limited health guarantees given by the supplier or the *Veterinary Authority* of the country of origin should not constitute an obstacle to imports, but very strict post import quarantine requirements should be imposed. Particularly, the quarantine should meet the standards set in Appendix 3.5.1., and should be of sufficient length to minimise the risk of transmission of diseases where tests are not readily available or of limited value.

Veterinary Authorities of *importing countries* may reduce the quarantine requirements for non-human primates imported from premises with permanent veterinary supervision provided that the animals were born or have been kept for at least 2 years on these premises, are individually identified and accompanied by proper certification issued by qualified officials, and the official certification is supplemented by a complete documentation of the clinical history of each animal and its group of origin.

In cases where it is necessary to import non-human primates which are known or suspected to be carriers of a zoonotic disease, the import should not be restricted by any of these recommendations, provided that the *Veterinary Authority* of the *importing country* requires the placing of the animals in an establishment located on its territory which has been approved to receive them and which meets the standards set in Chapter 1.4.6.

Article 2.10.1.3.

General certification and transportation requirements

Veterinary Authorities of *importing countries* should require:

<u>for all non-human primates</u>

1. the presentation of an *international veterinary certificate* attesting that the animals:
   a) have been individually identified (the means of identification should be stated in the certificate); and
   b) have been examined on the day of shipment and found to be healthy, free from clinical signs of contagious disease, and fit for transport;
2. the attachment to the *international veterinary certificate* of all relevant records, including all vaccinations, tests and treatments performed during the lifetime of each primate before shipment;
3. the transport of the animals by air in accordance with the Live Animals Regulations of the International Air Transport Association or by rail or road under equivalent standards for surface transport.

Article 2.10.1.4.

Quarantine requirements for non-human primates from an uncontrolled environment

Veterinary Authorities of *importing countries* should require for shipments which originate from the wild or other sources where they were not subjected to permanent veterinary supervision:

1. the presentation of the documentation referred to in Article 2.10.1.3.;
2. the immediate placement of the animals in a *quarantine station* meeting the standards set in Chapter 1.4.6. for at least 12 weeks; and during this quarantine:
   a) all animals to be monitored daily for signs of illness and, if necessary, be subjected to a clinical examination;
   b) all animals dying for any reason to be subjected to complete post-mortem examination at a laboratory approved for this purpose;
   c) any cause of illness or death to be determinated before the group to which the animals belong is released from quarantine;

d) animals to be subjected to the following diagnostic tests and treatments in accordance with Appendix 3.4.3.:

Disease/agent	Animal groups	Schedule	Methods
Hepatitis B	Gibbons and great apes	First test during first week; second test after 3 to 4 weeks	Serological tests for anti-hepatitis B core antigen and for hepatitis B surface antigen, and additional parameters as appropriate.
Tuberculosis (*Mycobacterium hominis* and *M. bovis*)	Marmosets and tamarins Prosimians, New World monkeys, Old World monkeys, gibbons and great apes	Two tests at an interval of 2 to 4 weeks At least three tests at intervals of 2 to 4 weeks	Skin test or serology. Of the skin tests, the Mantoux test is the most reliable of all and has the advantage over others in that the size of the reaction to the test is related to the severity of infection. Skin tests in marmosets, tamarins or small prosimians should be performed in the abdominal skin rather than in the eyelid. In some species (e.g. orang utan), skin tests for tuberculosis are notorious for false positive results. Comparative tests using both mammalian and avian PPD, together with cultures, radiography and ELISA may eliminate confusion.
Other bacterial pathogens (*Salmonella*, *Shigella*, *Yersinia* and others as appropriate)	All species	Daily test for 3 days within the first 5 days after arrival, and at least one or two more tests at intervals of 2 to 4 weeks	Faecal culture. The fresh faeces or rectal swabs have to be cultured immediately or to be placed immediately in the transportation medium.
Endo- and ectoparasites	All species	At least two tests, one of which should be at the start, the other towards the end of the quarantine	Testing methods and antiparasitic treatment as appropriate to species of animal and parasitic agent.

In addition, *Veterinary Authorities* of *importing countries* should recognize the public health importance of other zoonoses such as measles, hepatitis A, monkey pox, Marburg disease or Ebola/Reston etc., even though this Article does not recommend specific testing or treatment protocols for these agents during the quarantine period. *Veterinary Authorities* should recognize that, if animals are infected, the importation and spread of many such agents will be best controlled by the detection of clinical signs of disease during the quarantine period if this is correctly implemented during a 12-week period. For some viral zoonoses, e.g. Herpes B, current diagnostic testing is not reliable, and for others, e.g. herpes viruses or retroviruses, which can be latent and relatively ubiquitous, producing life-long infections in some species, the diagnosis and exclusion of such infected animals may not be possible for the purposes of importation. Therefore, the precautions described in Article 2.10.1.7. must be strictly applied when handling such non-human primates in order to protect human health and safety.

Article 2.10.1.5.

Certification and quarantine requirements for marmosets and tamarins from premises under veterinary supervision

Veterinary Authorities of *importing countries* should require:

for marmosets and tamarins from premises under veterinary supervision

1. the presentation of an *international veterinary certificate* attesting that the shipment meets the requirements specified in Article 2.10.1.3., and that the animals:
   a) are either born in the premises of origin or have been kept there for at least 2 years;
   b) come from premises which are under permanent veterinary supervision, and where a suitable health monitoring programme is followed, including microbiological and parasitological tests as well as necropsies;
   c) have been kept in buildings and enclosures in which no *case* of tuberculosis has occurred during the last 2 years prior to shipment;
2. a description of the health monitoring programme implemented by the establishment of origin;
3. the placement of the animals in a *quarantine station* meeting the standards set in Chapter 1.4.6. for at least 30 days; and during this period:
   a) all animals to be monitored daily for signs of illness and, if necessary, be subjected to a clinical examination;
   b) all animals dying for any reason to be subjected to complete post-mortem examination at a laboratory approved for this purpose;
   c) animals to be subjected to the following diagnostic tests and treatments in accordance with Appendix 3.4.3.:

Disease/agent	Animal groups	Schedule	Methods
Bacterial pathogens (*Salmonella*, *Shigella*, *Yersinia* and others as appropriate)	All species	Daily test for 3 days within the first 5 days after arrival	Faecal culture. (See further comments in the Table of Article 2.10.1.4.)
Endo- and ectoparasites	All species	At least two tests, one of which should be at the start, the other towards the end of the quarantine	Testing methods and antiparasitic treatment as appropriate to species of animal and parasitic agent.

Veterinary Authorities of *importing countries* should not normally require any tests for viral diseases or for tuberculosis. However, stringent precautions to ensure human health and safety should be followed as recommended in Article 2.10.1.7.

Article 2.10.1.6.

Certification and quarantine requirements for other non-human primates from premises under veterinary supervision

Veterinary Authorities of *importing countries* should require:

for prosimians, New World monkeys, Old World monkeys, gibbons and great apes from premises under veterinary supervision

1. the presentation of an *international veterinary certificate* attesting that the shipment meets the requirements specified in Article 2.10.1.3., and that the animals:
   a) are either born in the premises of origin or have been kept there for at least 2 years;
   b) come from premises which are under permanent veterinary supervision, and where a suitable health monitoring programme is followed, including microbiological and parasitological tests as well as necropsies;
   c) have been kept in buildings and enclosures in which no *case* of tuberculosis has occurred during the last 2 years prior to shipment;

d) come from premises in which no *case* of tuberculosis or other zoonoses including rabies has occurred during the last 2 years prior to shipment in the building where the animals were kept;

e) were subjected to a tuberculosis test on two occasions with negative results, at an interval of at least 2 weeks between each test during the 30 days prior to shipment;

f) were subjected to a diagnostic test for pathogenic enteric bacteria including *Salmonella*, *Shigella* and *Yersinia*;

g) were subjected to diagnostic tests for, and appropriate treatment against, endo- and ectoparasites;

h) were subjected to a diagnostic test for hepatitis B virus and their current status documented (gibbons and great apes only);

2. the placement of the animals in a *quarantine station* for at least 30 days, and during this period:

a) all animals to be monitored daily for signs of illness and, if necessary, subjected to a clinical examination;

b) all animals dying for any reason to be subjected to complete post-mortem examination at a laboratory approved for this purpose;

c) any cause of illness or death to be determinated before the group to which the animals belong is released from quarantine;

d) animals to be subjected to the following diagnostic tests and treatments in accordance with Appendix 3.4.3.:

Disease/agent	Animal groups	Schedule	Methods
Tuberculosis	All species	One test	Skin test or serology. (See further comments in the Table of Article 2.10.1.4.)
Other bacterial pathogens (*Salmonella*, *Shigella*, *Yersinia* and others as appropriate)	All species	Daily test for 3 days within the first 5 days after arrival, and another test at least 1 week later	Faecal culture. (See further comments in the Table of Article 2.10.1.4.)
Endo- and ectoparasites	All species	At least two tests, one of which should be at the start, the other towards the end of the quarantine	Testing methods and antiparasitic treatment as appropriate to species of animal and parasitic agent.

Veterinary Authorities of *importing countries* should not normally require any tests for viral diseases. However, stringent precautions to ensure human health and safety should be followed as recommended in Article 2.10.1.7.

Article 2.10.1.7.

Precautionary measures to be followed by staff exposed to non-human primates or to their body fluids, faeces and tissues

The presence in most non-human primates of some zoonotic agents is almost unavoidable, even after release from quarantine. The relevant Authorities should, therefore, encourage the management of institutions whose staff are exposed to non-human primates or their body fluids, faeces or tissues (including when performing necropsies) to comply with the following guidelines:

1. to provide staff with training in the proper handling of primates, their body fluids, faeces and tissues, with respect to zoonoses containment and personal safety;

2. to inform their staff that certain species should be considered lifetime as having lifelong infections with some zoonotic agents, e.g. macaques with Herpes B virus;

3. to ensure that the staff follows personal hygiene practices, including the use of protective clothing, and the prohibition of eating, drinking and smoking in potentially infective areas;

4. to implement a screening programme for personnel health, including monitoring for tuberculosis, pathogenic enteric bacteria and endoparasites and other agents that are deemed necessary;
5. to implement an immunisation programme as appropriate, including e.g. tetanus, measles, poliomyelitis, rabies, hepatitis A and B, and other diseases endemic in the area of origin of the non-human primates;
6. to develop guidelines for the prevention and treatment of zoonoses that may be transmitted by bites and scratches, e.g. rabies and herpes viruses;
7. to issue to their staff a card which states that they work with non-human primates or with their body fluids, faeces or tissues, and which may be presented to the medical profession in case of illness;
8. to dispose of carcasses, body fluids, faeces and tissues in a manner which is not detrimental to public health.

CHAPTER 2.10.2.

SALMONELLA ENTERITIDIS AND *SALMONELLA TYPHIMURIUM* IN POULTRY

Article 2.10.2.1.

Veterinary Authorities of *importing countries* should require:

for *breeding birds*

the presentation of an *international veterinary certificate* attesting that the birds:

1. come from an *establishment* which has been regularly monitored for the presence of Salmonella in conformity with the provisions of Appendix 3.4.1. (see Article 3.4.1.9.);
2. come from a *flock of birds* within the *establishment* in which no evidence of *Salmonella enteritidis* and *Salmonella typhimurium* has been detected and have had no contact with birds or other material from poultry flocks which do not comply with this standard;
3. come from an *establishment* which complies with the hygiene and disease security procedures referred to in Appendix 3.4.1.

Article 2.10.2.2.

Veterinary Authorities of *importing countries* should require:

for *day-old birds*

the presentation of an *international veterinary certificate* attesting that the *day-old birds*:

1. showed no clinical sign of salmonellosis on the day of shipment;
2. come from an *establishment* and a hatchery which are regularly monitored for the presence of Salmonella in conformity with the provisions of Appendix 3.4.1. (see Article 3.4.1.9.);
3. come from a *flock of birds* within the *establishment* in which no evidence of *Salmonella enteritidis* or *Salmonella typhimurium* has been detected and have had no contact during setting, incubation or hatching with *hatching eggs* or other material from poultry flocks which do not comply with this standard;
4. come from an *establishment* and a hatchery which comply with the hygiene and disease security procedures referred to in Appendix 3.4.1.;
5. were shipped in clean and unused packages.

Article 2.10.2.3.

Veterinary Authorities of *importing countries* should require:

for *hatching eggs*

the presentation of an *international veterinary certificate* attesting that the *hatching eggs*:

1. come from an *establishment* which is regularly monitored for the presence of Salmonella in conformity with the provisions of Appendix 3.4.1. (see Article 3.4.1.9.);
2. come from a *flock of birds* within the *establishment* in which no evidence of *Salmonella enteritidis* or *Salmonella typhimurium* has been detected and have had no contact with *hatching eggs* or material from poultry flocks which do not comply with this standard;

3. come from an *establishment* which complies with the hygiene and disease security procedures referred to in Appendix 3.4.1.;
4. were shipped in clean and unused packages.

PART 3

APPENDICES

SECTION 3.1.

DIAGNOSTIC TESTS FOR INTERNATIONAL TRADE PURPOSES

APPENDIX 3.1.1.

PRESCRIBED AND ALTERNATIVE DIAGNOSTIC TESTS FOR OIE LISTED DISEASES

NOTE

In many of the *Terrestrial Code* chapters relating to specific diseases, the reader is referred to the *Terrestrial Manual* for information on OIE standards for the relevant diagnostic tests and vaccines.

However, some readers of the *Terrestrial Code* may need to know which diagnostic tests are recommended by the OIE for use in the *international trade* of *animals* or animal products, without requiring the details of how these tests should be performed.

The tables in this Appendix have been included to meet this need. These tables show, for each OIE *listed diseases*, the diagnostic tests which can be used when the *Terrestrial Code* recommends a testing procedure.

These tests should be performed according to the specifications in the *Terrestrial Manual*, in order to avoid any differences between the *exporting* and *importing countries* in the interpretation of results.

In the tables, the diagnostic tests have been divided into two categories - 'prescribed tests' and 'alternative tests' (a similar categorisation is made in the *Terrestrial Manual*). The 'prescribed tests' are those which are considered optimal for determining the health status of animals before shipment. 'Alternative tests' do not demonstrate the absence of infection in the tested animals with the same level of confidence as the prescribed tests do. However, the OIE Terrestrial Animal Health Standards Commission considers that an 'alternative test', chosen by mutual agreement between the *importing* and *exporting countries*, can provide valuable information for evaluating the risks of any proposed trade in *animals* or animal products. The disease for which the *Terrestrial Code* does not require any test are not included in the tables.

ABBREVIATIONS

Agent id.	Agent identification
Agg.	Agglutination test
AGID	Agar gel immunodiffusion
BBAT	Buffered *Brucella* antigen test
CF	Complement fixation (test)
DTH	Delayed-type hypersensitivity
ELISA	Enzyme-linked immunosorbent assay
FAVN	Fluorescent antibody virus neutralisation
FPA	Fluorescence polarisation assay
HI	Haemagglutination inhibition
IFA	Indirect fluorescent antibody (test)
MAT	Microscopic agglutination test
NPLA	Neutralising peroxidase-linked assay
PCR	Polymerase chain reaction
PRN	Plaque reduction neutralisation
VN	Virus neutralisation
_	No test designated yet

***Terrestrial Code* chapter No.**	***Terrestrial Manual* chapter No.**	**Disease name**	**Prescribed tests**	**Alternative tests**
		OIE listed diseases		
Multiple species				
2.2.2.	2.2.2.	Aujeszky's disease	ELISA, VN	_
2.2.4.	2.2.4.	Leptospirosis	_	MAT
2.2.5.	2.2.5.	Rabies	VN, ELISA	_
2.2.6.	2.2.6.	Paratuberculosis	_	DTH, ELISA
2.2.7.	2.2.7.	Heartwater	_	ELISA, IFA
2.2.8.	2.2.8.	New world screwworm (*Cochliomyia hominivorax*) and old world screwworm (*Chrysomya bezziana*)	_	Agent id.
2.2.9.	2.2.9.	Trichinellosis	Agent id.	ELISA
2.2.10.	2.1.1.	Foot and mouth disease	ELISA[1], VN	CF
2.2.11.	2.1.2.	Vesicular stomatitis	CF, ELISA, VN	_
2.2.12.	2.1.4.	Rinderpest	ELISA	VN
2.2.13.	2.1.9.	Bluetongue	Agent id., AGID, ELISA, PCR	VN
2.2.14.	2.1.8.	Rift Valley fever	VN	HI, ELISA
2.2.16.	2.8.2.	Tularemia	_	Agent id.
Cattle				
2.3.1.	2.3.1 .	Bovine brucellosis	BBAT, CF, ELISA, FPA	_
2.3.2.	2.3.2.	Bovine genital campylobacteriosis	Agent id.	_
2.3.3.	2.3.3.	Bovine tuberculosis	Tuberculin test	_
2.3.4.	2.3.4.	Enzootic bovine leukosis	AGID, ELISA	PCR
2.3.5.	2.3.5.	Infectious bovine rhinotracheitis / infectious pustular vulvovaginitis	VN, ELISA, Agent id. (semen only), PCR	_
2.3.6.	2.3.6.	Trichomonosis	Agent id.	Mucus agg.
2.3.7.	2.3.7.	Bovine anaplasmosis	_	CF, Agg. card
2.3.8.	2.3.8.	Bovine babesiosis	_	ELISA, IFA, CF
2.3.9.	2.3.9.	Bovine cysticercosis	_	Agent id.
2.3.11.	2.3.11.	Theileriosis	Agent id., IFA	_
2.3.12.	2.3.12.	Haemorrhagic septicaemia	_	Agent id.
2.3.14.	2.1.7.	Lumpy skin disease	_	VN

***Terrestrial Code* chapter No.**	***Terrestrial Manual* chapter No.**	**Disease name**	**Prescribed tests**	**Alternative tests**
OIE listed diseases (contd)				
2.3.15.	2.1.6.	Contagious bovine pleuropneumonia	CF, ELISA	_
Sheep and goats				
2.4.1.	2.4.1.	Ovine epididymitis (*Brucella ovis*)	CF	ELISA
2.4.2.	2.4.2.	Caprine and ovine brucellosis (excluding *Brucella ovis*)	BBAT, CF	Brucellin test, FPA
2.4.4.	2.4.4.	Caprine arthritis / encephalitis	AGID, ELISA	_
2.4.5.	2.4.5.	Maedi-visna	AGID, ELISA	_
2.4.6.	2.4.6.	Contagious caprine pleuropneumonia	CF	_
2.4.7.	2.4.7.	Enzootic abortion of ewes	_	CF
2.4.9.	2.1.5.	Peste des petits ruminants	VN	ELISA
2.4.10.	2.1.10.	Sheep pox and goat pox	_	VN
Equines				
2.5.1.	2.5.1.	Contagious equine metritis	Agent id.	_
2.5.2.	2.5.2.	Dourine	CF	IFA, ELISA
2.5.3.	2.5.3.	Equine encephalomyelitis (Eastern and Western)	_	HI, CF, PRN
2.5.4.	2.5.4.	Equine infectious anaemia	AGID	ELISA
2.5.5.	2.5.5.	Equine influenza	_	HI
2.5.6.	2.5.6.	Equine piroplasmosis	IFA, ELISA	CF
2.5.7.	2.5.7.	Equine rhinopneumonitis	_	VN
2.5.8.	2.5.8.	Glanders	Mallein test, CF	_
2.5.10.	2.5.10.	Equine viral arteritis	VN, Agent id. (semen only)	_
2.5.12.	2.5.12.	Venezuelan equine encephalomyelitis	_	HI, CF, PRN
2.5.14.	2.1.11.	African horse sickness	CF, ELISA	VN
Swine				
2.6.2.	2.6.2.	Porcine brucellosis	ELISA	BBAT, FPA
2.6.3.	2.6.3.	Enterovirus encephalomyelitis	_	VN
2.6.4.	2.6.4.	Transmissible gastroenteritis	_	VN, ELISA
2.6.5.	2.1.3.	Swine vesicular disease	VN	ELISA
2.6.6.	2.1.12.	African swine fever	ELISA	IFA

***Terrestrial Code* chapter No.**	***Terrestrial Manual* chapter No.**	**Disease name**	**Prescribed tests**	**Alternative tests**
OIE listed diseases (contd)				
2.6.7.	2.1.13.	Classical swine fever	NPLA, FAVN, ELISA	–
Birds				
2.7.1.	2.7.1.	Infectious bursal disease	–	AGID, ELISA
2.7.2.	2.7.2.	Marek's disease	–	AGID
2.7.3.	2.7.3.	Avian mycoplasmosis (*Mycoplasma gallisepticum*)	–	Agg., HI
2.7.5.	2.7.5.	Fowl typhoid and Pullorum disease	–	Agg., Agent id.
2.7.6.	2.7.6.	Avian infectious bronchitis	–	VN, HI, ELISA
2.7.7.	2.7.7.	Avian infectious laryngotracheitis	–	AGID, VN, ELISA
2.7.8.	2.7.8.	Avian tuberculosis	–	Tuberculin test, Agent id.
2.7.12.	2.1.14.	Avian influenza	–	AGID, HI
2.7.13.	2.1.15.	Newcastle disease	–	HI
Lagomorphs				
2.8.1.	2.8.1.	Myxomatosis	–	AGID, CF, IFA
2.8.2.	2.8.3.	Rabbit haemorrhagic disease	–	HI

1 Please refer to the relevant chapters in the *Terrestrial Manual* to verify which method is prescribed (this addition refers to reinstating the liquid-phase blocking ELISA as a prescribed test).

SECTION 3.2.

COLLECTION AND PROCESSING OF SEMEN

APPENDIX 3.2.1.

BOVINE AND SMALL RUMINANT SEMEN

Article 3.2.1.1.

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.

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

Article 3.2.1.2.

Conditions applicable to artificial insemination centres

1. The *artificial insemination centre* is comprised of:

   a) animal accommodation areas (including one isolation facility for sick animals) and a semen collection room, these two premises hereon designated as semen collection facilities; accommodation areas should be species specific where relevant;

   b) a semen laboratory and semen storage areas;

   c) administration offices.

   A *quarantine station* may also be attached to the centre, provided that it is on a different location from that of those two first parts.

2. The centre should be officially approved by the *Veterinary Authority*.

3. The centre should be under the supervision and control of the *Veterinary Services* which will be responsible for regular audits, at an interval of no more than 6 months, of protocols, procedures and prescribed records on the health and welfare of the animals in the centre and on the hygienic production, storage and dispatch of semen.

4. The centre should be under the direct supervision and control of a veterinarian designated by the *artificial insemination centre* and accredited by the *Veterinary Authority* for relevant official tasks.

Article 3.2.1.3.

Conditions applicable to semen collection facilities

1. The semen collection facilities should include separate and distinct areas for accommodating resident animals, for semen collection, for feed storage, for manure storage, and for the isolation of animals suspected of being infected.

2. Only animals associated with semen production should be permitted to enter the semen collection facilities. Other species of animals may be resident at the centre, if necessary for the movement or handling of the donors and teasers or for security, but contact with the donors and teasers should be minimised. All animals resident at the semen collection facilities must meet the minimum health requirements for donors.

3. The donors and teasers should be adequately isolated to prevent the transmission of diseases from farm livestock and other animals. Measures should be in place to prevent the entry of wild animals susceptible to OIE-listed ruminant diseases transmissible via semen.

4. Personnel at the centre should be technically competent and observe high standards of personal hygiene to preclude the introduction of pathogenic organisms. Special protective clothing and footwear for use only at the semen collection facilities should be provided and worn at all times inside.

5. Visitors to the semen collection facilities should be kept to a minimum, and visits should be subject to formal authorisation and control. Equipment for use with the livestock should be dedicated to the semen collection facilities or disinfected prior to entry. All equipment and tools brought on to the premises must be examined and treated if necessary to ensure that they cannot introduce disease.

6. *Vehicles* used for transport of animals to and from the semen collection facilities should not be allowed to enter the facilities.

7. The semen collection area should be cleaned daily after collection. The animals' accommodation and semen collection areas should be cleaned and disinfected at least once a year.

8. Fodder introduction and manure removal should be done in a manner which poses no significant animal health risk.

Article 3.2.1.4.

Conditions applicable to semen laboratories

1. The semen laboratory should be physically separated from the semen collection facilities, and include separate areas for artificial vagina cleaning and preparation, semen evaluation and processing, semen pre-storage and storage. Entry to the laboratory should be prohibited to unauthorised personnel.

2. The laboratory personnel should be technically competent and observe high standards of personal hygiene to preclude the introduction of pathogenic organisms during semen evaluation, processing and storage.

3. Visitors to the laboratory should be kept to a minimum, and visits should be subject to formal authorisation and control.

4. The laboratory should be constructed with materials that permit effective cleaning and *disinfection.*

5. The laboratory should be regularly cleaned. Work surfaces for semen evaluation and processing should be cleaned and disinfected at the end of each workday.

6. The laboratory should be treated against rodents and insects on a regular basis as needed to control these pests.

7. The storage rooms and individual semen containers should be easy to clean and disinfect.

8. Only semen collected from donors having a health status equivalent to or better than the donors at the semen collection facilities should be processed in the laboratory.

Article 3.2.1.5.

Conditions applicable to testing of bulls and teaser animals

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

1. Pre-quarantine

The animals should comply with the following requirements prior to entry into isolation at the *quarantine station.*

a) Bovine brucellosis

The animals should comply with point 3 or 4 of Article 2.3.1.5.

b) Bovine tuberculosis

The animals should comply with point 2, 3 or 4 of Article 2.3.3.4.

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

The animals should be subjected to the following tests:

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

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

d) Infectious bovine rhinotracheitis-infectious pustular vulvovaginitis (IBR/IPV)

If the *artificial insemination centre* is to be considered as IBR/IPV free, the animals should either:

i) come from an IBR/IPV free herd as defined in Article 2.3.5.3.; or

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

e) Bluetongue

The animals should comply with Article 2.2.13.6., 2.2.13.7. or 2.2.13.8., depending on the bluetongue status of the country of origin of the animals.

2. Testing in the quarantine station 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 *quarantine station* for at least 28 days. The animals should be subjected to diagnostic tests as described below a minimum of 21 days after entering the *quarantine station*, except for *Campylobacter fetus* subsp. *venerealis* and *Trichomonas foetus*, for which testing may commence after 7 days in quarantine. 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) All animals should be tested for viraemia as described in point 1c) above.

Only when all the animals in quarantine test negative for viraemia, may the animals enter the semen collection facilities upon completion of the 28-day quarantine period.

ii) After 21 days in quarantine, 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 *quarantine station*, 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 quarantine over a prolonged time until there is no more seroconversion in the group for a period of 3 weeks. Serologically positive animals may be allowed entry into the semen collection facilities.

c) *Campylobacter fetus* subsp. *venerealis*

i) Animals less than 6 months old or kept since that age only in a single sex group prior to quarantine should be tested once on a preputial specimen, with a negative result.

ii) Animals aged 6 months or older that could have had contact with females prior to quarantine should be tested three times at weekly intervals on a preputial specimen, with a negative result in each case.

d) *Trichomonas foetus*

i) Animals less than 6 months old or kept since that age only in a single sex group prior to quarantine, should be tested once on a preputial specimen, with a negative result.

ii) Animals aged 6 months or older that could have had contact with females prior to quarantine 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 *quarantine station* and the other animals of the same group should remain in quarantine and be retested, with negative results, not less than 21 days after removal of the positive animal.

f) Bluetongue

The animals should comply with Article 2.2.13.9., 2.2.13.10. or 2.2.13.11., depending on the bluetongue status of the country of origin of the animals.

3. 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.

4. 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 2.3.5.7.

5. 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 of origin 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 cultured.

ii) Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a lay off of more than 6 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 2.2.13.9., 2.2.13.10. or 2.2.13.11., depending on the bluetongue status of the country of origin of the animals.

f) *Trichomonas foetus*

i) A preputial specimen should be cultured.

ii) Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a lay off of more than 6 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 2.3.5.3.

Article 3.2.1.6.

Conditions applicable to testing of rams/bucks and teaser animals

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

1. Pre-quarantine

The animals should comply with the following requirements prior to entry into isolation at the *quarantine station*.

a) Caprine and ovine brucellosis

The animals should comply with Article 2.4.2.6.

b) Ovine epididymitis

The animals should comply with Article 2.4.1.3.

c) Contagious agalactia

The animals should comply with points 1 and 2 of Article 2.4.3.1.

d) Peste des petits ruminants

The animals should comply with points 1, 2, and 4 or 5 of Article 2.4.9.7.

e) Contagious caprine pleuropneumonia

The animals should comply with Article 2.4.6.5. or Article 2.4.6.7., depending on the CCPP status of the country of origin of the animals.

f) Paratuberculosis

The animals should be free from clinical signs for the past 2 years.

g) Scrapie

If the animals do not originate from a scrapie free country or zone as defined in Article 2.4.8.3., the animals should comply with points 1 and 2 of Article 2.4.8.8.

h) Maedi-visna

The animals should comply with Article 2.4.5.2.

i) Caprine arthritis/encephalitis

In the case of goats, the animals should comply with Article 2.4.4.2.

j) Bluetongue

The animals should comply with Article 2.2.13.6., 2.2.13.7. or 2.2.13.8., depending on the bluetongue status of the country of origin of the animals.

k) Tuberculosis

In the case of goats, the animals should be subject to a single or comparative tuberculin test, with negative results.

l) Border disease

The animals should be subject to a viral agent isolation test with negative results.

2. Testing in the quarantine station 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 *quarantine station* for at least 28 days. The animals should be subjected to diagnostic tests as described below a minimum of 21 days after entering the *quarantine station*, with negative results.

   a) Caprine and ovine brucellosis

      The animals should be subject to testing as described in point 1 b) or c) of Article 2.4.2.8.

   b) Ovine epididymitis

      The animals and semen should be subject to testing as described in points 1d) and 2 of Article 2.4.1.4.

   c) Maedi-visna and caprine arthritis/encephalitis

      The animals should be subjected to a serological test.

   d) Bluetongue

      The animals should comply with the provisions referred to in Article 2.2.13.9., 2.2.13.10. or 2.2.13.11., depending on the bluetongue status of the country of origin of the animals.

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 of origin 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.

Article 3.2.1.7.

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 3.2.1.8.

Conditions applicable to the management of bulls, rams and bucks

The objective is to keep the animals in a satisfactory state of cleanliness, particularly of the lower thorax and abdomen.

1. Whether on pasture or housed, the animal should be kept under hygienic conditions. If housed, the litter must be kept clean and renewed as often as necessary.

2. The coat of the animal should be kept clean.

3. For bulls, the length of the tuft of hairs at the preputial orifice, which is invariably soiled, should be cut to about 2 cm. The hair should not be removed altogether, because of its protective role. If cut too short, irritation of the preputial mucosa may result because these hairs aid the drainage of urine.

4. The animal should be brushed regularly, and where necessary on the day before semen collection, paying special attention to the underside of the abdomen.

5. In the event of obvious soiling, there should be careful cleaning, with soap or a detergent, of the preputial orifice and the adjoining areas, followed by thorough rinsing and drying.

6. When the animal is brought into the collection area, the technician must make sure that it is clean, and that it is not carrying any excessive litter or particles of feed on its body or its hooves, for such materials are always heavily contaminated.

Measures similar to the above should be adapted to rams and bucks.

Article 3.2.1.9.

Conditions applicable to the collection of semen

1. The floor of the mounting area should be easy to clean and to disinfect. A dusty floor should be avoided.
2. The hindquarters of the teaser, whether a dummy or a live teaser animal, must be kept clean. A dummy must be cleaned completely after each period of collection. A teaser animal must have its hindquarters cleaned carefully before each collecting session. The dummy or hindquarters of the teaser animal should be sanitized after the collection of each ejaculate. Disposable plastic covers may be used.
3. The hand of the person collecting the semen must 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 must be cleaned completely after each collection. 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 must be clean and should not be exposed to dust between successive collections.
6. The artificial vagina should not be shaken after ejaculation, otherwise lubricant and debris may pass down the cone to join the contents of the collecting tube.
7. When successive ejaculates are being collected, a new artificial vagina should be used for each mounting. The vagina should also be changed when the animal has inserted its penis without ejaculating.
8. The collecting tubes should be sterile, and either disposable or sterilised by autoclaving or heating in an oven at 180°C for at least 30 minutes. They should be kept sealed to prevent exposure to the environment while awaiting use.
9. After semen collection, the tube should be left attached to the cone and within its sleeve until it has been removed from the collection room for transfer to the laboratory.

Article 3.2.1.10.

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 must have been distilled or demineralised, sterilized (121°C for 30 minutes or equivalent), stored correctly and allowed to cool before use.

   d) 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 must 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: either gentamicin (250 µg), tylosin (50 µg), lincomycin-spectinomycin (150/300 µg) or penicillin (500 IU), streptomycin (500 µg), lincomycin-spectinomycin (150/300 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 these guidelines in 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 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.

1 The ICAR international standards on straws are contained in *Recording Guidelines* - Appendices to the international agreement of recording practices. Section 9, Appendix B relating to semen straw identification.

The text of this document is available at the following web site: www.icar.org

APPENDIX 3.2.2.

PORCINE SEMEN

Article 3.2.2.1.

Conditions applicable to artificial insemination centres

1. The centre should be officially approved by the *Veterinary Authority*.
2. The centre should be under the direct supervision and sanitary control of an *Official Veterinarian*.
3. The centre should be under the overall supervision of the *Veterinary Authority*, which is responsible for routine visits to check the health and welfare of animals, and the procedures and prescribed records at the centre at least every 6 months.
4. Only swine associated with semen production should be permitted to enter the centre. Other species of livestock may exceptionally be resident on the centre, provided that they are kept physically apart from the swine.
5. Swine on the centre should be adequately isolated from farm livestock on adjacent land or buildings for instance by natural or artificial means.
6. The entry of visitors should be strictly controlled. Personnel at a centre should be technically competent and observe high standards of personal hygiene to preclude the introduction of pathogenic organisms. Protective clothing and footwear for use only on the centre should be provided.
7. Individual semen containers and storage rooms should be capable of being disinfected.

Article 3.2.2.2.

Conditions applicable to the introduction of boars

1. Boars should only enter an *artificial insemination centre* if they fulfil the requirements laid down by the *Veterinary Authority*.
2. The semen from boars with genetic defects or associated with genetic defects in near relatives may not be eligible for export.
3. Boars must be clinically healthy and physiologically normal and must pass pre-entry tests within the 30 days prior to entry into isolation at an *artificial insemination centre*. The prescribed diseases and tests are listed in point 2. of Article 3.2.2.3.
4. Boars must remain in isolation at an *artificial insemination centre* for a period of at least 30 days before being retested to meet the standards listed in Article 3.2.2.3. Boars may only enter the stud on the successful completion of these tests and must be clinically healthy.

Article 3.2.2.3.

Testing programme for boars

1. Definitions

   Prescribed tests cover a minimal range of diseases from which all boars on an *artificial insemination centre* must be free.

   Routine tests are tests applied at regular intervals to confirm the continued freedom from disease of the stud.

2. Prescribed tests

   a) Bovine tuberculosis

      Boars to give negative results to intradermal tuberculin tests with mammalian tuberculin in accordance with the *Terrestrial Manual*.

   b) [1]Brucellosis (*B. abortus, B. suis*)

      Boars to give negative results to serological tests in accordance with the *Terrestrial Manual*.

3. Routine tests

   a) [1]Swine vesicular disease

      Boars to give negative results to a serum-neutralisation test in accordance with the *Terrestrial Manual* (see also Articles 2.6.5.9. and 2.6.5.10. of this *Terrestrial Code*).

      Routine tests to be applied at least every 12 months.

   b) [1]African swine fever

      Boars to give negative results to enzyme-linked immunoabsorbent assay and indirect immunofluorescent tests in accordance with the *Terrestrial Manual* (see also Articles 2.6.6.10. and 2.6.6.11. of this *Terrestrial Code*).

      Routine tests to be applied at least every 6 months.

   c) [1]Enterovirus encephalomyelitis (ex Teschen disease)

      Boars to meet certification standards in Articles 2.6.3.9. or 2.6.3.10. of this *Terrestrial Code*.

      Routine tests to be applied at least every 12 months.

Claims of country freedom from some viral and bacterial infections of swine may be given consideration providing such claims are backed by serological survey data and epidemiological investigation.

Article 3.2.2.4.

Optional tests and requirements

Artificial insemination centres may be required by the *Veterinary Authority* to include in their veterinary prophylactic programmes a number of other diseases, either through vaccination or by requiring negative results to serological tests.

Additionally, some *importing countries* may require assurances of freedom from a disease (for example: classical swine fever, Aujeszky's disease) based on negative serology or other biological tests. The range of infections to be covered is extensive and beyond the capacity of *artificial insemination centres* to support totally. Thus, only optional tests remain to be applied and interpreted by bilateral agreement when importation of semen is being considered.

Where a disease is covered by a Chapter in this *Terrestrial Code*, the testing requirements of the Chapter should be followed.

Records of the progeny of a donor boar should be maintained as far as possible to determine that he is not associated with any genetic defect. The records of the boar should indicate his fertility. The semen must be obtained from a boar with a normal libido.

Article 3.2.2.5.

Conditions applicable to diluents

Whenever milk, egg yolk or any other animal protein is used in preparing the semen diluent, the product must be free of pathogens or sterilised; milk heat-treated at 92°C for 3-5 minutes, eggs from SPF flocks when available. The inclusion of penicillin, streptomycin, polymixin etc. is permitted, provided that this is declared in the *international veterinary certificate*.

Article 3.2.2.6.

Conditions applicable to the packing and storage of semen

Semen for export should be stored separately in fresh liquid nitrogen in sterilised flasks for at least 28 days.

The examination of ejaculates, and the dilution and freezing of semen must be carried out in a laboratory maintaining the hygienic standards set by the *Veterinary Authority*. The pre-sperm fraction should not be included in material to be stored. Only semen of a health standard equivalent to that produced in an *artificial insemination centre* should be handled.

Semen straws or pellets shall be code marked in line with national standards.

Containers must be sealed before export and accompanied by an *international veterinary certificate* listing the contents.

1 In countries where the diseases marked with an asterisk have not occurred and where country freedom is claimed in accordance with the criteria set out in the relative chapter of this *Terrestrial Code*, the pre-entry/post-entry and routine tests may be dispensed with.

SECTION 3.3.

COLLECTION AND PROCESSING OF EMBRYOS/OVA

APPENDIX 3.3.1.

IN VIVO DERIVED EMBRYOS

Article 3.3.1.1.

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 3.3.1.2.

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 supervised by a team veterinarian.
2. 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.
3. The team veterinarian should be specifically approved for this purpose by an *Official Veterinarian*.
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 must 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 collection team must keep a record of its activities, which must be maintained for inspection by the approving authority for a period of at least 2 years after the embryos have been exported.
7. The collection team should be subjected to inspection at least once a year by an *Official Veterinarian* to ensure compliance with sanitary collection, processing and storage of embryos.
8. The collection team must not operate in an *infected zone* with regard to foot and mouth disease (except for the collection of *in vivo* derived bovine embryos), rinderpest, peste des petits ruminants, contagious bovine pleuropneumonia, African horse sickness, African swine fever and classical swine fever.

Article 3.3.1.3.

Conditions applicable to the processing laboratories

The 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 before freezing, storage and quarantine, pending results of diagnostic procedures.

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 laboratory should be under the direct supervision of the team veterinarian and regularly inspected by an *Official Veterinarian*.
2. While embryos for export are being handled prior to their storage in ampules, vials or straws, no embryos of a lesser health status should be processed.
3. The 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 following each occasion on which embryos are processed.
5. The laboratory must not be situated in an *infected zone* with regard to foot and mouth disease (except for the collection of *in vivo* derived bovine embryos), rinderpest, peste des petits ruminants, contagious bovine pleuropneumonia, African horse sickness, African swine fever and classical swine fever.

Article 3.3.1.4.

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 of origin of the donor animals.

   b) At the time of collection, donor animals should be clinically inspected by a veterinarian responsible to the team veterinarian and certified to be free of clinical signs of diseases not included in Category 1 of the IETS classification[1].

   c) The herd of origin must not be situated in an *infected zone* for the 30 days (60 days in the case of camelids) before and after embryo collection, with regard to foot and mouth disease (except for the collection of *in vivo* derived bovine embryos), rinderpest, peste des petits ruminants, contagious bovine pleuropneumonia, African horse sickness, African swine fever and classical swine fever.

   d) The donor animals should not have been imported from another country during the previous 60 days and should have been in the herd of origin for at least 30 days prior to collection.

2. Semen donors

   a) Semen used to inseminate donor animals artificially should have been produced and processed in accordance with the provisions of Appendix 3.2.1. or Appendix 3.2.2., as relevant.

   b) When the donor of the semen used to inseminate donor females for embryo production is no longer living, 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 subject an aliquot of semen from the same collection date to testing.

   c) Where natural service or fresh semen is used, donor sires should meet the same health requirements as donor females.

Article 3.3.1.5.

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 classification[1], comprises the 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.

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 must be washed at least ten times with at least 100-fold dilutions between each wash, and a fresh pipette for transferring the embryos through each wash.

   b) Only embryos from the same donor should be washed together.

   c) Sometimes, for example when inactivation or removal of certain virus (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, must 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 must 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 classification, encompasses the risk reductions resulting from:

   a) post-collection surveillance of the donors and donor herds 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 cryopreservation is possible) in the *exporting country*;

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

Article 3.3.1.6.

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, freezing 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 be sterilized prior to use as recommended in the IETS Manual[2].

   b) Used equipment should be transferred between countries for re-use by the embryo collection team only if cleaning and *disinfection* procedures appropriate to the disease risk concerned are followed.

Article 3.3.1.7.

Optional tests and treatments

1. The examination of embryos and collection or washing fluids can be requested by an *importing country*. Tests may be carried out on these samples to confirm the absence of pathogenic organisms, or to assess whether the degree of quality control of the collection team is at an acceptable level:

   a) Embryos/oocytes

   Where the viable, zona intact embryos are intended for export, all non-fertilized oocytes and degenerated or zona compromised embryos collected from a donor should be washed according to the IETS Manual[2] and pooled for possible testing. Only embryos/oocytes from one donor should be processed simultaneously.

   b) Collection 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 must be rinsed into the retained fluid.

   c) Washing fluids

   The last four washes of the embryos/oocytes (washes 7, 8, 9 and 10) should be pooled (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 3.3.1.5.), the procedure should be carried out according to the IETS Manual[2]. It should be noted that such enzymatic treatment is not necessarily 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 3.3.1.8.

Conditions applicable to the storage, quarantine and transport of embryos

1. Embryos should be frozen in fresh liquid nitrogen and then stored in fresh liquid nitrogen in cleaned and disinfected tanks or containers.

2. The embryos 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.

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

4. Ampoules, vials or straws must 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 must not be exported until the appropriate veterinary certification documents are completed.

Article 3.3.1.9.

Specific conditions applicable to porcine embryos

The herd of origin should be free of clinical signs of swine vesicular disease, brucellosis and pathogenic enterovirus encephalomyelitis.

[NOTE: The development of effective cryopreservation methods for zona pellucida-intact porcine embryos is still at a very early stage.]

Article 3.3.1.10.

Specific conditions applicable to ovine/caprine embryos

The herd of origin should be free of clinical signs of sheep pox, goat pox, brucellosis and bluetongue.

Article 3.3.1.11.

Specific conditions applicable to equine embryos

The recommendations apply principally to embryos from animals continuously resident in national equine populations and therefore may be found to be 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 from this condition where mutually agreed upon on a bilateral basis between the respective *Veterinary Authorities*.

Article 3.3.1.12.

Specific conditions applicable to camelid embryos

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

The herd of origin should be free of clinical signs of vesicular stomatitis, bluetongue, brucellosis and tuberculosis.

[NOTE: The development of cryopreservation methods for camelid embryos is still at a very early stage.]

Article 3.3.1.13.

Specific conditions applicable to cervid embryos

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

The herd of origin should be free of clinical signs of brucellosis and tuberculosis.

1 Based on available research and field information, the Research Subcommittee 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. Appendix 3.3.5. contains the list of IETS categorised diseases.

2 Manual of the International Embryo Transfer Society (1998).

APPENDIX 3.3.2.

IN VITRO FERTILISED BOVINE EMBRYOS/ *IN VITRO* MATURING OOCYTES

Article 3.3.2.1.

Conditions applicable to the embryo collection team

The embryo production team is a group of competent technicians, including at least one veterinarian, to perform the collection and processing of ovaries/oocytes and the production and storage of *in vitro* fertilised (IVF) embryos. The following conditions should apply:

1. The team should be supervised by a team veterinarian.
2. The team veterinarian is responsible for all team operations which include hygienic collection of ovaries and oocytes and all other procedures involved in the production of embryos intended for international movement.
3. The team veterinarian should be specifically approved for this purpose by an *official Veterinarian*.
4. Team personnel should be adequately trained in the techniques and principles of disease control. High standards of hygiene should be practised to preclude the introduction of infection.
5. The production team must have adequate facilities and equipment for:
   a) collecting oocytes;
   b) processing of oocytes and embryos;
   c) storing embryos.
6. The collection team must keep a record of its activities, which must be maintained for inspection by the approving authority for a period of at least 2 years after the embryos have been exported.
7. The production team should be subjected to regular inspection by an *Official Veterinarian* to ensure compliance with sanitary collection and processing of oocytes and production and storage of embryos.
8. The production team must not operate in an *infected zone* for foot and mouth disease and rinderpest.

Article 3.3.2.2.

Conditions applicable to the processing laboratories

The processing laboratory is a premises in which oocytes which have been recovered from ovaries are then matured and fertilised, and embryos are further cultured *in vitro*. It may be contiguous with the oocyte recovery area or may be at a separate location.

Embryos so produced may also be subjected to any required treatments such as washing before freezing, storage and quarantine in this laboratory.

Additionally:

1. The laboratory should be under the direct supervision of the team veterinarian and regularly inspected by an *Official Veterinarian*.
2. While embryos for export are being produced prior to their storage in ampules, vials or straws, no oocyte/embryo of a lesser health status should be recovered or processed in the laboratory.
3. The 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 following each occasion on which embryos are processed.

5. The laboratory must not be situated in an *infected zone* for foot and mouth disease or rinderpest.

Article 3.3.2.3.

Conditions applicable to the introduction of donor animals

Oocytes for the production of IVF embryos are obtained from donors in one of two ways: individual collection or batch collection. The recommended sanitary conditions for these differ.

Individual collection usually involves the aspiration of oocytes from the ovaries of live animals on the farm where the donor animal resides or at the laboratory. Occasionally oocytes may also be recovered from individual live donors by aspiration from surgically excised ovaries. When oocytes are recovered from individual live animals, the procedures for these donors should follow the recommendations set out in Article 3.3.1.4.

Cleaning and sterilisation of equipment is especially important and must be carried out between each donor in accordance with the requirements of the Procedures Manual of the International Embryo Transfer Society (IETS)[2].

Batch collection usually involves the removal of ovaries from slaughtered animals at an abattoir but may alternatively involve the surgical removal of ovaries from live donors; these ovaries are then transported to the laboratory where oocytes are removed by aspiration. Batch collection involving abattoir derived ovaries has the disadvantage that it is usually impractical to relate ovaries which are transported to the laboratory to the donors which were slaughtered at the abattoir. Nevertheless, it is critical to ensure that only healthy tissues are obtained and that they are removed from the donors in a hygienic manner.

Additionally:

1. The *Veterinary Authority* should have knowledge of, and authority over, the herd(s) of origin of the donor animals.
2. The donor females should not originate from an *infected zone* for foot and mouth disease or rinderpest and the removal of any tissue should not take place in an *infected zone* for foot and mouth disease or rinderpest.
3. The abattoir should be officially approved and under the supervision of a veterinarian whose responsibility it is to ensure that ante-mortem and post-mortem inspections of potential donor animals are carried out and to certify them to be free of signs of contagious diseases of concern transmissible to cattle.
4. The donor females should not have been designated for compulsory slaughter for a *notifiable disease* and other animals of a lesser health status must not be slaughtered at the same time as donors from which ovaries and other tissues will be removed.
5. Records of the identities and origins of all donors must be kept.
6. Batches of ovaries should not be transported to the processing laboratory before confirmation has been obtained that ante and post-mortem inspection of donors has been satisfactorily completed.
7. Equipment for removal and transport of ovaries and other tissues should be cleaned and sterilised before use and exclusively used for these purposes.

Article 3.3.2.4.

Testing of oocytes, embryos, semen and culture media

The main approach for ensuring IVF embryos are free of pathogenic organisms is the testing of non-viable oocytes/embryos and associated co-culture cells, fluid and media.

Tests may also be used to assess whether quality control procedures being applied in the processing laboratory are acceptable.

Tests may be carried out on the following materials to confirm the absence of pathogenic organisms which are of concern to the *importing country*:

a) non-viable oocytes/embryos: all non-viable oocytes/embryos at any stage of the production line from batches intended for export should be pooled for testing;

b) *in vitro* maturation medium prior to mixing the oocytes with semen for the fertilisation process;

c) embryo culture medium taken immediately prior to embryo storage.

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

In the case of oocyte recovery from individual animals or batch collection from live donors, monitoring of clinical health status and post collection testing of donors for diseases of concern may be considered.

Additionally:

1. Semen used to fertilise oocytes *in vitro* should meet the health requirements and standards set out in Appendix 3.2.1.

   When the donor of the semen used to fertilise the oocytes is no longer living, 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 on the spare IVF embryos may be required to verify that these infectious diseases were not transmitted. An alternative may be to subject an aliquot of semen from the same collection date to testing.

2. Any biological product of animal origin, including co-culture cells and media constituents, used in oocyte recovery, maturation, fertilisation, culture, washing and storage should be free of living pathogenic micro-organisms. Media should be sterilised 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 all fluids and media as recommended in the IETS Manual[2].

3. All equipment used to recover, handle, culture, wash, freeze and store oocytes/embryos should be cleaned and sterilised prior to use as recommended in the IETS Manual[2].

Article 3.3.2.5.

Conditions applicable to the processing, storage, quarantine and transport of embryos/ova

1. After the culture period is finished but prior to freezing, storage and transport, the embryos should be subjected to washing and other treatments similar to those specified for *in vivo* derived embryos in accordance with the IETS Manual[2].

2. Only embryos from the same donor, in the case of individual animal recovery, or from the same batch collection, should be washed together.

3. The zona pellucida of each embryo must be examined over its entire surface area at not less than 50X magnification and certified to be intact.

4. The IVF embryos should be stored in sealed sterile ampules, vials or straws and then frozen in fresh liquid nitrogen or other cryoprotectant in cleaned and sterilised containers under strict hygienic conditions at a storage place, approved by the *Veterinary Authority* of the *exporting country*, where no risk of contamination of the embryos can occur.

5. Only embryos from the same individual donor or batch collection should be stored together in the same ampule, vial or straw.

6. Ampules, vials or straws must be sealed at the time of freezing and should be labelled according to the IETS Manual[2].

7. Liquid nitrogen containers should be sealed prior to shipment from the *exporting country*.

8. Embryos must not be exported until the appropriate veterinary certification documents are completed.

Article 3.3.2.6.

Procedure for micromanipulation

When micromanipulation of the embryos is to be carried out, this should be done after completion of the treatments described in Article 3.3.2.5. and conducted in accordance with Appendix 3.3.3.

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1 Where transportation of *in vitro* maturing (IVM) oocytes is intended, the conditions outlined in this Appendix are also applicable.

2 Manual of the International Embryo Transfer Society (1998).

An up-to-date list of relevant scientific publications is available on the IETS Website Homepage at http://www.iets.uiue.edu where the link entitled 'Embryo-Pathogen Research and Reference Lists' may be visited.

APPENDIX 3.3.3.

MICROMANIPULATED BOVINE EMBRYOS

Article 3.3.3.1.

Introduction

Appendix 3.3.1. recommends official sanitary control measures for the international movement of intact, *in vivo* derived bovine embryos, and likewise Appendix 3.3.2. recommends measures for *in vitro* fertilized bovine embryos/*in vitro* maturing oocytes. Neither of those Appendices covers embryos which have been subjected to biopsy, splitting, transgene injection, intracytoplasmic sperm injection (ICSI), nuclear transplantation or other micromanipulations which breach the integrity of the zona pellucida. Such embryos are subsequently referred to here as 'micromanipulated embryos'.

It should be noted that complete removal of granulosa cells prior to micromanipulation of oocytes, zygotes and embryos is necessary to avoid lowering their health status.

To bring micromanipulated embryos within the scope of the above mentioned Appendices, the following conditions shall apply:

Article 3.3.3.2.

1. Prior to any micromanipulation which involves breaching the zona pellucida, all embryos/oocytes must be collected and processed according to the sanitary conditions laid down in Appendix 3.3.1. (*in vivo* derived embryos) or produced according to the sanitary conditions laid down in Appendix 3.3.2. (*in vitro* fertilised bovine embryos/*in vivo* maturing oocytes).
2. Responsibility for the embryos/oocytes must remain with the embryo collection team (*in vivo* derived embryos) or with the embryo production team (*in vitro* fertilised bovine embryos), and all processing involving micromanipulation should be carried out in an approved processing laboratory under supervision of an approved team veterinarian (see Articles 3.3.1.2. and 3.3.1.3., and Articles 3.3.2.1. and 3.3.2.2., as relevant).
3. Donor animals must comply with the conditions laid down in Article 3.3.1.4. (*in vivo* derived embryos) or Article 3.3.2.3. (*in vitro* fertilised bovine embryos/*in vivo* maturing oocytes), whichever is appropriate. The criteria for testing samples to ensure that embryos are free of pathogenic organisms are laid down in Article 3.3.1.5. and Article 3.3.2.4. respectively, and these should be followed.
4. All embryos to be micromanipulated must be washed according to the protocols laid down in the IETS Manual (1998)[1] and they must be observed to have an intact zona pellucida before and after washing. Only embryos from the same donor, or, in the case of some *in vitro* produced embryos (see Appendix 3.3.2.) from the same batch collection, should be washed together at the same time. After washing, but before micromanipulation, the zona pellucida of each embryo should be examined over its entire surface area at not less than 50X magnification and certified to be intact and free of adherent material.
5. If surrogate zonae are used, they should be of bovine origin and the embryos/oocytes from which they are obtained should be treated in the same manner as if they were *in vivo* derived or *in vitro* produced embryos intended for international movement.

Article 3.3.3.3.

Procedures for micromanipulation

The term ‘micromanipulation’ covers several different procedures and a variety of specialised microsurgical instruments and other equipment may be used. However, from the standpoint of animal health, any cutting,

penetrating or breaching of the integrity of the zona pellucida is an action that can alter the health status of an embryo. To maintain health status during and after micromanipulation, the following conditions should apply:

1. Media

Any product of animal origin, including co-culture cells and media constituents, used in the collection of embryos, oocytes or other cells, and in their micromanipulation, culture, washing and storage should be free of pathogenic micro-organisms (including transmissible spongiform encephalopathy agents, sometimes called prions). All media and solutions should be sterilized by approved methods according to the IETS Manual[1] and handled in such a manner as to ensure that sterility is maintained. Antibiotics should be added to all fluids and media as recommended in the IETS Manual[1].

2. Equipment

Equipment (e.g. microsurgical instruments which have direct contact with embryos) should either be of the single-use type (disposed of after each embryo) or should be effectively sterilised between embryos in accordance with recommendations in the IETS Manual[1].

3. Nuclei for transfer

a) Where it is intended to transplant nuclei derived from pre-hatching stage (i.e. zona pellucida intact) embryos, the parent embryos from which those nuclei are derived should fulfil the conditions of this Appendix. Where nuclei derived from other types of donor cell (e.g. post-hatching stage embryos, embryonic, fetal and adult cells, including spermatozoa/spermatids for ICSI) are to be transplanted, the parent embryo, fetus or animal from which those donor cells originate, and the methods whereby they are derived, including cell culture, should comply with the relevant animal health standards recommended elsewhere in this *Terrestrial Code* and in the *Terrestrial Manual.*

b) Where it is intended to transplant a nucleus into an oocyte (for ICSI), or into an enucleated oocyte (for nuclear transfer), those oocytes should be collected, cultured and manipulated according to the recommendations in this Appendix and/or in Appendix 3.3.2.

Article 3.3.3.4.

Optional tests and treatments

The *importing country* may request that tests[2] be carried out on certain samples or that embryos are treated to ensure that specified pathogenic organisms are absent.

1. Samples

Samples to be tested may include those referred to in Article 3.3.1.7. and/or in Article 3.3.2.4. Where cells other that from zona pellucida-intact embryos (e.g. somatic or sperm cells) are used as donors of nuclei for transplantation, then samples or cultures of those donor cells may also be tested.

2. Treatments

Treatments of embryos with the enzyme trypsin or other substances proven to inactivate or remove pathogenic organisms, and which are harmless to the embryo, may be requested, but these also should be applied prior to any micromanipulation, and according to the IETS Manual[1].

Article 3.3.3.5.

Conditions applicable to storage, quarantine and transport

Micromanipulated embryos should be stored, quarantined and transported according to the conditions laid down in Article 3.3.1.8. or in points 4, 5, 6, 7 and 8 of Article 3.3.2.5. Veterinary certification documents should identify all micromanipulations, where and when they were carried out.

1 Manual of the International Embryo Transfer Society (1998).

2 If the samples mentioned above in point 1. of Article 3.3.3.4. are to be tested for pathogenic agents, then the microbiological techniques in current use for those agents would be appropriate.

APPENDIX 3.3.4.

LABORATORY RODENT AND RABBIT EMBRYOS/OVA

Article 3.3.4.1.

Conditions applicable to the maintenance of laboratory animal colonies

Maintenance of laboratory animal colonies of specific genotypes requires intensive breeding management within specialised premises. They may be kept in a gnotobiotic environment, in either a 'germfree' system or a 'barrier' room (usually with defined flora), in a conventional colony, or under undefined conditions. In both the germfree and barrier systems, the animals are raised in a controlled environment according to protocols that attempt to eliminate potential sources of microbiological contamination. The primary difference is that the barrier maintained animals have been inoculated with known (defined) microbes[1] using a cocktail of non-pathogenic flora, whereas germfree animals are kept free from both pathogenic and non-pathogenic microbes.

A second category is where laboratory animals are kept in closed, conventional colonies within which known pathogens may exist. Here, less rigid colony management protocols are used to control potential sources of contamination, but implementation of simple aseptic precautions (e.g. autoclaving of feed and bedding) should allow animals to be maintained in a microbiologically defined system. Finally, laboratory animals may live in environments with undefined microbiological conditions (e.g. non-restricted colonies, free-ranging animals).

Disease testing and donor animal/embryo handling requirements can therefore be considered as being of three distinct types, depending on the type of colony being dealt with, i.e. defined floral, conventional and undefined. The health status of all colonies should be confirmed quarterly by bacteriological, virological, parasitological, serological and immunohistochemical tests on pre-designated sentinel animals or other representative animals of the colony (e.g. older breeding males which have sired multiple litters).

Article 3.3.4.2.

Conditions applicable to the embryo production team/laboratory

1. The embryo production team must be composed of competent technicians supervised by an experienced embryologist holding a graduate academic degree (e.g. M.S., Ph.D., D.V.M.).

2. Team personnel should be trained in the principles of disease control and the use of aseptic techniques in embryo handling. Laboratory sanitary procedures must conform with requirements in the IETS Manual[2].

3. The embryo production team must use all necessary precautions to protect the animal facilities, laboratory and equipment against microbiological contamination. In particular, the zoonotic potential of specific pathogens should be identified and understood by staff members to avoid contamination of colonies via human vectors, or vice versa. Restrictions should be established to prevent free access of personnel into the embryo handling laboratory after their exposure to other animal facilities.

4. Proper records must be maintained for inspection by the chief embryologist (i.e. supervisor).

   Until standardised record sheets are developed for laboratory animals, it is the responsibility of each laboratory to maintain complete animal and embryo records (i.e. embryo collection, cryopreservation data). Information of the type shown in standard IETS record sheets[2] for livestock species should be incorporated, where applicable, and data such as embryo quality grading system, morphological stage at cryopreservation and genotypic identification of the donors should be clearly given in the records.

5. It is the responsibility of the chief embryologist (i.e. laboratory supervisor) to ensure that the embryos are properly stored in sterile, sealed containers (e.g. ampules or straws). In addition, the containers must be correctly identified using a standard format which includes embryo species/genotype, cryopreservation date, number and stage of embryos, container number and indication of any specialised procedure (e.g. *in vitro* fertilisation, micromanipulation) or condition (e.g. germfree, microbiologically defined).

Article 3.3.4.3.

Conditions applicable to the embryo team/institute veterinarian

1. The veterinarian, certified in laboratory animal care or laboratory animal accredited, must ensure that the required colony health profiling procedures are implemented, and the results are reviewed and properly recorded before shipment of embryos. He/she is also responsible for confirming that proper animal management/sanitation conditions have been maintained.
2. The veterinarian is responsible for certifying that the embryo handling procedures and laboratory conditions were maintained in accordance with the IETS Manual[2].
3. The veterinarian must supervise all quarantine practices to protect against unwanted contamination and spread of disease, and to ensure that valid results are generated.
4. The veterinarian must authorise all embryo shipments, ensuring that the correct veterinary certification documents and embryo collection records are completed and included in the shipments.

Article 3.3.4.4.

Test programmes for donor animals

Sentinel animals in each donor colony should be subjected to routine monthly microbial screening. Testing for specific pathogens is species dependent and will undoubtedly also be influenced by geographic location. Recommendations regarding specific microbial agents to be tested for in mice, rats, cotton rats, hamsters, guinea pigs, gerbils and rabbits have been published elsewhere[3].

Article 3.3.4.5.

Conditions applicable to the embryo/animal handling

1. Defined microbial conditions

   a) Germfree and microbiologically defined, barrier maintained animals represent the cleanest sources of gametes, and the embryos recovered from these can be regarded as pathogen free.

   b) Since the animals themselves are pathogen free or possess defined flora (usually based on random, monthly testing of sentinel animals), dissection of the reproductive tract and embryo isolation procedures can be performed under aseptic laboratory conditions, and do not require the use of a biological safety cabinet.

   c) Strict aseptic procedures should nevertheless be followed and, while embryo washing is not essential to safeguard against any possible air-borne contamination in the laboratory, it is recommended that embryos undergo at least a 3-step washing procedure. In each wash, embryos should be gently agitated in the medium, and the wash volume must constitute at least a one hundred-fold dilution of the volume in which the embryos are transferred.

   d) Microbial testing of flush or washing media is not required.

   e) Cryopreserved embryos should be designated, in the appropriate records, as coming from a germfree or microbiologically defined, barrier maintained colony, thus indicating that additional safeguards for pathogen removal are not necessary. Isolation and health status monitoring of the embryo recipients should be considered but the need to quarantine them is a decision for the importing laboratory.

2. Conventional conditions

   a) Animals maintained under these conditions generally represent closed colonies whose health status is routinely profiled. They may have been exposed to various pathogens, resulting in the isolation of infectious agents, positive antibody titres or even active clinical disease. However, prior to embryo collection there should be familiarity with the pathogen(s) of particular concern in the colony.

b) Reproductive tracts (uteri, oviducts and/or ovaries) should be removed at a separate site and then taken into the embryo laboratory. These procedures should be performed by separate technicians or, at the very minimum, their protective clothing should be changed between locations. If the animals are to be handled in the laboratory, the tracts should be dissected out within a biological safety cabinet. This will help protect against the possible shedding of pathogens into the laboratory itself.

c) Once the reproductive tracts have been removed, embryo recovery should be performed under aseptic conditions. Embryos must be inspected (≥100x) for the presence of cracks in the zona pellucida and only zona-intact embryos should be kept. They must then be washed using the standard 10-step procedure, described in the IETS Manual[2]. This guideline could be waived in the future if sufficient research evidence from embryo-pathogen interaction studies warranted it.

d) Embryos derived from animals that have positive antibody titres or other evidence of specific pathogens should only be transferred into a new colony via a quarantine system, using microbiologically defined recipient females. As an additional safeguard, if there is any uncertainty about the donor or disease status of the embryos, quarantining of recipients should be applied. In certain situations where embryos might have been exposed to bacterial infection (e.g. mycoplasma), they should be cultured in a medium containing an appropriate antibiotic for 24 h pre-freezing, or post-thawing and prior to transfer.

e) If the embryos were not handled in the recommended manner, this must be indicated on the shipment records, and mandatory quarantining of the recipient dam and offspring should be imposed by the recipient institution until their health status is confirmed. The recipient dam should then be tested post-weaning for pathogens, and introduction of the progeny into the colony should only take place if test results are satisfactory.

3. Undefined microbial conditions

a) These animals are derived from either the wild or from colonies of unknown health status and embryos from them require maximum precautions. The health status of breeder males and donor females should be determined 15 days before and on the day of breeding (for males) or at embryo collection (for females). Alternatively, the animals could be incorporated into a conventional colony, where, over time, a health history can be documented to reduce the strict monitoring and embryo handling requirements.

b) A biological safety cabinet should be used for all animal, tissue and embryo handling.

c) An aliquot of flush fluid from each donor, or a pooled sample, should be tested for the presence of specific pathogens of concern to the *importing country* and laboratory.

d) Embryos must be washed in accordance with the protocols in the IETS Manual[2] (i.e. the 10-step wash, possibly including trypsin treatment in the case of certain herpesviruses) and an aliquot of media from the last four (pooled) washes should be tested for pathogens.

e) Cryopreserved embryos must be stored in the exporting laboratory until such time as the necessary disease screening of tissues and fluids is completed. All embryos from these animals must be transferred into a colony via a quarantine system, as discussed above. In addition to testing the recipient dam, all offspring should be tested at 12 weeks of age and/or individuals from successive generations should be tested before their introduction into breeding colonies outside the quarantine facility.

Article 3.3.4.6.

Special experimental circumstances

If embryos are to be cryopreserved following specialised micromanipulation procedures that involve penetration of the zona pellucida, they must undergo the required washing steps (depending on colony status) before treatment. In the case of *in vitro* fertilisation, to minimise possible pathogen exposure, it is also advised that only washed sperm should be used. Embryos should be washed again before cryopreservation.

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1 **Recommendations for the health monitoring of mouse, rat, hamster, guineapig and rabbit breeding colonies**.- Report of the Federation of European Laboratory Animal Science Associations (FELASA), Working Group on Animal Health accepted by the FELASA Board of Management, November 1992.

2 Manual of the International Embryo Transfer Society (1998).

3 Schiewe M.C., Hollifield V.M., Kasbohm L.A. & Schmidt P.M. (1995) - Embryo importation and cryobanking strategies for laboratory animals and wildlife species. *Theriogenology*, **43**, 97-104.

APPENDIX 3.3.5.

CATEGORISATION OF DISEASES AND PATHOGENIC AGENTS BY THE INTERNATIONAL EMBRYO TRANSFER SOCIETY

Article 3.3.5.1.

In 2004, the Research Subcommittee of the International Embryo Transfer Society (IETS) Health and Safety Advisory Committee again reviewed available research and field information on infectious diseases which have been studied regarding the risk of their transmission via *in vivo* derived embryos. As a result of this review, the IETS has categorised the following diseases and pathogenic agents into four categories. Please note that this categorisation applies only to *in vivo* derived embryos.

The following methodology is used by the Research Subcommittee to categorise infectious diseases with regard to the risk of their transmission:

1. Research procedures used to handle and process the embryos will comply with criteria that have been set out by A. Bielanksi and W.C.D. Hare in Appendix A of the IETS Manual[1].

2. The data used by the Subcommittee to categorise or re-categorise diseases will have been published in peer-reviewed articles in reputable scientific journals. This is to ensure that scientific procedures and results, as well as the interpretation of results, have undergone another level of review.

3. Decisions regarding disease categorisation are based on a consensus judgement which is taken annually by the Subcommittee. The names of members of the Subcommittee who are present when the decisions are made are recorded, as are the names of any others whose opinions were solicited in the decision making process.

4. Questions considered in the decision-making process include the following:

   a) What is the nature of the disease? For example, is the causal agent a uterine pathogen? Does it occur in blood? Does it persist in blood? Do asymptomatic shedders occur? What is the minimum infective dose?

   b) Has the causal agent been found in the ovarian/oviductal/uterine (OOU) environment?

   c) Is the causal agent's presence in the OOU environment incidental or is it a consequence of the pathogenesis of the disease?

   d) Is the causal agent's presence in the OOU environment consistent with obtaining viable embryos?

   e) Has the causal agent been found in flushing fluids?

   f) Has the causal agent been found to penetrate or cross the intact zona pellucida (ZP)?

   g) Has the causal agent been found to adhere to the ZP?

   h) Is the causal agent removed by washing the embryo?

   i) Will special treatments (e.g. with trypsin) remove or inactivate the causal agent?

   j) How many embryos have been transferred with or without disease transmission?

   k) What is the accumulated evidence for non-transmission of the disease by embryo transfer?

   l) What evidence is there that the disease could be transmitted by embryo transfer?

   m) Have negative (or positive) results been duplicated by the same or different investigators?

   n) Has evidence been accumulated for different animal species as well as for a range of different types and strains of the causal agent?

Article 3.3.5.2.

Category 1

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[1].

The following diseases or pathogenic agents are in category 1:

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

Article 3.3.5.3.

Category 2

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[1], but for which additional transfers are required to verify existing data.

The following diseases are in category 2:

- Bluetongue (sheep)
- Classical swine fever (hog cholera)
- Scrapie (sheep).

Article 3.3.5.4.

Category 3

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[1], but for which additional *in vitro* and *in vivo* experimental data are required to substantiate the preliminary findings.

The following diseases or pathogenic agents are in category 3:

- Bovine immunodeficiency virus
- Bovine spongiform encephalopathy (goats)
- Bovine viral diarrhea virus (cattle)
- *Campylobacter fetus* (sheep)
- Caprine arthritis/encephalitis
- Foot and mouth disease (swine, sheep and goats)
- *Haemophilus somnus* (cattle)
- *Mycobacterium paratuberculosis* (cattle)
- *Neospora caninum* (cattle)
- Ovine pulmonary adenomatosis
- Porcine reproductive and respiratory disease syndrome (PRRS)
- Rinderpest (cattle)

- Swine vesicular disease.

Article 3.3.5.5.

Category 4

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

1. that no conclusions are yet possible with regard to the level of transmission risk; or
2. the risk of transmission via embryo transfer might not be negligible even if the embryos are properly handled according to the IETS Manual[1] between collection and transfer.

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
- Ovine epididymitis (*Brucella ovis*)
- *Chlamydia psittaci* (cattle, sheep)
- Enterovirus (cattle, swine)
- *Escherichia coli* 09:K99 (cattle)
- *Leptospira borgpetersenii* serovar *hardjobovis* (cattle)
- *Leptospira* sp. (swine)
- Maedi-visna (sheep)
- *Mycobacterium bovis* (cattle)
- *Mycoplasma* spp. (swine)
- Parainfluenza-3 virus (cattle)
- Parvovirus (swine)
- Scrapie (goats)
- *Trichomonas foetus* (cattle)
- Porcine circovirus (type 2) (pigs)
- *Ureaplasma / Mycoplasma* spp. (cattle, goats)
- Vesicular stomatitis (cattle, swine).

1 Manual of the International Embryo Transfer Society (1998).

SECTION 3.4.

BIOSECURITY IN ESTABLISHMENTS

APPENDIX 3.4.1.

HYGIENE AND DISEASE SECURITY PROCEDURES IN POULTRY BREEDING FLOCKS AND HATCHERIES

Article 3.4.1.1.

Recommendations applicable to breeding establishments

1. The choice of a suitably isolated geographical location, taking into account the direction of the prevailing winds, facilitates hygiene and disease control. The *establishment* should be surrounded by a security fence and a gateway to control traffic and access to the site. A sign indicating restricted entry should be posted at the entrance.
2. Poultry breeding *establishments* should be single purpose - single species enterprises, and ideally an all in all out single age group principle should be adopted whenever possible.
3. Where several flocks are maintained on one *establishment*, the individual flocks should be managed as separate entities.
4. Buildings housing poultry or those used to store feed or eggs should be free of vermin and not accessible to wild birds.
5. Poultry houses should be constructed so that all surfaces inside the buildings are of an impervious smooth material so that cleaning and *disinfection* can be carried out adequately.
6. The area immediately surrounding the poultry houses should be free from vegetation and debris and ideally this should consist of an area of concrete or other similar material. An exception to this would be trees for heat control, with the exception of fruit trees which could be attractive to birds.
7. Domestic animals should not be permitted access to poultry houses.
8. Appropriate disease security precautions, which could include showering and changing facilities, should be adopted for all visitors to the *establishment* and for all staff entering individual poultry houses.
9. When a poultry house or *establishment* is depopulated, all manure should be removed from the houses and effective cleaning and *disinfection* procedures applied. Bacteriological monitoring of the efficacy of *disinfection* procedures is recommended. When necessary, rodent and insect control procedures should also be carried out.
10. Repopulation of poultry houses or *establishments* should only be made from poultry flocks of known high health status and which are regularly monitored for salmonella and other poultry pathogens.
11. All feed used in poultry houses and *establishments* should be monitored for salmonella prior to use. The use of pelletised feeds or feeds subjected to other salmonella decontamination procedures is recommended. Feed should be stored in clean closed containers.
12. The water supply to poultry houses should be of a satisfactory potable status.
13. Sick and dead birds should be removed from poultry houses as soon as possible and effective and safe disposal procedures implemented.

14. Full records relating to mortality, disease diagnosis, treatments and vaccinations should be maintained on an individual flock basis within the *establishment*. Such records should be readily available for inspection.

Article 3.4.1.2.

Recommendations applicable to hatching egg hygiene and transport

1. The litter in the laying house should be kept dry and in good condition. The nest box litter should be clean and adequate in quantity.
2. Eggs should be collected at frequent intervals of not less than twice per day and placed in clean disinfected containers.
3. Dirty, broken, cracked, leaking and dented eggs should be collected in a separate container and should not be used for hatching purposes.
4. The clean eggs should be sanitised as soon as possible after collection. The methods of sanitisation are described in Article 3.4.1.7.
5. The sanitised eggs should be stored in a clean, dust free room used exclusively for this purpose and kept at a temperature of 13-15°C (55°-60°F) and at a relative humidity of 70-80%.
6. The eggs should be transported to the hatchery in new or clean cases which have been fumigated or sanitised with a liquid disinfectant (see Table I). The cleaning and *disinfection* of *vehicles* must be a regular part of the hatchery routine.

Article 3.4.1.3.

Recommendations applicable to hatchery buildings

1. The choice of a suitably isolated geographical location facilitates hygiene and disease control. The building should be located as far as possible from other buildings housing livestock and poultry in particular, and the direction of the prevailing winds should be taken into consideration.
2. The design of the hatchery should be based on suitable work flow and air circulation principles. It should be constructed so that there is a one way flow for the movement of eggs and chicks, and the air flow also follows this same one way direction.
3. The hatchery buildings should include physical separation of all work areas. If possible, separate ventilation should be provided for these work areas, namely, the rooms for:
   a) egg receiving and egg storage;
   b) egg traying;
   c) fumigation;
   d) setting or initial incubation;
   e) hatching;
   f) sorting, sexing and placing chicks in boxes;
   g) material storage, including egg and chick boxes, egg flats, box pads, chemicals and other items;
   h) facilities for washing equipment and disposal of waste;
   i) room for employees to have meals;
   j) office.
4. Openable windows, ventilators and other open areas should be screened against insects and vermin.

Article 3.4.1.4.

Recommendations applicable to hatchery building hygiene

1. The area adjacent to the hatchery buildings should be surrounded by a security fence and a gateway to control all traffic.
2. Wild birds, domestic and wild animals must be excluded from the hatchery area. When necessary, a specific programme for fly control should be implemented.
3. The hatchery area should be maintained free from all hatchery waste, garbage of all kinds and discarded equipment.
4. Approved disposal methods and adequate drainage must be available.
5. All hatchery equipment, tables and horizontal surfaces in rooms must be promptly and thoroughly vacuumed, cleaned, washed, scrubbed, rinsed with clean water and finally disinfected with an approved disinfectant.

Article 3.4.1.5.

Requirements applicable to personnel and visitors

1. Clean coveralls or overalls, hats and footwear must be provided for all personnel and visitors entering the *establishment* or the hatchery.
2. A disinfectant foot-bath for footwear is necessary and the disinfectant solution should be changed frequently. Washing the hands in disinfectant solution or with soap and water should be required.
3. Personnel and visitors should have no direct contact with other poultry or poultry products.

Article 3.4.1.6.

Hygiene measures during the handling of eggs and day-old birds

1. Egg handlers in the hatchery should wash their hands with soap and water and change to clean outer garments before handling *hatching eggs* received from the poultry farm.
2. Chick sexers and chick handlers must wash and disinfect their hands and change into clean protective clothing and boots before commencing work and between different lots of chicks.
3. Day-old chicks or other poultry must be delivered or distributed in new chick boxes; or in used boxes made of suitable material which have been thoroughly cleaned and disinfected or fumigated.
4. The chicks should be delivered directly from the hatchery by personnel wearing clean, disinfected outer clothing. Outer clothing should be changed or disinfected between each delivery.
5. The delivery truck must be cleaned, and disinfected before loading each consignment of chicks.

Article 3.4.1.7.

Sanitisation of hatching eggs and hatchery equipment

Sanitisation means:

a) fumigation with formaldehyde, or

b) spraying with or immersion in an egg shell disinfectant in accordance with the manufacturers instructions, or

c) made hygienic by another method approved by the *Veterinary Authority*.

Formaldehyde gas has been used for many years for the *disinfection* of *hatching eggs* and hatchery equipment. As a fumigant, formaldehyde gas has proved to be a very effective means of destroying micro-organisms on eggs, egg cases, chick boxes, hatching machines and other hatchery equipment, provided these items have been subjected to

preliminary cleaning. When the correct mixture of formalin and potassium permanganate is used, a dry brown powder will remain after the reaction is completed.

At the present time, there is lack of uniform opinion on the optimum concentration of formaldehyde required for the sanitisation of eggs and hatchery equipment. In general, three levels of concentration have been used. Also, two methods of use have been adopted.

1. Method 1

   a) Concentration A

      53 ml formalin (37.5%) and 35 g potassium permanganate per m³ of space.

      This can be expressed as:

      5.25 oz by volume (148.5 ml) formalin (37.5%) and 3.5 oz by weight (98 g) potassium permanganate per 100 ft³ (2.8 m³) of space.

   b) Concentration B

      43 ml formalin (37.5%) and 21 g potassium permanganate per m³ of space.

      This can be expressed as:

      4 oz by volume (120 ml) formalin (37.5%) and 2 oz (60 g) potassium permanganate per 100 ft³ (2.8 m³) of space.

   c) Concentration C

      45 ml formalin (40%) and 30 g potassium permanganate per m³ of space.

      This can be expressed as:

      4.5 oz by volume formalin and 3 oz potassium permanganate per 100 ft³.

   d) Procedure

      Fumigation of *hatching eggs* and equipment should be carried out in a special chamber or in a room or building constructed of impermeable material which can be made as airtight as possible. A fan is necessary to circulate the gas during fumigation and to expel it after fumigation is completed.

      The total volume of the room is determined accurately from the internal measurements. The space occupied by trays, or eggs, or articles to be fumigated, is to be disregarded. The quantities of materials required are based on the total volume.

      Place in the centre of the floor, one or preferably several large metal basins, metal trays or containers of earthenware, enamelware, asbestos or other non-inflammable material.

      PLASTIC OR POLYETHYLEN CONTAINERS ARE NOT TO BE USED due to the heat generated by the chemical reaction. To avoid possible fire hazards, the containers should slope outwards. Also, the containers must be large enough so that the two chemicals occupy no more than one quarter of the volume of the container. Preferably, the container should have a capacity of at least 10 times the volume of the total ingredients.

      The eggs should be placed on wire racks, in wire baskets or on cup-type egg flats stacked in a manner that will permit air circulation and exposure to the formaldehyde gas.

      An electric or hot water heater should be available in the chamber to maintain the temperature at 75°-100°F (24°-38°C). Water pans or other equipment should be available to provide a relative humidity of 60-80%.

      Place required amount of potassium permanganate into the containers **BEFORE** adding the formalin.

      Pour the required amount of formalin onto the potassium permanganate in the containers.

      Leave the chamber as quickly as possible and close the door. Some operators may wish to use a gas mask when pouring the formalin into the containers.

      The door of the chamber should be securely closed and permanently labelled to prevent accidental opening.

The fans should be operated to circulate the formaldehyde and the fumigation time should be 20 minutes.

After 20 minutes, the gas should be expelled through a controlled vent leading to the outside of the building.

The door may be opened to facilitate expelling the formaldehyde to the outside.

2. Method 2

An alternative method to the above is to use formaldehyde gas produced by the evaporation of paraformaldehyde. Proprietary preparations are available and the operation is carried out by placing the requisite amount of powder on a pre-heated hot plate.

In this method it is necessary to ensure that the relative humidity of the chamber is sufficiently high (60-80%).

Ten g paraformaldehyde powder or pellet is used per m^3 of space.

3. Warning

In carrying out fumigation, the following points should be borne in mind:

a) Caution is necessary when formalin and potassium permanganate are mixed together in large amounts because of the risk of personal injury and fire through careless use. Formaldehyde gas causes irritation to the eyes and nose of the operator and the use of a gas mask is advised.

b) Effective fumigation depends on optimum conditions of temperature and humidity. Formaldehyde gas rapidly loses its efficiency at low temperatures or in a very dry atmosphere.

Article 3.4.1.8.

Fumigation procedures at the hatchery

1. Fumigation of eggs in setting machines

Eggs should be fumigated within 12 hours after setting and after the temperature and humidity has returned to normal operating levels. The temperature of the machines must remain at the operating level.

The setting machine doors and ventilators should be closed, but the circulation fan should be kept operating.

After fumigation for 20 minutes, the ventilators should be opened to the normal operating position in order to release the gas.

Warning

Do not fumigate eggs that have been incubated for 24 to 96 hours, as this can result in embryo mortality.

2. Fumigation of eggs in hatching machines

This is a common practice in certain areas and under certain conditions. The eggs should be fumigated after being transferred from the setting machine to the hatching machine and before **10% of the chicks have begun to break the shell**. After transfer of the eggs, the hatching machines are permitted to return to normal operating temperatures and humidity. The ventilators are closed and fumigation is conducted with the fans running. In some countries, the standard amounts of formalin (53 ml) and potassium permanganate (35 g) per m^3 are used. Fumigation time is 20 minutes. In other countries, 0.8 cc formalin (37.5%) is added to 0.4 g potassium permanganate for each ft^3 of space; or 25 ml formalin to 12.5 g potassium permanganate per m^3. Fumigation time is 20 minutes.

3. Fumigation of empty setting and hatching machines

Following removal of all the eggs or the chicks and the subsequent cleaning and *disinfection* of the empty machine, the disinfected egg trays are replaced and the machine prepared for the next batch of incubating eggs.

The doors and ventilators should be closed and the temperature and humidity returned to normal operating levels. Fumigation time should be at least 3 hours or preferably overnight, using the standard amounts of formalin and potassium permanganate (Concentration A).

The machines should be well ventilated before use to remove any residual fumigant.

Warning

The above fumigation procedure applies to a machine in which there are no *hatching eggs*. Eggs and chicks cannot be fumigated using the above fumigation time.

4. Neutralisation of formaldehyde gas

This can be achieved with a 25% solution of ammonium hydroxide using an amount not more than one half the volume of formalin used. The ammonia can be spread on the floor of the machine and the doors closed quickly.

Table 1. ***Properties and uses of disinfectants***

Properties	Chlorine	Iodine	Phenol	Quats	Formaldehyde
Bactericidal	+	+	+	+	+
Bacteriostatic	-	-	+	+	+
Fungicidal	-	+	+	±	+
Virucidal	±	+	+	±	+
Toxicity	+	-	+	-	+
Activity with organic matter*	++++	++	+	+++	+
Use area					
Hatchery equipment	+	+	+	+	±
Water equipment	+	+	-	+	-
Personnel	+	+	-	+	-
Egg washing	+	-	-	+	+
Floor	-	-	+	+	+
Foot baths	-	-	+	+	-
Rooms	±	+	±	+	+

Quats	=	Quaternary ammonium compounds
*	=	Number of + indicates degree of affinity for organic material and the corresponding loss of disinfecting action
+	=	Positive property
-	=	Negative property
±	=	Limited activity for specific property

Article 3.4.1.9.

Monitoring of poultry breeding flocks and hatcheries for salmonella

1. At the present time the only method for monitoring poultry breeding flocks and hatcheries for salmonella is by means of bacteriological examination of samples obtained from these *establishments*.

2. Samples for bacteriological monitoring of *poultry flocks* are obtained in the case of rearing flocks from the premises in which the birds are housed or in the case of adult laying birds either from the premises in which the birds are housed or from the hatchery to which the *hatching eggs* from that flock are consigned.

3. The samples to be taken are:

   a) on the premises in which birds are housed - fresh faeces (each sample at least 1 gram), dead or culled birds, or in the case of *day-old birds* the chick box liners;

   b) at the hatchery - meconium, dead in shell and culled chicks.

   Additionally, it is recommended that environmental samples such as drag swabs, litter, feather, down and dust, are also taken in both the premises and the hatchery at a similar frequency. Where the laying flock is sampled only on the premises, environmental sampling of the hatchery is required.

4. The total number of samples to be taken on each occasion is shown in Table 2 and is based on the random statistical sample required to give a probability of 95% to detect one positive sample given that infection is present in the population at a level of 5% or greater.

Table 2. ***Number of samples***

Number of birds in the flock	Number of samples to be taken on each occasion
25-29	20
30-39	25
40-49	30
50-59	35
60-89	40
90-199	50
200-499	55
500 or more	60

5. All samples should be selected at random to represent the house or in the case of samples taken at the hatchery to represent the *hatching eggs* from that poultry flock.

6. The following minimum frequency of sampling is recommended:

   a) Rearing flocks

   At day-old and 3 weeks before moving to laying accomodation.

   Where birds are moved from the rearing premises other than direct to laying accomodation, a further sample should be taken 3 weeks before such movement.

   b) Breeding flocks in lay

   The laying flocks should be sampled at least at monthly intervals during the laying period.

7. All samples should be fully marked and identified as to the date of sampling and the flock to which the samples relate.

8. Samples should be stored in a refrigerator at between 1°C and 4°C until they are dispatched to the laboratory (not more than 5 days).

9. All samples should be examined in a laboratory authorised for that purpose by the *Veterinary Authority*.

APPENDIX 3.4.2.

HYGIENE AND DISEASE SECURITY PROCEDURES IN APIARIES

Article 3.4.2.1.

In each country, official health control of bee diseases should include:

a) an organisation for permanent health surveillance;

b) approval of breeding apiaries for export trade;

c) measures for cleaning, *disinfection* and disinsectisation of apicultural equipment;

d) rules precisely stating the requirements for issuing an *international veterinary certificate*.

Article 3.4.2.2.

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 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 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 3.4.2.3.

Conditions for approval of breeding apiaries for export trade

The apiaries must:

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;

2. have received, for at least the past 2 years, visits by a health inspector and adviser, carried out at least 3 times a year (in spring, during the breeding period and in autumn), for the systematic examination of the hives containing bees and of all the apicultural equipment, and for the collection of samples to be sent to an official laboratory.

Bee-keepers must:

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 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 days, during the breeding and despatch period, samples from breeding material, brood-combs, queen-bees and bees (including possibly separately raised accompanying bees), to be sent to an official laboratory.

Article 3.4.2.4.

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 guidelines.

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.
4. Infected or contaminated equipment which cannot be subjected to the above-mentioned measures must 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 be destroyed by burning.
5. The products and means used for sanitation and *disinfection* shall be 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 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 3.4.2.5.

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 Appendix 4.1.9.

APPENDIX 3.4.3.

HYGIENE PRECAUTIONS, IDENTIFICATION, BLOOD SAMPLING AND VACCINATION

Article 3.4.3.1.

The use of microchip implanters, needles and syringes in a wide range of routine veterinary procedures relative to identification, blood sampling, vaccination and the injection of medicinal products or devices is now commonplace.

Unsterilised equipment and the use of opened vials of vaccine and medicinal products for different herds should be unacceptable professionally.

The use of unsterilised and contaminated equipment (microchip implanters, needles, syringes, etc.) or products is of special importance for different herds and animals to be exported. It is a requirement, particularly applicable for animals to be exported, that care is taken to ensure the sterility of all equipment and veterinary products associated with the conditions of the export certificate.

These precautions have particular importance for teams of veterinarians and para-veterinarians.

The range of organisms capable of being transmitted includes viruses, bacteria and protozoa. The list of infectious agents transmissible in the context of this Appendix continues to expand for all species of animals.

SECTION 3.5.

IDENTIFICATION AND TRACEABILITY OF LIVE ANIMALS

APPENDIX 3.5.1.

GENERAL PRINCIPLES

Article 3.5.1.1.

1. *Animal identification* and *animal traceability* are tools for addressing animal health (including zoonoses) and food safety issues. These tools may significantly improve the effectiveness of activities such as: the management of *disease outbreaks* and food safety incidents, vaccination programmes, herd/flock husbandry, zoning/compartmentalisation, surveillance, early response and notification systems, animal movement controls, inspection, certification, fair practices in trade and the utilisation of veterinary drugs, feed and pesticides at farm level.

2. There is a strong relationship between *animal identification* and the *traceability of animals* and products of animal origin.

3. *Animal traceability* and traceability of products of animal origin should have the capability to be linked to achieve traceability throughout the animal production and food chain taking into account relevant OIE and Codex Alimentarius standards.

4. The objective(s) of *animal identification* and *animal traceability* for a particular country, *zone* or *compartment* and the approach used should be clearly defined following an *assessment of the risks* to be addressed and a consideration of the factors listed below. They should be defined through consultation between the *Veterinary Authority* and relevant sectors/stakeholders prior to implementation, and periodically reviewed.

5. There are various factors which may determine the system chosen for *animal identification* and *animal traceability*. Factors such as the outcomes of the *risk assessment*, the animal and public health situation (including zoonoses) and related programmes, animal population parameters (such as species and breeds, numbers and distribution), types of production, animal movement patterns, available technologies, trade in *animals* and animal products, cost/benefit analysis and other economic, geographical and environmental considerations, and cultural aspects, should be taken into account when designing the system.

6. *Animal identification* and *animal traceability* should be under the responsibility of the *Veterinary Authority*. It is recognised that other Authorities may have jurisdiction over other aspects of the food chain, including the traceability of food.

7. The *Veterinary Authority*, with relevant governmental agencies and in consultation with the private sector, should establish a legal framework for the implementation and enforcement of *animal identification* and *animal traceability* in the country. In order to facilitate compatibility and consistency, relevant international standards and obligations should be taken into account. This legal framework should include elements such as the objectives, scope, organisational arrangements including the choice of technologies used for identification and registration, obligations of all the parties involved including third parties implementing traceability systems, confidentiality, accessibility issues and the efficient exchange of information.

8. Whatever the specific objectives of the chosen *animal identification system* and *animal traceability*, there is a series of common basic factors, and these must be considered before implementation, such as the legal framework, procedures, the *Competent Authority*, identification of *establishments*/owners, *animal identification* and animal movements.

9. The equivalent outcomes based on performance criteria rather than identical systems based on design criteria should be the basis for comparison of *animal identification systems* and *animal traceability*

SECTION 3.6.

INACTIVATION OF PATHOGENS AND VECTORS

APPENDIX 3.6.1.

GENERAL RECOMMENDATIONS ON DISINFECTION AND DISINSECTISATION

Article 3.6.1.1.

Veterinary Authorities are requested to draw up regulations in their respective countries concerning the use of disinfectants and insecticides on the basis of the principles described below:

1. The choice of disinfectants and of procedures for *disinfection* should be made taking into account the causal agents of infection and the nature of the premises, *vehicles* and objects which are to be treated.

2. Disinfectants and insecticides should be authorised only after thorough tests have been carried out under field condition.

3. The following should be considered:

   a) few universal disinfectants exist;

   b) whereas hypochlorite, which is very often used, may be regarded as a universal disinfectant, its effectiveness is diminished by prolonged storage and it is therefore necessary to check its activity before use; a concentration of 0.5% active chlorine appears necessary for satisfactory *disinfection*;

   c) foot and mouth disease virus is easily destroyed by a high or low pH but the disinfectants used may be caustic or corrosive in concentrated form;

   d) tubercle bacillus is very resistant to disinfectants and a high concentration is required to destroy the organism, as well as prolonged action;

   e) no matter what substances are used, *disinfection* techniques should comprise the following:

      i) thorough soaking of bedding and litter as well as faecal matter with the disinfectant;

      ii) washing and cleaning by careful brushing and scrubbing of the ground, floors and walls;

      iii) then further washing with the disinfectant;

      iv) washing and disinfecting the outside of *vehicles*; these procedures will be carried out, if possible, with liquids applied under pressure and the washing, disinfecting or destroying of articles used for tying up the animals (ropes, reins, etc.) should not be omitted.

APPENDIX 3.6.2.

FOOT AND MOUTH DISEASE VIRUS INACTIVATION PROCEDURES

Article 3.6.2.1.

Meat

For the inactivation of viruses present in meat, one of the following procedures should be used:

1. Canning

   Meat is subjected to heat treatment in a hermetically sealed container to reach an internal core temperature of at least 70°C for a minimum of 30 minutes or to any equivalent treatment which has been demonstrated to inactivate the FMD virus.

2. Thorough cooking

   Meat, previously deboned and defatted, shall be subjected to heating so that an internal temperature of 70°C or greater is maintained for a minimum of 30 minutes.

   After cooking, it shall be packed and handled in such a way that it cannot be exposed to a source of virus.

3. Drying after salting

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

   'Drying' is defined in terms of the ratio between water and protein which must not be greater than 2.25:1.

Article 3.6.2.2.

Wool and hair

For the inactivation of viruses present in wool and hair for industrial use, one of the following procedures should be used:

1. industrial washing, which consists of the immersion of the wool in a series of baths of water, soap and sodium hydroxyde (soda) or potassium hydroxyde (potash);
2. chemical depilation by means of slaked lime or sodium sulphide;
3. fumigation in formaldehyde in a hermetically sealed chamber for at least 24 hours. The most practical method is to place potassium permanganate in containers (which must NOT be made of plastic or polyethylene) and add commercial formalin; the amounts of formalin and potassium permanganate are respectively 53 ml and 35 g per cubic metre of the chamber;
4. industrial scouring which consists of the immersion of wool in a water-soluble detergent held at 60-70°C;
5. storage of wool at 18°C for 4 weeks, or 4°C for 4 months, or 37°C for 8 days.

Article 3.6.2.3.

Bristles

For the inactivation of viruses present in bristles for industrial use, one of the following procedures should be used:

1. boiling for at least one hour;

2. immersion for at least 24 hours in a 1% solution of formaldehyde prepared from 30 ml commercial formalin per litre of water.

Article 3.6.2.4.

Raw hides and skins

For the inactivation of viruses present in raw hides and skins for industrial use, the following procedure should be used: salting for at least 28 days in sea salt containing 2% sodium carbonate.

Article 3.6.2.5.

Milk and cream for human consumption

For the inactivation of viruses present in *milk* and cream for human consumption, one of the following procedures should be used:

1. a sterilisation process applying a minimum temperature of 132°C for at least one second (ultra-high temperature [UHT]), or
2. if the milk has a pH less than 7.0, a sterilisation process applying a minimum temperature of 72°C for at least 15 seconds (high temperature - short time pasteurisation [HTST]), or
3. if the milk has a pH of 7.0 or over, the HTST process applied twice.

Article 3.6.2.6.

Milk for animal consumption

For the inactivation of viruses present in *milk* for animal consumption, one of the following procedures should be used:

1. the HTST process applied twice;
2. HTST combined with another physical treatment, e.g. maintaining a pH 6 for at least one hour or additional heating to at least 72°C combined with dessication;
3. UHT combined with another physical treatment referred to in point 2 above.

Article 3.6.2.7.

Skins and trophies from wild animals susceptible to foot and mouth disease

For the inactivation of viruses present in skins and trophies from wild animals susceptible to FMD, one of the following procedures should be used prior to complete taxidermal treatment:

1. boiling in water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers or teeth is removed;
2. gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher);
3. soaking, with agitation, in a 4% (w/v) 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).

APPENDIX 3.6.3.

PROCEDURES FOR THE REDUCTION OF INFECTIVITY OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY AGENTS

Article 3.6.3.1.

Meat-and-bone meal

The following procedure should be used to reduce the infectivity of any transmissible spongiform encephalopathy agents which may be present during the production of *meat-and-bone meal* containing ruminant proteins.

1. The raw material should be reduced to a maximum particle size of 50 mm before heating.
2. The raw material should be heated under saturated steam conditions to a temperature of not less than 133°C for a minimum of 20 minutes at an absolute pressure of 3 bar.

APPENDIX 3.6.4.

CLASSICAL SWINE FEVER VIRUS INACTIVATION PROCEDURES

Article 3.6.4.1.

Swill

For the inactivation of classical swine fever (CSF) virus 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 3.6.4.2.

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 must 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.

APPENDIX 3.6.5.

GUIDELINES FOR THE INACTIVATION OF THE AVIAN INFLUENZA VIRUS

Article 3.6.5.1.

Eggs and egg products

The following times for industry standard temperatures are suitable for the inactivation of highly pathogenic notifiable avian influenza (HPNAI) virus present in eggs and egg products:

	Temperature (°C)	Time
Whole egg	60	188 seconds
Whole egg blends	60	188 seconds
Whole egg blends	61.1	94 seconds
Liquid egg white	55.6	870 seconds
Liquid egg white	56.7	232 seconds
10% salted yolk	62.2	138 seconds
Dried egg white	67	0.83 days
Dried egg white	54.4	21.38 days

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

Article 3.6.5.2.

Meat

A procedure which produces a core temperature of 70ºC for 3,5 seconds is suitable for the inactivation of HPNAI virus present in meat.

	Temperature (°C)	Time
Poultry meat	60.0	507 seconds
	65.0	42 seconds
	70.0	3.5 seconds
	73.9	0.51 seconds

APPENDIX 3.6.6.

GENERAL GUIDELINES FOR THE DISPOSAL OF DEAD ANIMALS

Article 3.6.6.1.

Introduction

The mass disposal of dead animals associated with an animal *disease outbreak* is often subject to intense public and media scrutiny thereby obligating the *Veterinary Authority* of a Member Country to not only conduct disposal operations within acceptable scientific principles to destroy the causative pathogen but also to address public and environmental concerns.

The guidelines in this Appendix are general in nature. The choice of one or more of the recommended methods should be in compliance with relevant local and national legislation and be attainable with the resources available. The guidelines should also be applied in conjunction with the procedures described for the killing of animals in Appendix 3.7.6.

Strategies for the disposal of dead animals (entire animals or parts thereof) should be prepared well in advance of any emergency. Major issues related to the disposal of dead animals include the number of animals involved, biosecurity concerns over the movement of infected or exposed animals, people and equipment, environmental concerns, and the psychological distress experienced by farmers and *animal handlers*.

Article 3.6.6.2.

Regulations and jurisdiction

The legislation regulating animal health and the organisation of the *Veterinary Authority* should give the *Veterinary Services* the authority and the legal powers to carry out the activities necessary for the efficient and effective disposal of dead animals. Cooperation between the *Veterinary Service* and other relevant government bodies is necessary to developing a coherent set of legal measures for the disposal of dead animals in advance of any emergency. In this context the following aspects should be regulated:

1. Powers of *Veterinary Services* (inspectors, veterinary officers, etc.) to effect controls and direct persons as well as the right of entry to an *establishment* for the *Veterinary Services* and associated personnel;

2. movement controls and the authority to make exemptions under certain biosecurity conditions, for example for transport of dead animals to another location for disposal;

3. the obligation on the involved farmer and *animal handlers* to cooperate with the *Veterinary Services*;

4. any need to transfer the ownership of animals to the competent authority;

5. the determining of the method and location of disposal, and the necessary equipment and facilities, by the *Veterinary Services*, in consultation with other involved authorities including national and local governmental organisations competent for the protection of human health and of the environment.

Should the chosen option for the disposal of dead animals be applied near the border of a neighbouring country, the competent authorities of that country should be consulted.

Article 3.6.6.3.

Preparedness

The mass killing and disposal of animals in the event of a *disease outbreak* or disposal of animals in the event of natural disasters such as floods, usually must proceed with the minimum delay. The success is determined by the structures, policies and infrastructure established in advance:

1. Relationship with industry

   A relationship with industry organisations, such as farmer associations, commodity representatives, animal welfare organisations, security services, media and consumer representatives is essential to obtain compliance with animal health policies.

2. Standard operating procedures

   Standard operating procedures should be developed (including documented decision-making processes, training of staff).

3. Financial preparedness

   Financial preparedness means a compensation or insurance mechanism, an access to emergency funding and an access to personnel through agreements with private veterinarians.

4. Communication plan

   Information sharing with officials involved in the *outbreak*, affected farmers, professional organizations, politicians and the media is essential. A well informed spokesperson should be available at all times to answer enquiries.

5. Resources

   The management of resources should address such items as personnel, transport, storage facilities, equipment (such as mobile handling facilities for animals, disinfection equipment), fuel, protective and disposable material and logistical support.

6. Special equipment

   Special equipment such as trucks, tractors, bulldozers, and front-end loaders should be available.

Article 3.6.6.4.

Critical elements

Critical elements which need to be considered in planning and implementation include:

1. Timeliness

   Early detection of new infections, immediate killing of infected animals and rapid removal of the dead animals with inactivation of the pathogen are important. Spread of the pathogen from the dead animals and their surroundings should be blocked as soon and as effectively as possible.

2. Occupational health and safety

   Disposal should be organised in such a way that the workers are safeguarded against the risks of handling decomposing dead animals. Special attention should be given to zoonotic aspects. Workers should receive appropriate training and be sufficiently protected against infection with protective clothing, gloves, face masks, effective respirators, goggles, vaccination, and effective anti viral medicines. Workers should also receive regular health checks.

3. Pathogen inactivation

   The disposal procedure should be selected to result in inactivation of the pathogen.

4. Environmental concerns

   Different methods of the disposal of dead animals have different effects on the environment. For instance, pyre burning will produce smoke and smells; burial might lead to gas and leachate production resulting in potential contamination of air, soil, surface and sub surface water.

5. Availability of capacity

   An assessment of capacities of different methods of disposal should be made prior to any emergency. Temporary storage of dead animals in cold stores may relieve a lack of processing capacity.

6. Adequate funding

   Adequacy of funding for the options chosen must be ascertained and committed at the earliest possible stage.

7. Staff resources

   Availability of sufficient and well trained staff resources in particular for extended and /or large operations should be ensured. This is particularly important for technical and inspection personnel who are usually in short supply.

8. Societal acceptance

   Societal acceptance is an important point in choosing a disposal method.

9. Acceptance by farmers

   Farmers will be sensitive to the safety measures taken to prevent spread of the disease by disposal method selected and the transport of the dead animals to the disposal site. Adequate compensation of owners for the loss of animals or for burial or burning sites will improve acceptability.

10. Equipment

    Equipment used in the disposal of dead animals can transfer infection to other premises. The cleaning and disinfection of the outside surfaces of equipment such as cranes, containers and trucks, and the departure of *vehicles* from the farm should receive special attention. Trucks transporting dead animals should be leak proof.

11. Scavengers and vectors

    When disposing of dead animals, full attention should be given to preventing scavengers and vectors gaining access to dead animals, which might cause spread of disease.

12. Economic impact (short and long term including recovery)

    The method of disposal used has a significant bearing on economic impact.

Article 3.6.6.5.

Practical considerations

1. Selection of disposal site

   Sufficient top soil to cover the site; soil type; water drainage; prevailing wind conditions; easy access to transport; availability of meteorological data; separation from sensitive public sites, and the effect on future use.

2. Contractors

   Contractors — availability of manpower, materials and equipment including transport *vehicles*; can they supply in all the needs; exclusive use of *vehicles* or would they also be used for other purposes (risk of disease transmission); access to available roads; suitable for the purpose to be used.

3. Logistical preparedness for the appropriate technology

   Availability of fuel; sufficient manual labour available; sites and availability of disinfection tents for personnel; storage and disposal of protective clothing; housing for personnel to minimise the spread of infection; facilities for entry and exit control; availability of electricity for night operations; personal facilities for personnel such as toilets, drinking water; availability of communication – mobile phone reception; protection (e.g. vaccination) of personnel; rendering capacity at rendering plants; arms and ammunition, additional cold storage and holding facilities at rendering plants and abattoirs.

4. Procedures and policies for disposal of other possibly contaminated products

   Animal products such as litter, manure, wool, eggs and milk; animal feed; non-animal products such as protective clothing.

5. Wildlife

   Need to minimise the risks posed by wildlife, including by excluding or repelling them from the disposal site.

Article 3.6.6.6.

Recommended methods for the disposal of dead animals

The method(s) chosen should be based on local conditions and the required capacity and speed of outcome and on the conditions required for the inactivation of the causative agent.

Some of the methods below may require on-farm pre-processing prior to transportation of dead animals to central facilities for rendering or incineration. Preprocessing could include the grinding of dead animals which can then be transported in sealed containers, or be subjected to fermentation, composting or freezing.

1. Rendering

   This is a closed system for mechanical and thermal treatment of animal tissues leading to stable, sterilized products, e.g. animal fat and dried animal protein. The technology exists in dedicated facilities. It produces an effective inactivation of all pathogens with the exception of prions where infectivity is reduced. The availability of the capacity should be determined in advance.

2. Incineration in a dedicated facility

   In such a facility, whole dead animals or parts of animals can be completely burned and reduced to ash, often in conjunction with other substances (such as municipal waste, hazardous waste or hospital waste). Effective inactivation of pathogens, including spores, occurs. Fixed facility incineration is wholly contained and has some advantages from the environmental viewpoint as the exhausts may be fitted with afterburner chambers to completely burn hydrocarbon gases and particulate matter from the main combustion chamber.

3. Rendering and incineration

   These may be combined for improved security and to provide additional fuel for furnaces in facilities used for other purposes such as in cement kilns and electricity generation plants.

4. Air curtain incineration

   This process fan-forces a mass of air through a manifold, thereby creating a turbulent environment in which incineration is accelerated up to six times for example in a burn-pit. The equipment can be mobile and, because it can be used on site, there is no requirement for transportation of the animal material. It also produces effective inactivation of pathogens.

5. Pyre burning

   This open system of burning dead animals is a well established procedure that can be conducted on site with no requirement for transportation of animal material. However, it takes an extended period of time and has no way of verifying pathogen inactivation, and there may be particulate dissemination from incomplete combustion. Further, because the process is open to view, there may be a lack of acceptance by the public.

6. Composting

   Composting is a natural biological decomposition process that takes place in the presence of oxygen. In the first phase, the temperature of the compost pile increases, organic materials break down into relatively small compounds, soft tissue decomposes, and bones soften partially. In the second phase, the remaining materials, mainly bones, break down fully to a dark brown or black humus containing primarily non-pathogenic bacteria and plant nutrients. However, some viruses and spore forming bacteria, such as *Bacillus anthracis*, and other pathogens such as *Mycobacterium tuberculosis* may survive.

7. Burial

   In this method, whole dead animals are buried and covered by soil. Burial is an established procedure which may be conducted on site. It may not inactivate all pathogens. In some circumstances, dead animals may be disposed of by mounding whereby they are covered by a layer of soil above ground.

8. Biogas production

   This is a closed system of anaerobic fermentation which would require for the disposal of dead animals or their parts prior mechanical and thermal treatment of the input material (such as the liquid product of rendering plants). This process may not inactivate all pathogens.

9. Alkaline hydrolysis

   This method uses sodium hydroxide or potassium hydroxide to catalyse the hydrolysis of biological material into a sterile aqueous solution consisting of small peptides, amino acids, sugars, and soaps. Heat is applied (150°C) to accelerate the process. The only solid byproducts are the mineral constituents of bones and teeth. This residue (2% of the original weight of the animal) is sterile and easily crushed into a powder. The temperature and alkali conditions of the process destroy the protein coats of viruses and the peptide bonds of prions. Both lipids and nucleic acids are degraded. The process is carried out in an insulated steam-jacketed, stainless steel pressure vessel.

10. Bio-refining

    This is a high pressure, high temperature hydrolytic process, conducted in a sealed pressurised vessel. The waste material is treated at 180ºC at 12 bar pressure for 40 minutes, heated by the indirect application of steam kj, other compostable material, paper and comparable materials, and cereal straws either alone or in combination. The process inactivates all microbiological agents.

11. Dead animal disposal at sea

    International Conventions define the conditions to be met for the disposal of dead animals at sea.

Article 3.6.6.7.

Guidelines for decision-making for the disposal of dead animals

The disposal of large numbers of dead animals will be expensive. As well, fixed and variable costs will vary with the choice of the disposal method. Each method used will result in indirect costs on the environment, local economies, producers, and the livestock industry. In addition to biosecurity considerations, decision makers need to understand the economic, social, environmental protection and aesthetic impact of various disposal technologies.

A disposal option hierarchy may be incapable of fully capturing and systematizing the relevant dimensions at stake, and decision makers may be forced to consider the least preferred means. It therefore requires a comprehensive understanding of any array of dead animal disposal technologies and must reflect a balance between the scientific, economic, and social issues at stake. Timely slaughter, maintenance of security and prevention of further spread of disease, are the essential considerations in terms of disease control.

The following is an example of a possible process for aiding decision-making by comparing the suitability of various disposal options against factors that are considered important for the specific disposal event in question:

1. Step 1 - Define the factors to be considered. Include all relevant factors and allow enough flexibility to permit modifications for different situations and locations. Examples of possible factors include operator safety, community concerns, international acceptance, transport availability, industry standards, cost effectiveness and speed of resolution. These factors can be modified or changed, as is shown in the following example, to best fit the situation of event involved.

2. Step 2 - Assess the relative importance of the factors by weighting each on their considered importance to addressing the event in question. The sum of all the weightings, regardless of the number of factors, must total 100.

3. Step 3 - Identify and list all disposal options under consideration. Rate each disposal option against each factor and assign a Utility Rating of between 1 to 10 to each comparison. The Utility Rating (U) is a number between 1 and 10 which is allocated according to how well the option achieves the ideal with respect to each factor (eg 1 = the worst possible fit, and 10 = the best fit).

4. Step 4 - For each factor and each disposal option, multiply the Factor Weight (F) x Utility Rating (U) to yield a numeric Balanced Value (V), (eg V = F x U).

5. Step 5 - By adding the Balanced Values to a sum for each disposal option, it is possible to compare the suitability of disposal options by numerically ranking the sums of the Balanced Values for each disposal option. The largest sum would suggest that disposal option is the best balanced choice.

An example of the use of this process follows in Table 1. In this example, rendering achieved the highest sum and would be considered as the best balanced choice and the most suitable disposal option for the factors considered.

Table 1: Decision Making Process

Method		Rendering		Fixed Incineration		Pyre Burning		Composting		Mass Burial		On-Farm Burial		Commercial Landfill	
Factors	Weight	Utility	Value	Utility	Value	Utility	Value	Utility	Value	Utility	Value	Utility	Value	Utility	Value
Operator Safety	20	7	140	4	80	8	160	3	60	7	140	8			
Speed of Resolution	20	8	160	8	160	2	40	5	100	5	100	6			
Pathogen Inactivation	15	10	150	10	150	8	120	5	75	4	60	4			
Impact on Environment	10	10	100	8	80	3	30	10	100	3	30	3			
Reaction of the Public	10	10	100	7	70	1	10	9	90	3	30	4			
Transport Availability	5	1	5	1	5	8	40	5	25	3	15	8			
Acceptable to Industry	5	7	35	7	35	7	35	7	35	6	30	7			
Cost	5	4	20	1	5	6	30	9	45	8	40	9			
Risk to Wildlife	5	10	50	10	50	5	25	4	20	5	25	5			
Capacity to Meet Requirements	5	5	25	3	15	9	45	9	45	9	45	9			
Total Weight to Equal 100 Units	100	sum	785	sum	650	sum	535	sum	595	sum	515	sum		sum	

SECTION 3.7.

ANIMAL WELFARE

APPENDIX 3.7.1.

INTRODUCTION TO THE GUIDELINES FOR ANIMAL WELFARE

Article 3.7.1.1.

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 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 guidelines.

Article 3.7.1.2.

Scientific basis for guidelines

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 guidelines.
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.

APPENDIX 3.7.2.

GUIDELINES FOR THE TRANSPORT OF ANIMALS BY SEA

Preamble: These guidelines apply to the following live domesticated animals: cattle, buffaloes, deer, camelids, sheep, goats, pigs and equines. They may also be applicable to other domesticated animals.

Article 3.7.2.1.

The amount of time animals spend on a *journey* should be kept to the minimum.

Article 3.7.2.2.

I. 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 herds and follow a leader by instinct.

Animals which are likely to be hostile to each other in a group situation should not be mixed.

The desire of some animals to control their personal space should be taken into account in designing *loading* and *unloading* facilities, transport *vessels* and *containers*.

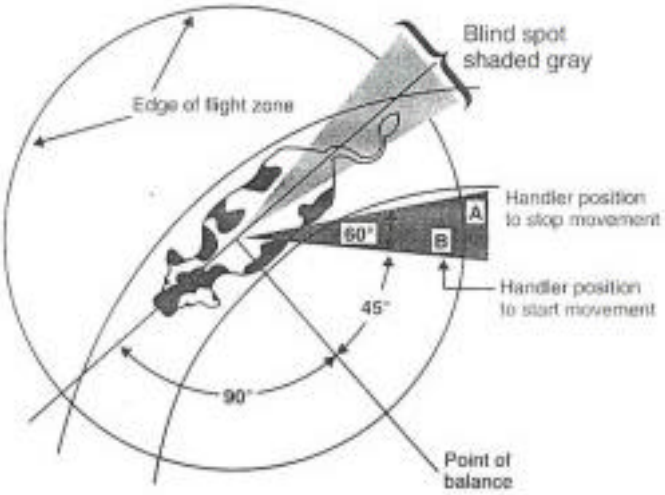
Domestic animals will try to escape if any person approaches closer than a certain distance. This critical distance, which defines the flight zone, varies among species and individuals of the same species, and depends upon previous contact with humans. Animals reared in close proximity to humans (i.e. 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.

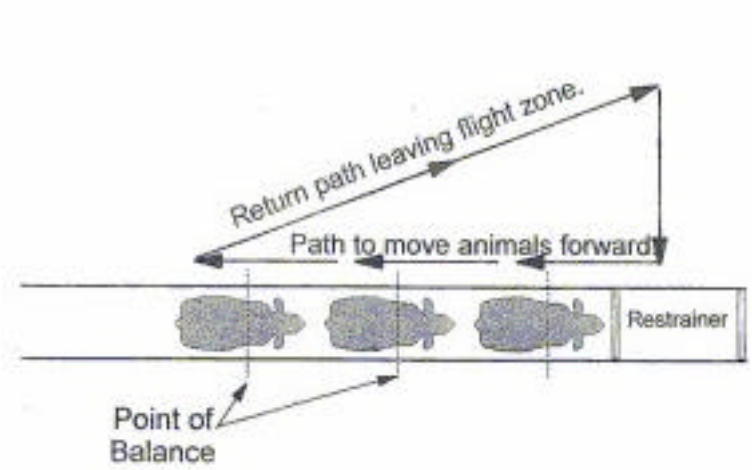
Domestic animals have a wide-angle vision but only have a limited forward binocular vision and poor perception of depth. This means that they can detect objects and movements beside and behind them, but can only judge distances directly ahead.

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 noises 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



2. Distractions and their removal

Design of new *loading* and *unloading* facilities or modification of existing facilities should aim to minimise the potential for distractions that may cause approaching animals to stop, baulk or turn back. 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 - illuminate with indirect lighting which does not shine directly into the eyes of approaching animals;

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 – avoid uneven floor surfaces or install a solid false floor 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. Dead ends - avoid if possible by curving the passage, or make an illusory passage.

Article 3.7.2.3.

Responsibilities

Once the decision to transport the animals by sea has been made, the welfare of the animals during their *journey* is the paramount consideration and is the joint responsibility of all people involved. The individual responsibilities of persons involved will be described in more detail in this Article. These guidelines may also be applied to the transport of animals by water within a country.

The management of animals at post-discharge facilities is outside the scope of this Appendix.

1. General considerations

a) Exporters, importers, owners of animals, business or buying/selling agents, shipping companies, masters of *vessels* and managers of facilities are jointly responsible for the general health of the animals and their fitness for the *journey*, and for their overall welfare during the *journey*, regardless of whether duties are subcontracted to other parties during transport.

b) Exporters, shipping companies, business or buying/selling agents, and masters of *vessels* are jointly responsible for planning the *journey* to ensure the care of the animals, including:

i) choosing appropriate *vessels* and ensuring that *animal handlers* are available to care for the animals;

ii) developing and keeping up-to-date contingency plans to address emergencies (including adverse weather conditions) and minimise stress during transport;

iii) correct *loading* of the ship, provision of appropriate food, water, ventilation and protection from adverse weather, regular inspections during the *journey* and for appropriate responses to problems arising;

iv) disposal of carcasses according to international law.

c) To carry out the above mentioned responsibilities, the parties involved should be competent regarding transport regulations, equipment usage, and the humane handling and care of animals.

2. Specific considerations

a) The responsibilities of the exporters include:

i) the organisation, carrying out and completion of the *journey*, regardless of whether duties are subcontracted to other parties during transport;

ii) ensuring that equipment and medication are provided as appropriate for the species and the *journey*;

iii) securing the presence of the appropriate number of *animal handlers* competent for the species being transported;

iv) ensuring compliance of the animals with any required veterinary certification, and their fitness to travel;

v) in case of animals for export, ensuring compliance with any requirements of the *importing* and *exporting countries*.

b) The responsibilities of the importers include:

(under study)

c) The responsibilities of the owners of the animals include the selection of animals that are fit to travel based on veterinary recommendations.

d) The responsibilities of the business or buying/selling agent include:

i) selection of animals that are fit to travel based on veterinary recommendations;

ii) availability of suitable facilities for the assembly, *loading*, transport, *unloading* and holding of animals at the start and at the end of the *journey*, and for emergencies.

e) The responsibilities of shipping companies include:

(under study)

f) The responsibilities of masters of *vessels* include the provision of suitable premises for animals on the *vessel*.

g) The responsibilities of managers of facilities during *loading* include:

i) providing suitable premises for *loading* the animals;

ii) providing an appropriate number of *animal handlers* to load the animals with minimum stress and the avoidance of injury;

iii) minimising the opportunities for disease transmission while the animals are in the facilities;

iv) providing appropriate facilities for emergencies;

v) providing facilities, *veterinarians* or *animal handlers* capable of *killing* animals humanely when required.

h) The responsibilities of managers of facilities during *unloading* include:

i) providing suitable facilities for *unloading* the animals onto transport *vehicles* for immediate movement or securely holding the animals in lairage, with shelter, water and feed, when required, for transit;

ii) providing *animal handlers* to unload the animals with minimum stress and injury;

iii) minimising the opportunities for disease transmission while the animals are in the facilities;

iv) providing appropriate facilities for emergencies;

v) providing facilities, and *veterinarians* or *animal handlers* capable of *killing* animals humanely when required.

i) The responsibilities of the *animal handlers* include humane handling and care of the animals, especially during *loading* and *unloading*.

j) The responsibilities of the *Competent Authority* of the *exporting country* include:

i) establishing minimum standards for animal welfare, including requirements for inspection of animals before and during their travel, and for certification and record keeping;

ii) approving facilities, *containers*, *vehicles* and *vessels* for the holding and transport of animals;

iii) setting competence standards for *animal handlers* and managers of facilities;

iv) implementation of the standards, including through accreditation of / interaction with other organisations and *Competent Authorities*;

v) monitor and evaluate health and welfare performance, including the use of any veterinary medications.

k) The responsibilities of the *Competent Authority* of the *importing country* include:

i) establishing minimum standards for animal welfare, including requirements for inspection of animals after their travel, and for certification and record keeping;

ii) approve facilities, *containers*, *vehicles* and *vessels* for the holding and transport of animals;

iii) setting competence standards for *animal handlers* and managers of facilities;

iv) implementation of the standards, including through accreditation of / interaction with other organisations and *Competent Authorities*;

v) ensuring that the *exporting country* is aware of the required standards for the *vessel* transporting the animals;

vi) monitor and evaluate health and welfare performance, including the use of any veterinary medications;

vii) give animal consignments priority to allow import procedures to be completed without unnecessary delay.

l) The responsibilities of *veterinarians* or in the absence of a *veterinarian*, the *animal handlers* travelling on the *vessel* with the animals include:

i) humane handling and treatment of animals during the *journey*, including in emergencies, such as humane *killing* of the animals;

ii) possess ability to report and act independently;

iii) meet daily with the master of the *vessel* to obtain up-to-date information on animal health and welfare status.

m) The receiving *Competent Authority* should report back to the sending *Competent Authority* on significant animal welfare problems which occurred during the *journey*.

Article 3.7.2.4.

Competence

1. All people responsible for animals during *journeys* should be competent to carry out the relevant responsibilities listed in Article 3.7.2.3. Competence in areas other than animal welfare would need to be addressed separately. Competence may be gained through formal training and/or practical experience.

2. The assessment of competence of *animal handlers* should at a minimum address knowledge, and ability to apply that knowledge, in the following areas:

a) planning a *journey*, including appropriate *space allowance*, feed, water and ventilation requirements;

b) responsibilities for the welfare of animals during the *journey*, including *loading* and *unloading*;

c) sources of advice and assistance;

d) animal behaviour, general signs of disease, and indicators of poor animal welfare such as stress, pain and fatigue, and their alleviation;

e) assessment of fitness to travel; if fitness to travel is in doubt, the animal should be examined by a *veterinarian*;

f) relevant authorities and applicable transport regulations, and associated documentation requirements;

g) general disease prevention procedures, including cleaning and *disinfection*;

h) appropriate methods of animal handling during transport and associated activities such as assembling, *loading* and *unloading*;

i) methods of inspecting animals, managing situations frequently encountered during transport such as adverse weather conditions, and dealing with emergencies, including euthanasia;

j) species-specific aspects and age-specific aspects of animal handling and care, including feeding, watering and inspection; and

k) maintaining a *journey* log and other records.

3. Assessment of competence for exporters should at a minimum address knowledge, and ability to apply that knowledge, in the following areas:

a) planning a *journey*, including appropriate *space allowances*, and feed, water and ventilation requirements;

b) relevant authorities and applicable transport regulations, and associated documentation requirements;

c) appropriate methods of animal handling during transport and associated activities such as cleaning and *disinfection*, assembling, *loading* and *unloading*;

d) species-specific aspects of animal handling and care, including appropriate equipment and medication;

e) sources of advice and assistance;

f) appropriate record keeping; and

g) managing situations frequently encountered during transport, such as adverse weather conditions, and dealing with emergencies.

Article 3.7.2.5.

Planning the journey

1. General considerations

a) Adequate planning is a key factor affecting the welfare of animals during a *journey*.

b) Before the *journey* starts, plans should be made in relation to:

i) preparation of animals for the *journey*;

ii) type of transport *vessel* required;

iii) route, taking into account distance, expected weather and sea conditions;

iv) nature and duration of *journey*;

v) daily care and management of the animals, including the appropriate number of *animal handlers*, to help ensure the health and welfare of all the animals;

vi) avoiding the mixing of animals from different sources in a single pen group;

vii) provision of appropriate equipment and medication for the numbers and species carried; and

viii) emergency response procedures.

2. Preparation of animals for the journey

a) When animals are to be provided with a novel diet or unfamiliar methods of supplying of feed or water, they should be preconditioned.

b) There should be planning for water and feed availability during the *journey*. Feed should be of appropriate quality and composition for the species, age, condition of the animals, etc.

c) Extreme weather conditions are hazards for animals undergoing transport and require appropriate *vessel* design to minimise risks. Special precautions should be taken for animals that have not been acclimatised or which are unsuited to either hot or cold conditions. In some extreme conditions of heat or cold, animals should not be transported at all.

d) Animals more accustomed to contact with humans and with being handled are likely to be less fearful of being loaded and transported. Animals should be handled and loaded in a manner that reduces their fearfulness and improves their approachability.

e) Behaviour-modifying (such as tranquillisers) or other medication should not be used routinely during transport. Such medicines should only be administered when a problem exists in an individual animal, and should be administered by a *veterinarian* or other person who has been instructed in their use by a *veterinarian*. Treated animals should be placed in a dedicated area.

3. Control of disease

As animal transport is often a significant factor in the spread of infectious diseases, *journey* planning should take into account the following:

a) When possible and agreed by the *Veterinary Authority* of the *importing country*, animals should be vaccinated against diseases to which they are likely to be exposed at their destination.

b) Medications used prophylactically or therapeutically should only be administered by a *veterinarian* or other person who has been instructed in their use by a *veterinarian*.

c) Mixing of animals from different sources in a single consignment should be minimized.

4. Vessel and container design and maintenance

a) *Vessels* used for the sea transport of animals should be designed, constructed and fitted as appropriate to the species, size and weight of the animals to be transported. Special attention should be paid to the avoidance of injury to animals through the use of secure smooth fittings free from sharp protrusions and

the provision of non-slippery flooring. The avoidance of injury to *animal handlers* while carrying out their responsibilities should be emphasised.

b) *Vessels* should be properly illuminated to allow animals to be observed and inspected.

c) *Vessels* should be designed to permit thorough cleaning and *disinfection*, and the management of faeces and urine.

d) *Vessels* and their fittings should be maintained in good mechanical and structural conditions.

e) *Vessels* should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported. The ventilation system should be effective when the *vessel* is stationary. An emergency power supply should be available to maintain ventilation in the case of primary machinery breakdown.

f) The feeding and watering system should be designed to permit adequate access to feed and water appropriate to the species, size and weight of the animals, and to minimise soiling of pens.

g) *Vessels* should be designed so that the faeces or urine from animals on upper levels do not soil animals on lower levels, or their feed or water.

h) Loading and stowage of feed and bedding should be carried out in such a way to ensure protection from fire hazards, the elements and sea water.

i) Where appropriate, suitable bedding, such as straw or sawdust, should be added to *vessel* floors to assist absorption of urine and faeces, provide better footing for animals and protect animals (especially young animals) from hard or rough flooring surfaces and adverse weather conditions.

j) The above principles apply also to *containers* used for the transport of animals.

5. Special provisions for transport in road vehicles on roll-on/roll-off vessels or for containers

a) Road *vehicles* and *containers* should be equipped with a sufficient number of adequately designed, positioned and maintained securing points enabling them to be securely fastened to the *vessel*.

b) Road *vehicles* and *containers* should be secured to the ship before the start of the sea journey to prevent them being displaced by the motion of the *vessel*.

c) *Vessels* should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported, especially where the animals are transported in a secondary *vehicle/container* on enclosed decks.

d) Due to the risk of limited airflow on certain decks of a *vessel*, a road *vehicle* or *container* may require a forced ventilation system of greater capacity than that provided by natural ventilation.

6. Nature and duration of the journey

The maximum duration of a *journey* should be determined taking into account factors that determine the overall welfare of animals, such as:

a) the ability of the animals to cope with the stress of transport (such as very young, old, lactating or pregnant animals);

b) the previous transport experience of the animals;

c) the likely onset of fatigue;

d) the need for special attention;

e) the need for feed and water;

f) the increased susceptibility to injury and disease;

g) *space allowance* and *vessel* design;

h) weather conditions;

i) *vessel* type used, method of propulsion and risks associated with particular sea conditions.

7. Space allowance

a) The number of animals which should be transported on a *vessel* and their allocation to different pens on the *vessel* should be determined before *loading*.

b) The amount of space required, including headroom, depends on the species of animal and should allow the necessary thermoregulation. Each animal should be able to assume its natural position for transport (including during *loading* and *unloading*) without coming into contact with the roof or upper deck of the *vessel*. When animals lie down, there should be enough space for every animal to adopt a normal lying posture.

c) Calculations for the *space allowance* for each animal should be carried out in reference to a relevant national or international document. The size of pens will affect the number of animals in each.

d) The same principles apply when animals are transported in *containers*.

8. Ability to observe animals during the journey

Animals should be positioned to enable each animal to be observed regularly and clearly by an *animal handler* or other responsible person, during the *journey* to ensure their safet and good welfare.

9. Emergency response procedures

There should be an emergency management plan that identifies the important adverse events that may be encountered during the *journey*, the procedures for managing each event and the action to be taken in an emergency. For each important event, the plan should document the actions to be undertaken and the responsibilities of all parties involved, including communications and record keeping.

Article 3.7.2.6.

Documentation

1. Animals should not be loaded until the documentation required to that point is complete.

2. The documentation accompanying the consignment should include:

a) *journey* travel plan and emergency management plan;

b) time, date and place of *loading*;

c) the *journey* log – a daily record of inspection and important events which includes records of morbidity and mortality and actions taken, climatic conditions, food and water consumed, medication provided, mechanical defects;

d) expected time, date and place of arrival and *unloading*;

e) veterinary certification, when required;

f) *animal identification* to allow animal *traceability of animals* to the premises of departure, and, where possible, to the premises of origin;

g) details of any animals considered at particular risk of suffering poor welfare during transport (point 3e) of Article 3.7.2.7.);

h) number of *animal handlers* on board, and their competencies; and

i) *stocking density* estimate for each load in the consignment.

3. When veterinary certification is required to accompany consignments of animals, it should address:

a) when required, details of *disinfection* carried out;

b) fitness of the animals to travel;

c) *animal identification* (description, number, etc.); and

d) health status including any tests, treatments and vaccinations carried out.

Article 3.7.2.7.

Pre-journey period

1. General considerations

   a) Before each *journey*, *vessels* should be thoroughly cleaned and, if necessary, treated for animal and public health purposes, using chemicals approved by the *Competent Authority*. When cleaning is necessary during a *journey*, this should be carried out with the minimum of stress to the animals.

   b) In some circumstances, animals may require pre-*journey* assembly. In these circumstances, the following points should be considered:

      i) Pre-*journey* rest is necessary if the welfare of the animals has become poor during the collection period because of the physical environment or the social behaviour of the animals.

      ii) For animals such as pigs which are susceptible to motion sickness, and in order to reduce urine and faeces production during the *journey*, a species-specific short period of feed deprivation prior to *loading* is desirable.

      iii) When animals are to be provided with a novel diet or unfamiliar methods of supplying feed or water, they should be preconditioned.

   c) Where an *animal handler* believes that there is a significant risk of disease among the animals to be loaded or significant doubt as to their fitness to travel, the animals should be examined by a *veterinarian*.

   d) Pre-*journey* assembly / holding areas should be designed to:

      i) securely contain the animals;

      ii) maintain an environment safe from hazards, including predators and disease;

      iii) protect animals from exposure to adverse weather conditions;

      iv) allow for maintenance of social groups; and

      v) allow for rest, watering and feeding.

2. Selection of compatible groups

   Compatible groups should be selected before transport to avoid adverse animal welfare consequences. The following guidelines should be applied when assembling groups of animals:

   a) animals of different species should not be mixed unless they are judged to be compatible;

   b) animals of the same species can be mixed unless there is a significant likelihood of aggression; aggressive individuals should be segregated (recommendations for specific species are described in detail in Article 3.7.2.12.). For some species, animals from different groups should not be mixed because poor welfare occurs unless they have established a social structure;

   c) young or small animals may need to be separated from older or larger animals, with the exception of nursing mothers with young at foot;

   d) animals with horns or antlers should not be mixed with animals lacking horns or antlers, unless judged to be compatible; and

   e) animals reared together should be maintained as a group; animals with a strong social bond, such as a dam and offspring, should be transported together.

3. Fitness to travel

   a) Animals should be inspected by a *veterinarian* or an *animal handler* to assess fitness to travel. If its fitness to travel is in doubt, it is the responsibility of a *veterinarian* to determine its ability to travel. Animals found unfit to travel should not be loaded onto a *vessel*.

   b) Humane and effective arrangements should be made by the owner or agent for the handling and care of any animal rejected as unfit to travel.

   c) Animals that are unfit to travel include, but may not be limited to:

      i) those that are sick, injured, weak, disabled or fatigued;

ii) those that are unable to stand unaided or bear weight on each leg;

iii) those that are blind in both eyes;

iv) those that cannot be moved without causing them additional suffering;

v) newborn with an unhealed navel;

vi) females travelling without young which have given birth within the previous 48 hours;

vii) pregnant animals which would be in the final 10% of their gestation period at the planned time of *unloading*;

viii) animals with unhealed wounds from recent surgical procedures such as dehorning.

d) Risks during transport can be reduced by selecting animals best suited to the conditions of travel and those that are acclimatised to expected weather conditions.

e) Animals at particular risk of suffering poor welfare during transport and which require special conditions (such as in the design of facilities and *vehicles*, and the length of the *journey*) and additional attention during transport, may include:

i) very large or obese individuals;

ii) very young or old animals;

iii) excitable or aggressive animals;

iv) animals subject to motion sickness;

v) animals which have had little contact with humans;

vi) females in the last third of pregnancy or in heavy lactation.

f) Hair or wool length should be considered in relation to the weather conditions expected during transport.

Article 3.7.2.8.

Loading

1. Competent supervision

a) *Loading* should be carefully planned as it has the potential to be the cause of poor welfare in transported animals.

b) *Loading* should be supervised by the *Competent Authority* and conducted by *animal handler(s)*. *Animal handlers* should ensure that animals are loaded quietly and without unnecessary noise, harassment or force, and that untrained assistants or spectators do not impede the process.

2. Facilities

a) The facilities for *loading*, including the collecting area at the wharf, races and loading ramps should be designed and constructed to take into account the needs and abilities of the animals with regard to dimensions, slopes, surfaces, absence of sharp projections, flooring, sides, etc.

b) Ventilation during *loading* and the *journey* should provide for fresh air, and the removal of excessive heat, humidity and noxious fumes (such as ammonia and carbon monoxide). Under warm and hot conditions, ventilation should allow for the adequate convective cooling of each animal. In some instances, adequate ventilation can be achieved by increasing the *space allowance* for animals.

c) *Loading* facilities should be properly illuminated to allow the animals to be easily inspected by *animal handlers*, and to allow the ease of movement of animals at all times. Facilities should provide uniform light levels directly over approaches to sorting pens, chutes, loading ramps, with brighter light levels inside *vehicles / containers*, in order to minimise baulking. Dim light levels may be advantageous for the catching of some animals. Artificial lighting may be required.

3. Goads and other aids

When moving animals, their species specific behaviour should be used (see Article 3.7.2.12.). If goads and other aids are necessary, the following principles should apply:

a) 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.

b) 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.

c) 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 rattles; they should be used in a manner sufficient to encourage and direct movement of the animals without causing undue stress.

d) Painful procedures (including whipping, 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.

e) 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.

f) The use of well trained dogs to help with the *loading* of some species may be acceptable.

g) 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 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.

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

i) Performance standards should be established in which numerical scoring is used to evaluate the use of such instruments, and to measure the percentage of animals moved with an electric instrument and the percentage of animals slipping or falling as a result of their usage.

Article 3.7.2.9.

Travel

1. General considerations

a) *Animal handler(s)* should check the consignment immediately before departure to ensure that the animals have been loaded according to the load plan. Each consignment should be checked following any incident or situation likely to affect their welfare and in any case within 12 hours of departure.

b) If necessary and where possible adjustments should be made to the *stocking density* as appropriate during the *journey*.

c) Each pen of animals should be observed on a daily basis for normal behaviour, health and welfare, and the correct operation of ventilation, watering and feeding systems. There should also be a night patrol. Any necessary corrective action should be undertaken promptly.

d) Adequate access to suitable feed and water should be ensured for all animals in each pen.

e) Where cleaning or *disinfestation* is necessary during travel, it should be carried out with the minimum of stress to the animals.

2. Sick or injured animals

a) Sick or injured animals should be segregated.

b) Sick or injured animals should be appropriately treated or humanely killed, in accordance with a predetermined emergency response plan (Article 3.7.2.5.). Veterinary advice should be sought if necessary. All drugs and products should be used according to recommendations from a *veterinarian* and in accordance with the manufacturer's instructions.

c) A record of treatments carried out and their outcomes should be kept.

d) When humane killing is necessary, the *animal handler* must ensure that it is carried out humanely. Recommendations for specific species are described in Appendix 3.7.6. on killing of animals for disease control purposes. Veterinary advice regarding the appropriateness of a particular method of euthanasia should be sought as necessary.

Article 3.7.2.10.

Unloading and post-journey handling

1. General considerations

a) The required facilities and the principles of animal handling detailed in Article 3.7.2.8. apply equally to *unloading*, but consideration should be given to the likelihood that the animals will be fatigued.

b) *Unloading* should be carefully planned as it has the potential to be the cause of poor welfare in transported animals.

c) A livestock *vessel* should have priority attention when arriving in port and have priority access to a berth with suitable *unloading* facilities. As soon as possible after the *vessel*'s arrival at the port and acceptance of the consignment by the *Competent Authority*, animals should be unloaded into appropriate facilities.

d) The accompanying veterinary certificate and other documents should meet the requirements of the *importing country*. The veterinary inspection should be completed as quickly as possible.

e) *Unloading* should be supervised by the *Competent Authority* and conducted by *animal handler(s)*. The *animal handlers* should ensure that animals are unloaded as soon as possible after arrival but sufficient time should be allowed for *unloading* to proceed quietly and without unnecessary noise, harassment or force, and that untrained assistants or spectators do not impede the process.

2. Facilities

a) The facilities for *unloading* including the collecting area at the wharf, races and unloading ramps should be designed and constructed to take into account of the needs and abilities of the animals with regard to dimensions, slopes, surfaces, absence of sharp projections, flooring, sides, etc.

b) All *unloading* facilities should have sufficient lighting to allow the animals to be easily inspected by the *animal handlers*, and to allow ease of movement of animals at all times.

c) There should be facilities to provide animals with appropriate care and comfort, adequate space, access to quality feed and clean drinking water, and shelter from extreme weather conditions.

3. Sick or injured animals

a) An animal that has become sick, injured or disabled during a journey should be appropriately treated or humanely killed (see Appendix 3.7.6.). When necessary, veterinary advice should be sought in the care and treatment of these animals.

b) In some cases, where animals are non-ambulatory due to fatigue, injury or sickness, it may be in the best welfare interests of the animal to be treated or humanely killed aboard the *vessel*.

c) If *unloading* is in the best welfare interests of animals that are fatigued, injured or sick, there should be appropriate facilities and equipment for the humane *unloading* of such animals. These animals should be

unloaded in a manner that causes the least amount of suffering. After *unloading*, separate pens and other appropriate facilities and treatments should be provided for sick or injured animals.

4. Cleaning and disinfection

   a) *Vessels* and *containers* used to carry the animals should be cleaned before re-use through the physical removal of manure and bedding, by scraping, washing and flushing *vessels* and *containers* with water until visibly clean. This should be followed by *disinfection* when there are concerns about disease transmission.

   b) Manure litter and bedding should be disposed of in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.

Article 3.7.2.11.

Actions in the event of a refusal to allow the importation of a shipment

1. The welfare of the animals should be the first consideration in the event of a refusal to import.

2. When animals have been refused import, the *Competent Authority* of the *importing country* should make available suitable isolation facilities to allow the *unloading* of animals from a *vessel* and their secure holding, without posing a risk to the health of the national herd, pending resolution of the situation. In this situation, the priorities should be:

   a) The *Competent Authority* of the *importing country* should provide urgently in writing the reasons for the refusal.

   b) In the event of a refusal for animal health reasons, the *Competent Authority* of the *importing country* should provide urgent access to an OIE-appointed *veterinarian(s)* to assess the health status of the animals with regard to the concerns of the *importing country*, and the necessary facilities and approvals to expedite the required diagnostic testing.

   c) The *Competent Authority* of the *importing country* should provide access to allow continued assessment of the ongoing health and welfare situation.

   d) If the matter cannot be promptly resolved, the *Competent Authorities* of the *exporting* and *importing countries* should call on the OIE to mediate.

3. In the event that the animals are required to remain on the *vessel*, the priorities should be:

   a) The *Competent Authority* of the *importing country* should allow provisioning of the *vessel* with water and feed as necessary.

   b) The *Competent Authority* of the *importing country* should provide urgently in writing the reasons for the refusal.

   c) In the event of a refusal for animal health reasons, the *Competent Authority* of the *importing country* should provide urgent access to an OIE-appointed *veterinarian(s)* to assess the health status of the animals with regard to the concerns of the *importing country*, and the necessary facilities and approvals to expedite the required diagnostic testing.

   d) The *Competent Authority* of the *importing country* should provide access to allow continued assessment of the ongoing health and other aspects of the welfare of the animals, and the necessary actions to deal with any issues which arise.

   e) If the matter cannot be urgently resolved, the *Competent Authorities* of the *exporting* and *importing countries* should call on the OIE to mediate.

4. The OIE should utilise its dispute settlement mechanism to identify a mutually agreed solution which will address the animal health and welfare issues in a timely manner.

Species specific issues

Camelids of the new world in this context comprise llamas, alpacas, guanaco and vicuna. They have good eyesight and, like sheep, can negotiate steep slopes, though ramps should be as shallow as possible. They load most easily in a bunch as a single animal will strive to rejoin the others. Whilst they are usually docile, they have an unnerving habit of spitting in self-defence. During transport, they usually lie down. They frequently extend their front legs forward when lying, so gaps below partitions should be high enough so that their legs are not trapped when the animals rise.

Cattle are sociable animals and may become agitated if they are singled out. Social order is usually established at about two years of age. When groups are mixed, social order has to be re-established and aggression may occur until a new order is established. Crowding of cattle may also increase aggression as the animals try to maintain personal space. Social behaviour varies with age, breed and sex; *Bos indicus* and *B. indicus*-cross animals are usually more temperamental than European breeds. Young bulls, when moved in groups, show a degree of playfulness (pushing and shoving) but become more aggressive and territorial with age. Adult bulls have a minimum personal space of six square metres. Cows with young calves can be very protective, and handling calves in the presence of their mothers can be dangerous. Cattle tend to avoid "dead end" in passages.

Goats should be handled calmly and are more easily led or driven than if they are excited. When goats are moved, their gregarious tendencies should be exploited. Activities which frighten, injure or cause agitation to animals should be avoided. Bullying is particularly serious in goats. Housing strange goats together could result in fatalities, either through physical violence, or subordinate goats being refused access to food and water.

Horses in this context include all solipeds, donkeys, mules, hinnies and zebra. They have good eyesight and a very wide angle of vision. They may have a history of *loading* resulting in good or bad experiences. Good training should result in easier *loading*, but some horses can prove difficult, especially if they are inexperienced or have associated *loading* with poor transport conditions. In these circumstances, two experienced *animal handlers* can load an animal by linking arms or using a strop below its rump. Blindfolding may even be considered. Ramps should be as shallow as possible. Steps are not usually a problem when horses mount a ramp, but they tend to jump a step when descending, so steps should be as low as possible. Horses benefit from being individually stalled, but may be transported in compatible groups. When horses are to travel in groups, their shoes should be removed.

Pigs have poor eyesight, and may move reluctantly in unfamiliar surroundings. They benefit from well lit loading bays. Since they negotiate ramps with difficulty, these should be as level as possible and provided with secure footholds. Ideally, a hydraulic lift should be used for greater heights. Pigs also negotiate steps with difficulty. A good 'rule-of-thumb' is that no step should be higher than the pig's front knee. Serious aggression may result if unfamiliar animals are mixed. Pigs are highly susceptible to heat stress.

Sheep are sociable animals with good eyesight and tend to "flock together", especially when they are agitated. They should be handled calmly and their tendency to follow each other should be exploited when they are being moved. Sheep may become agitated if they are singled out for attention and will strive to rejoin the group. Activities which frighten, injure or cause agitation to sheep should be avoided. They can negotiate steep ramps.

APPENDIX 3.7.3.

GUIDELINES FOR THE TRANSPORT OF ANIMALS BY LAND

Preamble: These guidelines apply to the following live domesticated animals: cattle, buffaloes, camels, sheep, goats, pigs, poultry and equines. They will also be largely applicable to some other animals (e.g., deer, other camelids and ratites). Wild, feral and partly domesticated animals may need different conditions.

Article 3.7.3.1.

The amount of time animals spend on a *journey* should be kept to the minimum.

Article 3.7.3.2.

I. 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 herds and follow a leader by instinct.

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

The desire of some animals to control their personal space should be taken into account in designing *loading* and *unloading* facilities, transport *vessels* and *containers*.

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.

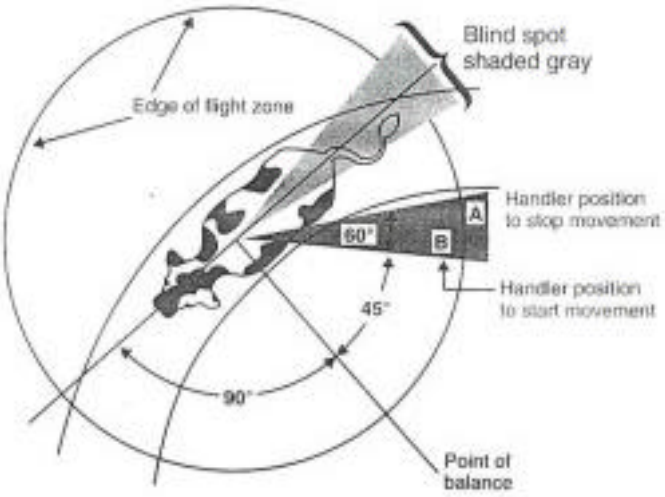
Animal handlers should use the point of balance at the animal's shoulder to move animals, adopting a position behind the point of balance to move an animal forward and in front of the point of balance to move it backward.

Domestic animals have a wide-angle vision but only have a 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.

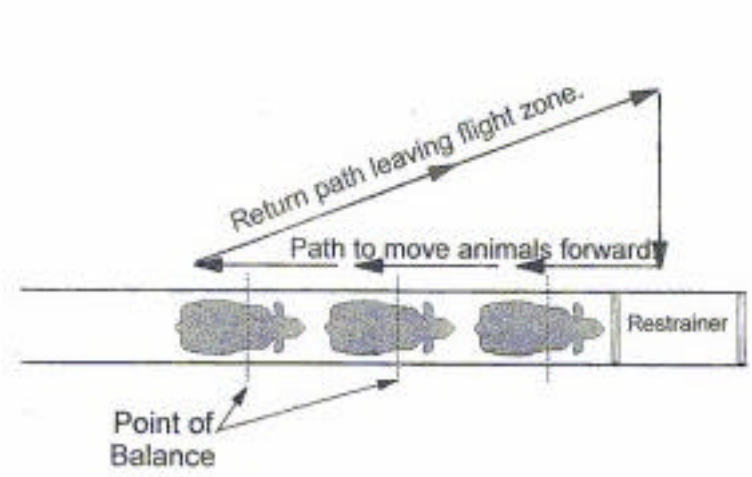
Although all domestic animals have a highly sensitive sense of smell, they may react differently to the smells encountered during travel. Smells which cause fear or other negative responses should be taken into consideration when managing animals.

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 noises 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



2. Distractions and their removal

Design of new *loading* and *unloading* facilities or modification of existing facilities should aim to minimise the potential for distractions that may cause approaching animals to stop, baulk or turn back. 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 - illuminate with indirect lighting which does not shine directly into the eyes of approaching animals;

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 – avoid uneven floor surfaces or install a solid false floor 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.

Article 3.7.3.3.

Responsibilities

Once the decision to transport the animals has been made, the welfare of the animals during their *journey* is the paramount consideration and is the joint responsibility of all people involved. The individual responsibilities of persons involved will be described in more detail in this Article.

The roles of each of those responsible are defined below:

1. The owners and managers of the animals are responsible for:

   a) the general health, overall welfare and fitness of the animals for the *journey*;

   b) ensuring compliance with any required veterinary or other certification;

   c) the presence of an *animal handler* competent for the species being transported during the *journey* with the authority to take prompt action; in case of transport by individual trucks, the truck driver may be the sole *animal handler* during the *journey*;

   d) the presence of an adequate number of *animal handlers* during *loading* and *unloading*;

   e) ensuring that equipment and veterinary assistance are provided as appropriate for the species and the *journey*.

2. Business agents or buying/selling agents are responsible for:

   a) selection of animals that are fit to travel;

   b) availability of suitable facilities at the start and at the end of the *journey* for the assembly; *loading*, transport, *unloading* and holding of animals, including for any stops at *resting points* during the *journey* and for emergencies.

3. *Animal handlers* are responsible for the humane handling and care of the animals, especially during *loading* and *unloading*, and for maintaining a *journey* log. To carry out their responsibilities, they should have the authority to take prompt action. In the absence of a separate *animal handler*, the driver is the *animal handler*.

4. Transport companies, *vehicle* owners and drivers are responsible for planning the *journey* to ensure the care of the animals; in particular they are responsible for:

   a) choosing appropriate *vehicles* for the species transported and the *journey*;

   b) ensuring that properly trained staff are available for *loading/unloading* of animals;

   c) ensuring adequate competency of the driver in matters of animal welfare for the species being transported in case a separate *animal handler* is not assigned to the truck;

   d) developing and and keeping up-to-date contingency plans to address emergencies (including adverse weather conditions) and minimise stress during transport;

   e) producing a *journey* plan which includes a *loading* plan, *journey* duration, itinerary and location of resting places;

   f) *loading* only those animals which are fit to travel, for their correct *loading* into the *vehicle* and their inspection during the *journey*, and for appropriate responses to problems arising; if its fitness to travel is in doubt, the animal should be examined by a *veterinarian* in accordance with point 3a) of Article 3.7.3.7.;

   g) welfare of the animals during the actual transport.

5. Managers of facilities at the start and at the end of the *journey* and at *resting points* are responsible for:

   a) providing suitable premises for *loading*, *unloading* and securely holding the animals, with water and feed when required, until further transport, sale or other use (including rearing or slaughter);

   b) providing an adequate number of *animal handlers* to load, unload, drive and hold animals in a manner that causes minimum stress and injury; in the absence of a separate *animal handler*, the driver is the *animal handler*;

   c) minimising the opportunities for disease transmission;

   d) providing appropriate facilities, with water and feed when required;

   e) providing appropriate facilities for emergencies;

   f) providing facilities for washing and disinfecting *vehicles* after *unloading*;

   g) providing facilities and competent staff to allow the humane *killing* of animals when required;

   h) ensuring proper rest times and minimal delay during stops.

6. The responsibilities of *Competent Authorities* include:

   a) establishing minimum standards for animal welfare, including requirements for inspection of animals before, during and after their travel, defining 'fitness to travel' and appropriate certification and record keeping;

   b) setting standards for facilities, *containers* and *vehicles* for the transport of animals;

   c) setting standards for the competence of *animal handlers*, drivers and managers of facilities in relevant issues in animal welfare;

   d) ensuring appropriate awareness and training of *animal handlers*, drivers and managers of facilities in relevant issues in animal welfare;

   e) implementation of the standards, including through accreditation of / interaction with other organisations;

   f) monitoring and evaluating the effectiveness of standards of health;

   g) monitoring and evaluating the use of veterinary medications;

   h) giving animal consignments priority at frontiers in order to allow them to pass without unnecessary delay.

7. All individuals, including *veterinarians*, involved in transporting animals and the associated handling procedures should receive appropriate training and be competent to meet their responsibilities.

8. The receiving *Competent Authority* should report back to the sending *Competent Authority* on significant animal welfare problems which occurred during the *journey*.

Article 3.7.3.4.

Competence

1. All people responsible for animals during *journeys*, should be competent according to their responsibilities listed in Article 3.7.3.3. Competence may be gained through formal training and/or practical experience.

2. The assessment of the competence of *animal handlers* should at a minimum address knowledge, and ability to apply that knowledge, in the following areas:

   a) planning a *journey*, including appropriate *space allowance*, and feed, water and ventilation requirements;

   b) responsibilities for animals during the *journey*, including *loading* and *unloading*;

   c) sources of advice and assistance;

   d) animal behaviour, general signs of disease, and indicators of poor animal welfare such as stress, pain and fatigue, and their alleviation;

   e) assessment of fitness to travel; if fitness to travel is in doubt, the animal should be examined by a *veterinarian*;

f) relevant authorities and applicable transport regulations, and associated documentation requirements;

g) general disease prevention procedures, including cleaning and *disinfection*;

h) appropriate methods of animal handling during transport and associated activities such as assembling, *loading* and *unloading*;

i) methods of inspecting animals, managing situations frequently encountered during transport such as adverse weather conditions, and dealing with emergencies, including humane *killing*;

j) species-specific aspects and age-specific aspects of animal handling and care, including feeding, watering and inspection; and

k) maintaining a *journey* log and other records.

Article 3.7.3.5.

Planning the journey

1. General considerations

a) Adequate planning is a key factor affecting the welfare of animals during a *journey*.

b) Before the *journey* starts, plans should be made in relation to:

i) preparation of animals for the *journey*;

ii) choice of road, rail, roll-on roll-off vessels or *containers*;

iii) nature and duration of the *journey*;

iv) *vehicle* design and maintenance, including roll-on roll-off vessels;

v) required documentation;

vi) *space allowance*;

vii) rest, water and feed;

viii) observation of animals en route;

ix) control of disease;

x) emergency response procedures;

xi) forecast weather conditions (e.g. conditions being too hot or too cold to travel during certain periods of the day);

xii) transfer time when changing mode of transport, and

xiii) waiting time at frontiers and inspection points.

c) Regulations concerning drivers (for example, maximum driving periods) should take into account animal welfare whenever is possible.

2. Preparation of animals for the journey

a) When animals are to be provided with a novel diet or method of water provision during transport, an adequate period of adaptation should be planned. Species-specific short period of feed deprivation prior to *loading* may be desirable.

b) Animals more accustomed to contact with humans and with being handled are likely to be less fearful of being loaded and transported. *Animal handlers* should handle and load animals in a manner that reduces their fearfulness and improves their approachability.

c) Behaviour-modifying compounds (such as tranquillisers) or other medication should not be used routinely during transport. Such compounds should only be administered when a problem exists in an individual animal, and should be administered by a *veterinarian* or other person who has been instructed in their use by a *veterinarian*.

3. Nature and duration of the journey

The maximum duration of a *journey* should be determined according to factors such as:

a) the ability of the animals to cope with the stress of transport (such as very young, old, lactating or pregnant animals);

b) the previous transport experience of the animals;

c) the likely onset of fatigue;

d) the need for special attention;

e) the need for feed and water;

f) the increased susceptibility to injury and disease;

g) *space allowance*, *vehicle* design, road conditions and driving quality;

h) weather conditions;

i) *vehicle* type used, terrain to be traversed, road surfaces and quality, skill and experience of the driver.

4. Vehicle and container design and maintenance

a) *Vehicles* and *containers* used for the transport of animals should be designed, constructed and fitted as appropriate for the species, size and weight of the animals to be transported. Special attention should be paid to avoid injury to animals through the use of secure smooth fittings free from sharp protrusions. The avoidance of injury to drivers and *animal handlers* while carrying out their responsibilities should be emphasised.

b) *Vehicles* and *containers* should be designed with the structures necessary to provide protection from adverse weather conditions and to minimise the opportunity for animals to escape.

c) In order to minimise the likelihood of the spread of infectious disease during transport, *vehicles* and *containers* should be designed to permit thorough cleaning and *disinfection*, and the containment of faeces and urine during a *journey*.

d) *Vehicles* and *containers* should be maintained in good mechanical and structural condition.

e) *Vehicles* and *containers* should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported; the ventilation system (natural or mechanical) should be effective when the *vehicle* is stationary, and the airflow should be adjustable.

f) *Vehicles* should be designed so that the faeces or urine from animals on upper levels do not soil animals on lower levels, nor their feed and water.

g) When *vehicles* are carried on board ferries, facilities for adequately securing them should be available.

h) If feeding or watering while the *vehicle* is moving is required, adequate facilities on the *vehicle* should be available.

i) When appropriate, suitable bedding should be added to *vehicle* floors to assist absorption of urine and faeces, to minimise slipping by animals, and protect animals (especially young animals) from hard flooring surfaces and adverse weather conditions.

5. Special provisions for transport in vehicles (road and rail) on roll-on/roll-off vessels or for containers

a) *Vehicles* and *containers* should be equipped with a sufficient number of adequately designed, positioned and maintained securing points enabling them to be securely fastened to the *vessel*.

b) *Vehicles* and *containers* should be secured to the *vessel* before the start of the sea *journey* to prevent them being displaced by the motion of the *vessel*.

c) Roll-on/roll-off *vessels* should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported, especially where the animals are transported in a secondary *vehicle/container* on enclosed decks.

6. Space allowance

a) The number of animals which should be transported on a *vehicle* or in a *container* and their allocation to compartments should be determined before *loading*.

b) The space required on a *vehicle* or in a *container* depends upon whether or not the animals need to lie down (for example, pigs, camels and poultry), or to stand (horses). Animals which will need to lie down often stand when first loaded or when the *vehicle* is driven with too much lateral movement or sudden braking.

c) When animals lie down, they should all be able to adopt a normal lying posture which allows necessary thermoregulation.

d) When animals are standing, they should have sufficient space to adopt a balanced position as appropriate to the climate and species transported.

e) The amount of headroom necessary depends on the species of animal. Each animal should be able to assume its natural position for transport (including during *loading* and *unloading*) without coming into contact with the roof or upper deck of the *vehicle*, and there should be sufficient headroom to allow adequate airflow over the animals.

f) Calculations for the *space allowance* for each animal should be carried out using the figures given in a relevant national or international document. The number and size of pens on the *vehicle* should be varied to where possible accommodate already established groups of animals while avoiding group sizes which are too large.

g) Other factors which may influence *space allowance* include:

i) *vehicle / container* design;

ii) length of *journey*;

iii) need to provide feed and water on the *vehicle*;

iv) quality of roads;

v) expected weather conditions;

vi) category and sex of the animals.

7. Rest, water and feed

a) Suitable water and feed should be available as appropriate and needed for the species, age, and condition of the animals, as well as the duration of the *journey*, climatic conditions, etc.

b) Animals should be allowed to rest at *resting points* at appropriate intervals during the *journey*. The type of transport, the age and species of the animals being transported, and climatic conditions should determine the frequency of rest stops and whether the animals should be unloaded. Water and feed should be available during rest stops.

8. Ability to observe animals during the journey

a) Animals should be positioned to enable each animal to be observed regularly during the *journey* to ensure their safety and good welfare.

b) If the animals are in crates or on multi-tiered *vehicles* which do not allow free access for observation, for example where the roof of the tier is too low, animals cannot be inspected adequately, and serious injury or disease could go undetected. In these circumstances, a shorter *journey* duration should be allowed, and the maximum duration will vary according to the rate at which problems arise in the species and under the conditions of transport.

9. Control of disease

As animal transport is often a significant factor in the spread of infectious diseases, *journey* planning should take the following into account:

a) mixing of animals from different sources in a single consignment should be minimised;

b) contact at *resting points* between animals from different sources should be avoided;

c) when possible, animals should be vaccinated against diseases to which they are likely to be exposed at their destination;

d) medications used prophylactically or therapeutically should be approved by the *Veterinary Authority* of the *importing country* and should only be administered by a *veterinarian* or other person who has been instructed in their use by a *veterinarian*.

10. Emergency response procedures

There should be an emergency management plan that identifies the important adverse events that may be encountered during the *journey*, the procedures for managing each event and the action to be taken in an emergency. For each important event, the plan should document the actions to be undertaken and the responsibilities of all parties involved, including communications and record keeping.

11. Other considerations

a) Extreme weather conditions are hazardous for animals undergoing transport and require appropriate *vehicle* design to minimise risks. Special precautions should be taken for animals that have not been acclimatised or which are unsuited to either hot or cold conditions. In some extreme conditions of heat or cold, animals should not be transported at all.

b) In some circumstances, transportation during the night may reduce thermal stress or the adverse effects of other external stimuli.

Article 3.7.3.6.

Documentation

1. Animals should not be loaded until the documentation required to that point is complete.

2. The documentation accompanying the consignment should include:

a) *journey* travel plan and emergency management plan;

b) date, time and place of *loading* and *unloading*;

c) veterinary certification, when required;

d) animal welfare competencies of the driver (under study);

e) *animal identification* to allow *animal traceability* to the premises of departure and, where possible, to the premises of origin;

f) details of any animals considered at particular risk of suffering poor welfare during transport (point 3e) of Article 3.7.3.7.);

g) documentation of the period of rest, and access to feed and water, prior to the *journey*;

h) *stocking density* estimate for each load in the consignment;

i) the *journey* log - daily record of inspection and important events, including records of morbidity and mortality and actions taken, climatic conditions, rest stops, travel time and distance, feed and water offered and estimates of consumption, medication provided, and mechanical defects.

3. When veterinary certification is required to accompany consignments of animals, it should address:

a) fitness of animals to travel;

b) *animal identification* (description, number, etc.);

c) health status including any tests, treatments and vaccinations carried out;

d) when required, details of *disinfection* carried out.

At the time of certification, the *veterinarian* should notify the *animal handler* or the driver of any factors affecting the fitness of animals to travel for a particular *journey*.

Article 3.7.3.7.

Pre-journey period

1. General considerations

   a) Pre-*journey* rest is necessary if the welfare of animals has become poor during the collection period because of the physical environment or the social behaviour of the animals. The need for rest should be judged by a *veterinarian* or other competent person.

   b) Pre-*journey* assembly/holding areas should be designed to:

      i) securely hold the animals;

      ii) maintain a safe environment from hazards, including predators and disease;

      iii) protect animals from exposure to severe weather conditions;

      iv) allow for maintenance of social groups;

      v) allow for rest, and appropriate water and feed.

   c) Consideration should be given to the previous transport experience, training and conditioning of the animals, if known, as these may reduce fear and stress in animals.

   d) Feed and water should be provided pre-*journey* if the *journey* duration is greater than the normal inter-feeding and drinking interval for the animal. Recommendations for specific species are described in detail in Article 3.7.3.12.

   e) When animals are to be provided with a novel diet or method of feed or water provision during the *journey*, an adequate period of adaptation should be allowed.

   f) Before each *journey*, *vehicles* and *containers* should be thoroughly cleaned and, if necessary, treated for animal health and public health purposes, using methods approved by the *Competent Authority*. When cleaning is necessary during a *journey*, this should be carried out with the minimum of stress to the animals.

   g) Where an *animal handler* believes that there is a significant risk of disease among the animals to be loaded or significant doubt as to their fitness to travel, the animals should be examined by a *veterinarian*.

2. Selection of compatible groups

   Compatible groups should be selected before transport to avoid adverse animal welfare consequences. The following guidelines should be applied when assembling groups of animals:

   a) Animals reared together should be maintained as a group; animals with a strong social bond, such as a dam and offspring, should be transported together.

   b) Animals of the same species can be mixed unless there is a significant likelihood of aggression; aggressive individuals should be segregated (recommendations for specific species are described in detail in Article 3.7.3.12.). For some species, animals from different groups should not be mixed because poor welfare occurs unless they have established a social structure.

   c) Young or small animals should be separated from older or larger animals, with the exception of nursing mothers with young at foot.

   d) Animals with horns or antlers should not be mixed with animals lacking horns or antlers unless judged to be compatible.

   e) Animals of different species should not be mixed unless they are judged to be compatible.

3. Fitness to travel

   a) Each animal should be inspected by a *veterinarian* or an *animal handler* to assess fitness to travel. If its fitness to travel is in doubt, the animal should be examined by a *veterinarian*. Animals found unfit to travel should not be loaded onto a *vehicle*, except for transport to receive veterinary treatment.

   b) Humane and effective arrangements should be made by the owner and the agent for the handling and care of any animal rejected as unfit to travel.

c) Animals that are unfit to travel include, but may not be limited to:

i) those that are sick, injured, weak, disabled or fatigued;

ii) those that are unable to stand unaided and bear weight on each leg;

iii) those that are blind in both eyes;

iv) those that cannot be moved without causing them additional suffering;

v) newborn with an unhealed navel;

vi) pregnant animals which would be in the final 10% of their gestation period at the planned time of *unloading*;

vii) females travelling without young which have given birth within the previous 48 hours;

viii) those whose body condition would result in poor welfare because of the expected climatic conditions.

d) Risks during transport can be reduced by selecting animals best suited to the conditions of travel and those that are acclimatised to expected weather conditions.

e) Animals at particular risk of suffering poor welfare during transport and which require special conditions (such as in the design of facilities and *vehicles*, and the length of the *journey*) and additional attention during transport, may include:

i) large or obese individuals;

ii) very young or old animals;

iii) excitable or aggressive animals;

iv) animals which have had little contact with humans;

v) animal subject to motion sickness;

vi) females in late pregnancy or heavy lactation, dam and offspring;

vii) animals with a history of exposure to stressors or pathogenic agents prior to transport;

viii) animals with unhealed wounds from recent surgical procedures such as dehorning.

4. Specific species requirements

Transport procedures should be able to take account of variations in the behaviour of the species. Flight zones, social interactions and other behaviour vary significantly among species and even within species. Facilities and handling procedures that are successful with one species are often ineffective or dangerous with another.

Recommendations for specific species are described in detail in Article 3.7.3.12.

Article 3.7.3.8.

Loading

1. Competent supervision

a) *Loading* should be carefully planned as it has the potential to be the cause of poor welfare in transported animals.

b) *Loading* should be supervised and/or conducted by *animal handlers*. The animals are to be loaded quietly and without unnecessary noise, harassment or force. Untrained assistants or spectators should not impede the process.

c) When *containers* are loaded onto a *vehicle*, this should be carried out in such a way to avoid poor animal welfare.

2. Facilities

a) The facilities for *loading* including the collecting area, races and loading ramps should be designed and constructed to take into account the needs and abilities of the animals with regard to dimensions, slopes, surfaces, absence of sharp projections, flooring, etc.

b) *Loading* facilities should be properly illuminated to allow the animals to be observed by *animal handler(s)*, and to allow the ease of movement of the animals at all times. Facilities should provide uniform light levels directly over approaches to sorting pens, chutes, loading ramps, with brighter light levels inside *vehicles / containers*, in order to minimise baulking. Dim light levels may be advantageous for the catching of poultry and some other animals. Artificial lighting may be required.

c) Ventilation during *loading* and the *journey* should provide for fresh air, the removal of excessive heat, humidity and noxious fumes (such as ammonia and carbon monoxide), and the prevention of accumulations of ammonia and carbon dioxide. Under warm and hot conditions, ventilation should allow for the adequate convective cooling of each animal. In some instances, adequate ventilation can be achieved by increasing the *space allowance* for animals.

3. Goads and other aids

When moving animals, their species specific behaviour should be used (see Article 3.7.3.12.). If goads and other aids are necessary, the following principles should apply:

a) 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.

b) 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.

c) 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 rattles; they should be used in a manner sufficient to encourage and direct movement of the animals without causing undue stress.

d) Painful procedures (including whipping, 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.

e) 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.

f) The use of well trained dogs to help with the *loading* of some species may be acceptable.

g) 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 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.

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

i) Performance standards should be established in which numerical scoring is used to evaluate the use of such instruments, and to measure the percentage of animals moved with an electric instrument and the percentage of animals slipping or falling as a result of their usage.

Travel

1. General considerations

   a) Drivers and *animal handlers* should check the load immediately before departure to ensure that the animals have been properly loaded. Each load should be checked again early in the trip and adjustments made as appropriate. Periodic checks should be made throughout the trip, especially at rest or refuelling stops or during meal breaks when the *vehicle* is stationary.

   b) Drivers should utilise smooth, defensive driving techniques, without sudden turns or stops, to minimise uncontrolled movements of the animals.

2. Methods of restraining or containing animals

   a) Methods of restraining animals should be appropriate to the species and age of animals involved and the training of the individual animal.

   b) Recommendations for specific species are described in detail in Article 3.7.3.12.

3. Regulating the environment within vehicles or containers

   a) Animals should be protected against harm from hot or cold conditions during travel. Effective ventilation procedures for maintaining the environment within *vehicles* or *containers* will vary according to whether conditions are cold, hot and dry or hot and humid, but in all conditions a build-up of noxious gases should be prevented.

   b) The environment within *vehicles* or *containers* in hot and warm weather can be regulated by the flow of air produced by the movement of the *vehicle*. In warm and hot weather, the duration of *journey* stops should be minimised and *vehicles* should be parked under shade, with adequate and appropriate ventilation.

   c) To minimise slipping and soiling, and maintain a healthy environment, urine and faeces should be removed from floors when necessary and disposed of in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.

4. Sick, injured or dead animals

   a) A driver or an *animal handler* finding sick, injured or dead animals should act according to a predetermined emergency response plan.

   b) Sick or injured animals should be segregated.

   c) Ferries (roll-on roll-off) should have procedures to treat sick or injured animals during the *journey*.

   d) In order to reduce the likelihood that animal transport will increase the spread of infectious disease, contact between transported animals, or the waste products of the transported animals, and other farm animals should be minimised.

   e) During the *journey*, when disposal of a dead animal becomes necessary, this should be carried out in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.

   f) When *killing* is necessary, it should be carried out as quickly as possible and assistance should be sought from a *veterinarian* or other person(s) competent in humane *killing* procedures. Recommendations for specific species are described in Appendix 3.7.6. on killing of animals for disease control purposes.

5. Water and feed requirements

   a) If *journey* duration is such that feeding or watering is required or if the species requires feed or water throughout, access to suitable feed and water for all the animals (appropriate for their species and age) carried in the *vehicle* should be provided. There should be adequate space for all animals to move to the feed and water sources and due account taken of likely competition for feed.

   b) Recommendations for specific species are described in detail in Article 3.7.3.12.

6. Rest periods and conditions including hygiene

   a) Animals that are being transported should be rested at appropriate intervals during the *journey* and offered feed and water, either on the *vehicle* or, if necessary, unloaded into suitable facilities.

   b) Suitable facilities should be used en route, when resting requires the *unloading* of the animals. These facilities should meet the needs of the particular animal species and should allow access of all animals to feed and water.

7. In-transit observations

   a) Animals being transported by road should be observed soon after a *journey* is commenced and whenever the driver has a rest stop. After meal breaks and refuelling stops, the animals should be observed immediately prior to departure.

   b) Animals being transported by rail should be observed at each scheduled stop. The responsible rail transporter should monitor the progress of trains carrying animals and take all appropriate action to minimise delays.

   c) During stops, it should be ensured that the animals continue to be properly confined, have appropriate feed and water, and their physical condition is satisfactory.

Article 3.7.3.10.

Unloading and post-journey handling

1. General considerations

   a) The required facilities and the principles of animal handling detailed in Article 3.7.3.8. apply equally to *unloading*, but consideration should be given to the likelihood that the animals will be fatigued.

   b) *Unloading* should be supervised and/or conducted by an *animal handler* with knowledge and experience of the behavioural and physical characteristics of the species being unloaded. Animals should be unloaded from the *vehicle* into appropriate facilities as soon as possible after arrival at the destination but sufficient time should be allowed for *unloading* to proceed quietly and without unnecessary noise, harassment or force.

   c) Facilities should provide all animals with appropriate care and comfort, adequate space and ventilation, access to feed (if appropriate) and water, and shelter from extreme weather conditions.

   d) For details regarding the *unloading* of animals at a *slaughterhouse*, see Appendix 3.7.5. on slaughter of animals for human consumption.

2. Sick or injured animals

   a) An animal that has become sick, injured or disabled during a *journey* should be appropriately treated or humanely killed (see Appendix 3.7.6. on killing of animals for disease control purposes). If necessary, veterinary advice should be sought in the care and treatment of these animals. In some cases, where animals are non-ambulatory due to fatigue, injury or sickness, it may be in the best welfare interests of the animal to be treated or killed aboard the *vehicle*. Assistance should be sought from a *veterinarian* or other person(s) competent in humane *killing* procedures.

   b) At the destination, the *animal handler* or the driver during transit should ensure that responsibility for the welfare of sick, injured or disabled animals is transferred to a *veterinarian* or other suitable person.

   c) If treatment or humane *killing* is not possible aboard the *vehicle*, there should be appropriate facilities and equipment for the humane *unloading* of animals that are non-ambulatory due to fatigue, injury or sickness. These animals should be unloaded in a manner that causes the least amount of suffering. After *unloading*, separate pens and other appropriate facilities should be available for sick or injured animals.

   d) Feed, if appropriate, and water should be available for each sick or injured animal.

3. Addressing disease risks

The following should be taken into account in addressing the greater risk of disease due to animal transport and the possible need for segregation of transported animals at the destination:

a) increased contact among animals, including those from different sources and with different disease histories;

b) increased shedding of pathogens and increased susceptibility to infection related to stress and impaired defences against disease, including immunosuppression;

c) exposure of animals to pathogens which may contaminate *vehicles*, *resting points*, *markets*, etc.

4. Cleaning and disinfection

a) *Vehicles*, crates, *containers*, etc. used to carry the animals should be cleaned before re-use through the physical removal of manure and bedding by scraping, washing and flushing with water and detergent. This should be followed by *disinfection* when there are concerns about disease transmission.

b) Manure, litter, bedding and the bodies of any animals which die during the *journey* should be disposed of in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.

c) Establishments like livestock *markets*, *slaughterhouses*, resting sites, railway stations, etc. where animals are unloaded should be provided with appropriate areas for the cleaning and *disinfection* of *vehicles*.

Article 3.7.3.11.

Actions in the event of a refusal to allow the completion of the journey

1. The welfare of the animals should be the first consideration in the event of a refusal to allow the completion of the *journey*.

2. When the animals have been refused import, the *Competent Authority* of the *importing country* should make available suitable isolation facilities to allow the *unloading* of animals from a *vehicle* and their secure holding, without posing a risk to the health of national herd or flock, pending resolution of the situation. In this situation, the priorities should be:

a) the *Competent Authority* of the *importing country* should provide urgently in writing the reasons for the refusal;

b) in the event of a refusal for animal health reasons, the *Competent Authority* of the *importing country* should provide urgent access to a *veterinarian*, where possible an OIE *veterinarian(s)* appointed by the Director General, to assess the health status of the animals with regard to the concerns of the *importing country*, and the necessary facilities and approvals to expedite the required diagnostic testing;

c) the *Competent Authority* of the *importing country* should provide access to allow continued assessment of the health and other aspects of the welfare of the animals;

d) if the matter cannot be promptly resolved, the *Competent Authorities* of the *exporting* and *importing countries* should call on the OIE to mediate.

3. In the event that a *Competent Authority* requires the animals to remain on the *vehicle*, the priorities should be:

a) to allow provisioning of the *vehicle* with water and feed as necessary;

b) to provide urgently in writing the reasons for the refusal;

c) to provide urgent access to an independent *veterinarian(s)* to assess the health status of the animals, and the necessary facilities and approvals to expedite the required diagnostic testing in the event of a refusal for animal health reasons;

d) to provide access to allow continued assessment of the health and other aspects of the welfare of the animals, and the necessary actions to deal with any animal issues which arise.

4. The OIE should utilise its dispute settlement mechanism to identify a mutually agreed solution which will address animal health and any other welfare issues in a timely manner.

Species specific issues

Camelids of the new world in this context comprise llamas, alpacas, guanaco and vicuna. They have good eyesight and, like sheep, can negotiate steep slopes, though ramps should be as shallow as possible. They load most easily in a bunch as a single animal will strive to rejoin the others. Whilst they are usually docile, they have an unnerving habit of spitting in self-defence. During transport, they usually lie down. They frequently extend their front legs forward when lying, so gaps below partitions should be high enough so that their legs are not trapped when the animals rise.

Cattle are sociable animals and may become agitated if they are singled out. Social order is usually established at about two years of age. When groups are mixed, social order has to be re-established and aggression may occur until a new order is established. Crowding of cattle may also increase aggression as the animals try to maintain personal space. Social behaviour varies with age, breed and sex; *Bos indicus* and *B. indicus*-cross animals are usually more temperamental than European breeds. Young bulls, when moved in groups, show a degree of playfulness (pushing and shoving) but become more aggressive and territorial with age. Adult bulls have a minimum personal space of six square metres. Cows with young calves can be very protective, and handling calves in the presence of their mothers can be dangerous. Cattle tend to avoid "dead end" in passages.

Goats should be handled calmly and are more easily led or driven than if they are excited. When goats are moved, their gregarious tendencies should be exploited. Activities which frighten, injure or cause agitation to animals should be avoided. Bullying is particularly serious in goats and can reflect demands for personal space. Housing strange goats together could result in fatalities, either through physical violence, or subordinate goats being refused access to food and water.

Horses in this context include donkeys, mules and hinnies. They have good eyesight and a very wide angle of vision. They may have a history of *loading* resulting in good or bad experiences. Good training should result in easier *loading*, but some horses can prove difficult, especially if they are inexperienced or have associated *loading* with poor transport conditions. In these circumstances, two experienced *animal handlers* can load an animal by linking arms or using a strop below its rump. Blindfolding may even be considered. Ramps should be as shallow as possible. Steps are not usually a problem when horses mount a ramp, but they tend to jump a step when descending, so steps should be as low as possible. Horses benefit from being individually stalled, but may be transported in compatible groups. When horses are to travel in groups, their shoes should be removed. Horses are prone to respiratory disease if they are restricted by period by tethers that prevent the lowering and lifting of their heads.

Pigs have poor eyesight, and may move reluctantly in unfamiliar surroundings. They benefit from well lit loading bays. Since they negotiate ramps with difficulty, these should be as level as possible and provided with secure footholds. Ideally, a hydraulic lift should be used for greater heights. Pigs also negotiate steps with difficulty. A good 'rule-of-thumb' is that no step should be higher than the pig's front knee. Serious aggression may result if unfamiliar animals are mixed. Pigs are highly susceptible to heat stress.

Sheep are sociable animals with good eyesight, a relatively subtle and undemonstrative behaviour and a tendency to "flock together", especially when they are agitated. They should be handled calmly and their tendency to follow each other should be exploited when they are being moved. Crowding of sheep may lead to damaging aggressive and submissive behaviours as animals try to maintain personal space. Sheep may become agitated if they are singled out for attention, or kept alone, and will strive to rejoin the group. Activities which frighten, injure or cause agitation to sheep should be avoided. They can negotiate steep ramps.

APPENDIX 3.7.4.

GUIDELINES FOR THE TRANSPORT OF ANIMALS BY AIR

Article 3.7.4.1.

Livestock containers

1. Design

a) General principles of design

The container should:

- conform to the size of the standard pallet of the aircraft that will be used to transport animals; the common sizes are: 224 x 318 cm (88 x 125 in.) and 244 x 318 cm (96 x 125 in.);
- not be constructed of material that could be harmful to the animals health or welfare;
- allow observation of the animals and be marked on opposite sides with the International Air Transport Association (IATA) symbols which indicate animals and the upright position;
- allow emergency access to animals;
- allow the animal to stand in its normal position without touching the roof of the container or, in the case of open containers, the restraining nets, and provide at least 10 cm (4 in.) clearance above the animal's head when standing in its normal position; in the case of horses, provide sufficient space above the horses head (21 cm, 8 in. recommended) to allow for the movement required to maintain the horses balance;
- protect the animals from adverse weather;
- ensure animals stand on a suitable floor to prevent slipping or injury;
- have adequate strength to ensure the safety of the animals and to prevent the animals from escaping;
- ensure doors can be opened and closed easily, but be secured so that they cannot be opened accidentally;
- be free of any nails, bolts and other protrusions or sharp edges that could cause injuries;
- be designed to minimise the risk of any opening or space entrapping any portion of the animals body;
- if reusable, crates should be constructed of impermeable material that is easily cleaned and disinfected;
- ensure faeces and urine cannot escape from the crate; this requires a minimum upturn of 20 cm but it must not block any ventilation openings;
- if designated for stacking be stable, not block any ventilation space and prevent urine and faeces from leaking into the containers below when stacked;
- allow for a facility for provision of water and possibly food during transportation of longer than 6 hours duration.

b) Ventilation

The container design should:

- provide adequate ventilation taking into consideration the species stocking density, maximum temperature and humidity of the points of departure, destination, and any interim technical stops;
- allow the normal resting or sleeping position to be assumed for certain species and juvenile animals;
- ensure there is no dead air space in the container;

- provide ventilation openings on the walls equal to at least 16% of the wall area; this may be reduced if the container has an open top;
- in the case of two-tiered containers, ventilation in the sides should be for cattle equivalent to not less than 20% of the floor area of each deck, and for pigs and sheep up to 40% of the floor area of each deck;
- have ventilation openings on all four sides of the crate except that two walls may have reduced ventilation space and the other walls have increased space where required by the positioning of the crates during transportation and/or the ventilation pattern of the aircraft;
- ensure that any internal supports or dividers do not block the cross ventilation;
- not have a solid wall above the height of the animal's head in normal resting position;
- in those species where the mouth is normally held near the floor, have at least 25 cm (10 in.) of ventilation space at the level of the animal's head; this opening should be divided in two with a maximum height for any opening of 13 cm; in all containers, there should be a sufficiently large ventilation opening at a height of 25 cm to 30 cm (10 to 11 in.) above floor level on all four sides to allow for circulation;
- have some physical means of ensuring the ventilation space is not blocked, such as the use of cleats (wedges) or allowing space between the outside of the container and the pallet.

2. Species requirements

In general, fractious animals or animals in late pregnancy should not be transported by air (see Article 3.7.4.2.).

a) Horses

Should be transported in containers and be separated from each other if they are more than 145 cm (57 in.) in height.

Crates used to transport horses should:

- be strong enough to prevent unruly horses from breaking or escaping from the container under any circumstances;
- in the case of multi-horse containers, have partitions of sufficient strength and size to separate the horses and to support each horse's weight;
- adjust to allow mare and foal to travel together;
- provide the same percentage of open space for ventilation as required in point 1 above, divided between the two side walls; however, if the access doors are constructed in such a manner that they may be left open during the flight, the door space may be included in the ventilation space;
- be constructed to minimise noise;
- allow access to the head during the flight;
- have the front end notched and padded to accept the neck of the animal;
- have a secure point for attaching restraining devices;
- have a front and rear barrier that will restrict the movement of the horse and will ensure that liquids are deflected into the container;
- ensure horses cannot bite other animals;
- be constructed to resist kicking;
- have no fittings or projections in the area likely to be kicked, metal plates should be covered with a protective material;
- ramps shall be non-skid in nature, have foot battens, and be of a maximum slope of 25 degrees when the container is on a standard 50 cm (20 in.) dolly;
- not have a step up or down of more than 25 cm (10 in.).

b) Swine

- Crate design and shipment planning should recognize that swine are extremely susceptible to high heat and humidity and that they normally carry their head near the floor.
- In the use of multi-tiered crates, special attention should be paid to ensure air can move through the crate, in accordance with the aircraft's ventilation pattern and capacity to remove heat.
- Crate construction should take into consideration the tendency for mature swine to chew.
- Litter should be dust-free, shavings or other non toxic materials may be used but not sawdust.
- Containers for immature swine should only be constructed when flight is imminent, since rapid growth can result in undersized containers if the flight is delayed.
- In order to reduce fighting, swine shipped in group pens should be housed together as a group prior to shipment and not be mixed with other swine before loading on the aircraft.
- Mature boars and incompatible females should be shipped in individual crates.
- Individual crates should be 20 cm (8 in.) longer than the body, 15 cm (6 in.) higher than the loin of the pig and of sufficient width, to allow the pigs to lie on their side.

c) Cattle

Crates used to transport cattle should:

- if multi-tiered or roofed, have at least 33% of the roof and four walls as open space;
- have at least one ventilation opening 20-25 cm (8-10 in.) above the floor which is of such width that it will not cause injuries to the feet.

Adult bulls should be transported separately unless they have been accustomed to each other. Cattle with and without horns should be separated from each other.

d) Other species

- Animals that normally exhibit a herding instinct, including buffalo and deer, can be shipped in group containers providing the mental and physical characteristics of the species are taken into consideration.
- All crates used to move such animals should have a roof or other method of preventing the animals from escaping.
- Animals in which the horns or antler cannot be removed, should be transported individually.
- Deer should not be transported in velvet nor in rut.

Article 3.7.4.2.

Guidelines for pregnant animals

Heavily pregnant animals should not be carried except under exceptional circumstances. Pregnant animals should not be accepted when the last service or exposure to a male prior to departure has exceeded the following time given here for guidance only:

Females		Maximum number of days since the last service or exposure to a male
Horses		300
Cows		250
Deer	(axis, fallow and sika)	170
	(red deer, reindeer)	185
Ewes (sheep)		115
Nannies (goats)		115
Sows (pigs)		90

Where service dates or date of last exposure to a male are not available, the animals should be examined by a veterinarian to ensure that pregnancy is not so advanced that animals are likely to give birth during transport or suffer unnecessarily.

Any animal showing udder engorgement and slackening of the pelvic ligament should be refused.

Article 3.7.4.3.

Stocking density

The current stocking densities agreed by the International Air Transport Association (IATA) should continue to be accepted. However, the graphs giving the space requirements should be extended to take into account animals larger and smaller than those dealt with currently.

1. General considerations

When calculating stocking rates, the following should be taken into account:

a) it is essential that accurate weights of animals are obtained in view of the limitations imposed by the load capabilities of the aircraft and the space required per animal;

b) in narrow bodied aircraft, there is a loss of floor area in the upper tier of two-tier penning due to the contours of the aircraft;

c) space available should be calculated on the inside measurements of the crates or penning system used, not on the floor space of the aircraft;

d) multi-tiered crates, high outdoor temperatures at departure, arrival or stopover points, or extreme length of the trip will require an increase in the amount of space per animal; a 10% decrease in stocking density is recommended for trips in excess of 24 hours;

e) special attention should be paid to the transport of sheep in heavy wool which require an increase in space allotted per animal and to pigs which have limited ability to dissipate heat;

f) animals confined in groups, especially in pens, should be stocked at a high enough density to prevent injuries at take-off, during turbulence and at landing, but not to the extent that individual animals cannot lie down and rise without risk of injury or crushing;

g) in multi-tiered shipments, it should be recognized that the ventilation and cooling capacity of the aircraft is the limiting factor, especially in narrow bodied aircraft. Ventilation capacity varies on each individual aircraft and between aircraft of the same model.

2. Guidelines for stocking densities

The following table gives stocking density guidelines for different domestic species:

Table 2. ***Calculation tables (in kilograms and metres)***

Species	Weight	Density	Space / animal	No. of animals per	Animals per single tier pallet	
	kg	kg / m^2	m^2	10 m^2	224x274 cm	224x318 cm
Calves	50	220	0.23	43	26	31
	70	246	0.28	36	22	25
Cattle	300	344	0.84	12	7	8
	500	393	1.27	8	5	6
	600	408	1.47	7	4	5
	700	400	1.75	6	3	4
Sheep	25	147	0.20	50	31	36
	70	196	0.40	25	15	18
Pigs	25	172	0.15	67	41	47
	100	196	0.51	20	12	14

Article 3.7.4.4.

Preparation for air transport of livestock

1. Health and customs requirements

   The legal requirements including animal health, welfare and species conservation, should be ascertained from the country of destination and any in transit countries before the animals are assembled or the transportation is arranged.

   Contact the *Veterinary Authorities* in the country of origin regarding veterinary certification.

   Planning of the transportation should take into account weekends, holidays and airport closures.

   Verify that any proposed intransit stops or alternates will not jeopardise the importing or in transit countries health requirements.

2. Environment

   Animals are affected by extremes of temperature. This is especially true of high temperature when compounded by high humidity. Temperature and humidity should therefore be taken into consideration when planning the shipment.

   Times of arrival, departure and stopovers should be planned so that the aircraft lands during the coolest hours.

   At outside temperatures of below 25°C at the landing point, the aircraft doors should be opened to ensure adequate ventilation. Confirmation should be received from government authorities that animal health legislation does not prevent opening of aircraft doors.

   When outside temperatures at any landing point exceed 25°C, prior arrangements should be made to have an adequate air-conditioning unit available when the plane lands.

3. Facilities and equipment

   Specific arrangements must be made to ensure that holding and loading facilities including ramps, trucks, and air-conditioning units are available at departure, all in transit and arrival airports. This should include identification of specific staff who are responsible and the method of contacting them, e.g. telephone number and address.

   Specific notification must be given to all those responsible for providing facilities or equipment at the destination and in transit stops immediately before departure.

   Containers should be loaded so as to ensure access can be made to the animals at all times.

4. Preparation of animals

   Vaccination must be done far enough in advance of the departure date to allow for immunity to develop.

   Veterinary certification and serological testing must be arranged several weeks in advance of livestock shipment.

   Many animals require acclimatisation before they are transported. Animals such as swine and wild herbivores must be separated and held in the groups that will occupy containers. Mixing of such animals immediately before or during transport is extremely stressing and should be avoided.

   Incompatible animals should be transported singly.

Article 3.7.4.5.

Disinfection and disinsectisation

1. Disinfection

   a) Those parts of the interior of the aircraft destined for the carriage of animals should be thoroughly cleaned of all foreign matters using methods acceptable to aircraft management before being loaded.

b) These parts should be sprayed with a disinfectant:

i) suitable for the diseases which could be carried by the animals;

ii) that does not cause problems with the aircraft;

iii) that will not leave a residue hazardous to the animals being transported.

If in doubt, the airline should be consulted on the suitability of the disinfectant. A mechanical nebuliser should be used to minimise the amount of disinfectant used.

Suggested disinfectants currently in use are:

iv) 4% sodium carbonate and 0.1% sodium silicate;

v) 0.2% citric acid.

c) All removeable equipment, penning and containers including loading ramps should be thoroughly cleaned and disinfected in accordance with the requirements of both the *exporting* and *importing countries.*

d) After *disinfection*, all equipment to be replaced in the aircraft should be washed with clean water to remove any traces of disinfectant to avoid any damage to the aircraft structures.

2. Disinsectisation

Where disinsectisation is required, the country requesting the action should be consulted for appropriate procedures.

The World Health Organisation (WHO) Recommendations on the Disinsectisation of Aircraft (*WHO Weekly Epidem. Rec.*, No. 7, 1985) are recognised as standard.

Article 3.7.4.6.

Radiation

Radioactive materials must be separated from live animals by a distance of at least 0.5 metre for journeys not exceeding 24 hours, and by a distance of at least 1.0 metre for journeys longer than 24 hours (reference: Technical instructions on storage and loading-separation of the International Civil Aviation Organisation). Special care should be taken with regard to pregnant animals, semen and embryos/ova.

Article 3.7.4.7.

Tranquilization

Experience has shown that there is considerable risk in sedating animals transported by air. Tranquilizers reduce the ability of the animals to respond to stress during transportation. In addition, the reaction of various species to tranquilization cannot always be foreseen. For these reasons, routine tranquilization is not recommended. Tranquilizers should only be used when a specific problem exists, and should be administered by a veterinarian or by a person who has been instructed in their use. Persons using these drugs should understand the full implications of the effects of the drug in air transport, e.g. certain animals such as horses and elephants should not go down in containers. Drugs should only be administered during the flight with the knowledge and consent of the captain.

In all cases, when tranquilizers are used, a note should be attached to the container stating the generic name of the drug used, the dose and the time given.

Article 3.7.4.8.

Destruction of carcasses

In the event of any animal death on board, the competent authority of the airport of destination should be notified in advance of landing.

Carcasses should be disposed of under the supervision of and to the satisfaction of the *Veterinary Authority* of the country the aircraft is in.

The method of disposal should be based on the risk of introducing a controlled disease.

For carcasses which represent a high risk of introducing disease, the following is recommended:

1. destruction by incineration, rendering or deep burial under the supervision of the *Veterinary Authority*;
2. if removed from the airport site, transportation in a closed, leakproof container.

Article 3.7.4.9.

Emergency slaughter

Emergency slaughter of animals in aircraft should, in general, only occur when the safety of the aircraft, crew or other animals are involved.

Every aircraft transporting animals should have a method of killing the animals with minimum pain and someone trained in that method.

In all cases when horses or other large animals are to be carried, the method of killing should be discussed with the airline during the planning stages. Suitable methods are:

1. Captive bolt stunner, followed by an injection of a lethal chemical
   a) Operator should be trained to use the captive bolt stunner on the species or type of animal being transported.
   b) An expert should determine that the type of captive bolt pistol is adequate for all the animals being transported.
   c) Some airlines and countries may prohibit the carriage of captive bolt pistols.
   d) The user should recognise that the noise associated with the captive bolt may excite other animals.
   e) The requirement that the captive bolt pistol is accurately centered may be difficult to achieve with an excited animal.
2. Injection of a chemical
   a) Various chemicals may be used to sedate, immobilize or kill animals.
   b) Central nervous system depressants such as barbiturate euthanasia solutions must be injected directly into a vein to be effective. This is not normally practical for anyone but an experienced veterinarian or an especially trained and experienced attendant, where the animal is sufficiently fractious to require euthanasia.
   c) Sedatives such as promazine and its derivatives may make the animal more fractious (see Article 3.7.4.7.).
   d) Immobilizing solutions such as succinylcholine are not humane.
3. Firearms

   Airlines do not permit the use of firearms which discharge a free bullet because of the danger to the aircraft.

Article 3.7.4.10.

Handling of food and waste material

Waste material which contains anything of animal origin including food, litter, manure, or animal feed should be handled, collected and disposed of in a manner that ensures it will not be fed to livestock. It should be collected in specified areas, and stored and transported in closed, leakproof containers.

Some *importing countries* legislation may prohibit or restrict the use of hay or straw during the transportation period. Unloading of hay, straw, other animal feed and litter may be restricted or prohibited by in transit countries.

Article 3.7.4.11.

Disposal of food and waste material

Recommended methods of disposal are:

a) incineration to an ash;

b) heating at an internal temperature of at least of 100°C for 30 minutes, then disposal in a land fill site;

c) controlled burial in a land fill site.

APPENDIX 3.7.5.

GUIDELINES FOR THE SLAUGHTER OF ANIMALS

Article 3.7.5.1.

General principles

1. Object

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

These guidelines 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 guidelines 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 guidelines outlined in the present Appendix 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 herds 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.

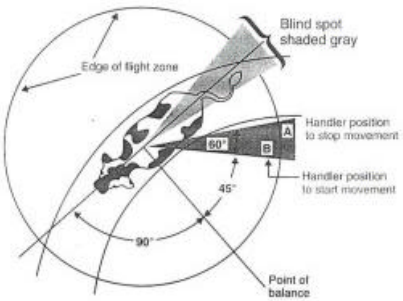
Animal handlers should use the point of balance at the animal's shoulder to move animals, adopting a position behind the point of balance to move an animal forward and in front of the point of balance to move it backward.

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.

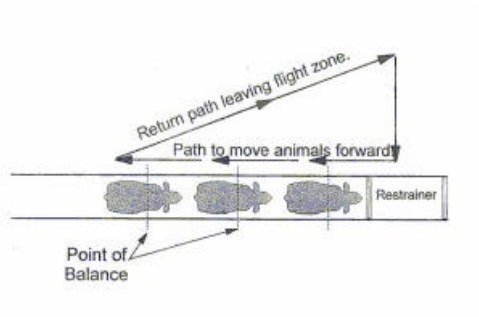
Although all domestic animals have a highly sensitive sense of smell, they react in different ways to the smells of *slaughterhouses*. Smells which cause fear or other negative responses should be taken into consideration when managing animals.

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;

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.

Article 3.7.5.2.

Moving and handling animals

1. General considerations

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 guidelines for the transportation of animals (Appendices 3.7.2. and 3.7.3.).

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 at the site where they are found in accordance with the OIE guidelines for the *killing* of animals for disease control purposes (Appendix 3.7.6.).

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

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

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

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

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

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, 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.

viii) 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.

2. 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.

3. Provisions relevant to restraining and containing animals

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

i) provision of a non-slippery floor;

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

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

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

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

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

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

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

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

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

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

Article 3.7.5.3.

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 guidelines may help to achieve this.

2. Design of lairages

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

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

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

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

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

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

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

h) 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 lairages

   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 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 3.7.5.4.

Care of animals in lairages

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

1. As far as possible, established groups of animals should be kept together. 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. If animals are not to be slaughtered as soon as possible, 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 euthanasia.

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.

Recommendations for specific species are described in detail in Articles 3.7.5.5. to 3.7.5.8.

Article 3.7.5.5.

Management of foetuses during slaughter of pregnant animals

Under normal circumstances, pregnant animals that would be in the final 10% of their gestation period at the planned time of *unloading* at the *slaughterhouse* should be neither transported nor slaughtered. If such an event occurs, an *animal handler* should ensure that females are handled separately, and the specific procedures described below are applied. In all cases, the welfare of 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 guidelines 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 3.7.5.6.

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

Summary analysis of handling and restraining methods

	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

Summary analysis of handling and restraining methods (contd)

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

Summary analysis of handling and restraining methods (contd)

	Presentation of animals	**Specific procedure**	**Specific purpose**	**Animal welfare concerns/ implications**	**Key animal welfare requirements**	**Applicable species**
Restraining methods (contd)	Upright restraint – manual or mechanical	Wing shackling	Electrical	Excessive tension applied prior to stunning	Competent animal handlers	Ostriches
Restraining and /or conveying methods	Mechanical - upright	V-restrainer	Electrical methods Captive bolt Slaughter without stunning	Loading of animal and overriding; excessive pressure, size mismatch between restrainer and animal	Proper design and operation of equipment	Cattle, calves, sheep, goats, pigs
	Mechanical-upright	Mechanical straddle – band restrainer (moving)	Electrical methods Captive bolt Slaughter without stunning	Loading of animal and overriding, size mismatch between restrainer and animal	Competent animal handlers, proper design and layout of restraint	Cattle, calves, sheep, goats, pigs
	Mechanical - upright	Flat bed/deck Tipped out of containers on to conveyors	Presentation of birds for shackling prior to electrical stunning Gas stunning	Stress and injury due to tipping in dump-module systems height of tipping conscious poultry broken bones and dislocations	Proper design and operation of equipment	Poultry
	Suspension and/or inversion	Poultry shackle	Electrical stunning Slaughter without stunning	Inversion stress; pain from compression on leg bones	Competent animal handlers; proper design and operation of equipment	Poultry
	Suspension and/or inversion	Cone	Electrical – head-only Captive bolt Slaughter without stunning	Inversion stress	Competent animal handlers; proper design and operation of equipment	Poultry
	Upright restraint	Mechanical leg clamping	Electrical – head-only	Stress of resisting restraint in ostriches	Competent animal handlers; proper equipment design and operation	Ostriches

Summary analysis of handling and restraining methods (contd)

	Presentation of animals	Specific procedure	Specific purpose	Animal welfare concerns / implications	Key animal welfare requirements	Applicable species
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
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

Summary analysis of handling and restraining methods (contd)

	Presentation of animals	Specific procedure	Specific purpose	Animal welfare concerns/ implications	Key animal welfare requirements	Applicable species
Leg restraints (contd)		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 3.7.5.7.

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 instrument 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.

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. 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.

Sheep

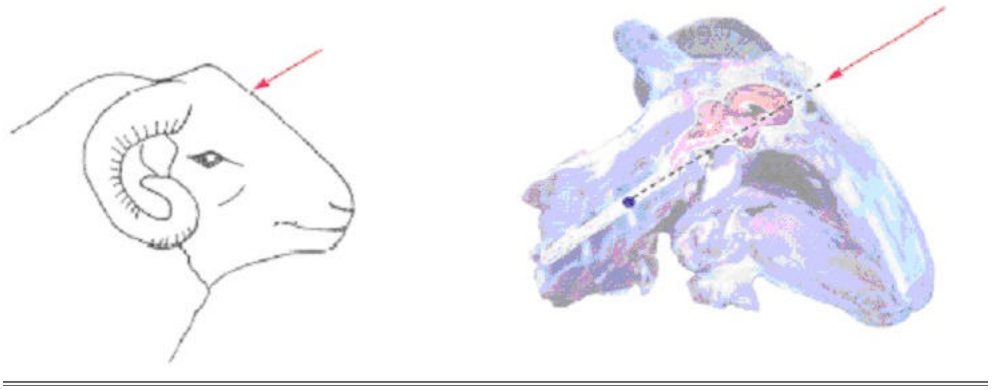


Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

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

Goats

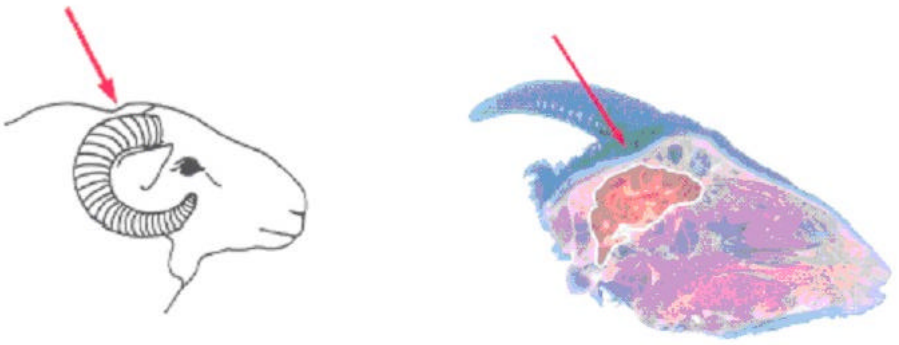


Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

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

Horses

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 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.

3. Electrical stunning

a) General considerations

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

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 required 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.

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

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.

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.

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

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

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

The shackle-to-leg contact should be wetted preferably before the birds are inserted in the shackles. In order to improve 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.

Birds should receive the current for at least 4 seconds.

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

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.

Frequency (Hz)	Chickens	Turkeys
< 200 Hz	100 mA	250 mA
From 200 to 400 Hz	150 mA	400 mA
From 400 to 1500 Hz	200 mA	400 mA

Every effort shall be made to ensure that no conscious or live birds enter th 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.

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% by volume but in any case no less than 80% by volume. After entering the *stunning* chamber, the animals should be conveyed to the point of maximum concentration of the gas as rapidly as possible and be kept until they are dead or brought into a state of insensibility which lasts until death occur due to bleeding. Ideally, pigs should be exposed to this concentration of 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 others.

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 dead or completely stunned.

b) Inert gas mixtures for stunning pigs

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

Such gas mixtures include:

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

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

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

c) Gas stunning of poultry

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

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.

i) Gas mixtures used for stunning poultry include:

- a minimum of 2 minutes exposure to 40% carbon dioxide, 30% oxygen and 30% nitrogen, followed by a minimum of one minute exposure to 80% carbon dioxide in air; or
- a minimum of 2 minutes exposure to any mixture of argon, nitrogen or other inert gases with atmospheric air and carbon dioxide, provided that the carbon dioxide concentration does not exceed 30% by volume and the residual oxygen concentration does not exceed 2% by volume; or
- a minimum of 2 minutes exposure to argon, nitrogen, other inert gases or any mixture of these gases in atmospheric air with a maximum of 2% residual oxygen by volume; or
- a minimum of 2 minutes exposure to a minimum of 55% carbon dioxide in air.

ii) Requirements for effective use are as follows:

- Compressed gases should be vaporised prior to administration into the chamber and should be at room temperature to prevent any thermal shock; under no circumstances, should solid gases with freezing temperatures enter the chamber.
- Gas mixtures should be humidified.
- Appropriate gas concentrations of oxygen and carbon dioxide should be monitored and displayed continuously at the level of the birds inside the chamber to ensure that anoxia ensues.

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

5. Bleeding

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

Stunning method	Maximum delay for bleeding to be started
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 3.7.5.8.

Summary analysis of stunning methods and the associated animal welfare issues

Summary analysis of stunning methods

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	(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	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.

Summary analysis of stunning methods (contd)

Method (contd)	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	

Summary analysis of stunning methods (contd)

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

Article 3.7.5.9.

Summary analysis of slaughter methods and the associated animal welfare issues

Summary of slaughter methods

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	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 60 seconds for mammals). The practice to remove hypothetical blood clots just after the bleeding should be discouraged since this may increase animal suffering.

Summary of slaughter methods (contd)

Slaughter methods (contd)	Specific method	Animal welfare concerns / implications	Key requirements	Species	Comments
Bleeding with prior stunning	Full frontal cutting across the throat	Failure to cut both common carotid arteries; occlusion of cut arteries; pain during and after the cut.	A very sharp blade or knife of sufficient length so that the point of the knife remains outside the incision during the cut; the point of the knife should not be used to make the incision. The incision should not close over the knife during the throat cut.	Cattle, buffalo, horses, camelids, sheep, goats	
	Neck stab followed by forward cut	Ineffective stunning; failure to cut both common carotid arteries; impaired blood flow; delay in cutting after reversible stunning	Prompt and accurate cutting	Camelids, sheep, goats, poultry, ratites	
	Neck stab alone	Ineffective stunning; failure to cut both common carotid arteries; impaired blood flow; delay in cutting after reversible stunning	Prompt and accurate cutting	Camelids, sheep, goats, poultry, ratites	
	Chest stick into major arteries or hollow-tube knife into heart	Ineffective stunning; inadequate size of stick wound inadequate length of sticking knife; delay in sticking after reversible stunning	Prompt and accurate sticking	Cattle, sheep, goats, pigs	
	Neck skin cut followed by severance of vessels in the neck	Ineffective stunning; inadequate size of stick wound; inadequate length of sticking knife; delay in sticking after reversible stunning	Prompt and accurate cutting of vessels	Cattle	

Summary of slaughter methods (contd)

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

Article 3.7.5.10.

Methods, procedures or practices unacceptable on animal welfare grounds

1. The restraining methods which work through 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.

APPENDIX 3.7.6.

GUIDELINES FOR THE KILLING OF ANIMALS FOR DISEASE CONTROL PURPOSES

Article 3.7.6.1.

General principles

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

1. All personnel involved in the humane *killing* of animals should have the relevant skills and competencies. Competence may be gained through formal training and/or practical experience.
2. As necessary, operational procedures should be adapted to the specific circumstances operating on the premises and should address, apart from animal welfare, aesthetics of the method of euthanasia, cost of the method, operator safety, biosecurity and environmental aspects, aesthetics of the method of euthanasia and cost of the method.
3. Following the decision to kill the animals, *killing* should be carried out as quickly as possible, and normal husbandry should be maintained until the animals are killed.
4. The handling and movement of animals should be minimised and when done, it should be done in accordance with the guidelines described below.
5. Animal *restraint* should be sufficient to facilitate effective *killing*, and in accordance with animal welfare and operator safety requirements; when *restraint* is required, *killing* should follow with minimal delay.
6. When animals are killed for disease control purposes, methods used should result in immediate death or immediate loss of consciousness lasting until death; when loss of consciousness is not immediate, induction of unconsciousness should be non-aversive and should not cause anxiety, pain, distress or suffering in animals.
7. For animal welfare considerations, young animals should be killed before older animals; for biosecurity considerations, infected animals should be killed first, followed by in-contact animals, and then the remaining animals.
8. There should be continuous monitoring of the procedures by the *Competent Authorities* to ensure they are consistently effective with regard to animal welfare, operator safety and biosecurity.
9. When the operational procedures are concluded, there should be a written report describing the practices adopted and their effect on animal welfare, operator safety and biosecurity.
10. These general principles should also apply when animals need to be killed for other purposes such as after natural disasters or for culling animal populations.

Article 3.7.6.2.

Organisational structure

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

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

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

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

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

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

In considering the animal welfare issues associated with *killing* animals, the key personnel, their responsibilities and competencies required are described in Article 3.7.6.3.

Article 3.7.6.3.

Responsibilities and competencies of the specialist team

1. Team leader
   a) Responsibilities
      i) plan overall operations on affected premises;
      ii) determine and address requirements for animal welfare, operator safety and biosecurity;
      iii) organise, brief and manage team of people to facilitate humane *killing* of the relevant animals on the premises in accordance with national regulations and these guidelines;
      iv) determine logistics required;
      v) monitor operations to ensure animal welfare, operator safety and biosecurity requirements are met;
      vi) report upwards on progress and problems;
      vii) provide a written report at the conclusion of the *killing*, describing the practices adopted and their effect on the animal welfare, operator safety and biosecurity outcomes.
   b) Competencies
      i) appreciation of normal animal husbandry practices;
      ii) appreciation of animal welfare and the underpinning behavioural, anatomical and physiological processes involved in the *killing* process;
      iii) skills to manage all activities on premises and deliver outcomes on time;
      iv) awareness of psychological effects on farmer, team members and general public;
      v) effective communication skills;
      vi) appreciation of the environmental impacts caused by their operation.
2. Veterinarian
   a) Responsibilities
      i) determine and supervise the implementation of the most appropriate *killing* method to ensure that animals are killed without avoidable pain and distress;
      ii) determine and implement the additional requirements for animal welfare, including the order of *killing*;
      iii) ensure that confirmation of the death of the animals is carried out by competent persons at appropriate times after the *killing* procedure;

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

v) continuously monitor animal welfare and biosecurity procedures;

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

b) Competencies

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

ii) ability to assess biosecurity risks.

3. Animal handlers

a) Responsibilities

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

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

iii) move and restrain animals;

iv) continuously monitor animal welfare and biosecurity procedures.

b) Competencies

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

ii) an appreciation of biosecurity and containment principles.

4. Animal killing personnel

a) Responsibilities

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

b) Competencies

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

ii) competent to use and maintain relevant equipment;

iii) competent to use techniques for the species involved;

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

5. Carcass disposal personnel

a) Responsibilities

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

b) Competencies

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

6. Farmer/owner/manager

a) Responsibilities

i) assist when requested.

b) Competencies

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

Article 3.7.6.4.

Considerations in planning the humane killing of animals

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

1. minimising handling and movement of animals;
2. *killing* the animals on the affected premises; however, there may be circumstances where the animals may need to be moved to another location for *killing*; when the *killing* is conducted at an *abattoir*, the guidelines in Appendix 3.7.5. on the slaughter of animals should be followed;
3. the species, number, age and size of animals to be killed, and the order of *killing* them;
4. methods of *killing* the animals, and their cost;
5. housing, husbandry, location of the animals as well as accessibility of the farm;
6. the availability and effectiveness of equipment needed for *killing* of the animals, as well as the time necessary to kill the required number of animals using such methods;
7. the facilities available on the premises that will assist with the *killing* including any additional facilities that may need to be brought on and then removed from the premises;
8. biosecurity and environmental issues;
9. the health and safety of personnel conducting the *killing*;
10. any legal issues that may be involved, for example where restricted veterinary drugs or poisons may be used, or where the process may impact on the environment;
11. the presence of other nearby premises holding animals;
12. possibilities for removal, disposal and destruction of carcasses.

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

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

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

Article 3.7.6.5.

Table summarising killing methods described in Articles 3.7.6.6.-3.7.6.17.

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

Summary of killing methods

Species	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
Cattle	all	free bullet	no	non-lethal wounding	3.7.6.6.

Summary of killing methods (contd)

Species (contd)	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
Cattle (contd)	all except neonates	penetrating captive bolt - followed by pithing or bleeding	yes	ineffective stunning	3.7.6.7.
	adults only	non-penetrating captive bolt, followed by bleeding	yes	ineffective stunning, regaining of consciousness before killing	3.7.6.8.
	calves only	electrical, two-stage application	yes	pain associated with cardiac arrest after ineffective stunning	3.7.6.10.
	calves only	electrical, single application (method 1)	yes	ineffective stunning	3.7.6.11.
	all	injection with barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	3.7.6.15.
Sheep and goats	all	free bullet	no	non-lethal wounding	3.7.6.6.
	all except neonates	penetrating captive bolt, followed by pithing or bleeding	yes	ineffective stunning, regaining of consciousness before death	3.7.6.7.
	all except neonates	non-penetrating captive bolt, followed by bleeding	yes	ineffective stunning, regaining of consciousness before death	3.7.6.8.
	neonates	non-penetrating captive bolt	yes	non-lethal wounding	3.7.6.8.
	all	electrical, two-stage application	yes	pain associated with cardiac arrest after ineffective stunning	3.7.6.10.
	all	electrical, single application (method 1)	yes	ineffective stunning	3.7.6.11.
	neonates only	CO_2 / air mixture	yes	slow induction of unconsciousness, aversiveness of induction	3.7.6.12.
	neonates only	nitrogen and/or inert gas mixed with CO_2	yes	slow induction of unconsciousness, aversiveness of induction	3.7.6.13.
	neonates only	nitrogen and/or inert gases	yes	slow induction of unconsciousness	3.7.6.14.

Summary of killing methods (contd)

Species (contd)	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
Sheep and goats (contd)	all	injection of barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	3.7.6.15.
Pigs	all, except neonates	free bullet	no	non-lethal wounding	3.7.6.6.
	all except neonates	penetrating captive bolt, followed by pithing or bleeding	yes	ineffective stunning, regaining of consciousness before death	3.7.6.7.
	neonates only	non-penetrating captive bolt	yes	non-lethal wounding	3.7.6.8.
	all[1]	electrical, two-stage application	yes	pain associated with cardiac arrest after ineffective stunning	3.7.6.10.
	all	electrical, single application (method 1)	yes	ineffective stunning	3.7.6.11.
	neonates only	CO_2 / air mixture	yes	slow induction of unconsciousness, aversiveness of induction	3.7.6.12.
	neonates only	nitrogen and/or inert gas mixed with CO_2	yes	slow induction of unconsciousness, aversiveness of induction	3.7.6.13.
	neonates only	nitrogen and/or inert gases	yes	slow induction of unconsciousness	3.7.6.14.
	all	injection with barbiturates and other	yes	non-lethal dose, pain associated with injection site	3.7.6.15.
Poultry	adults only	non-penetrating captive bolt	yes	ineffective stunning	3.7.6.8.
	day-olds and eggs only	maceration	no	non-lethal wounding, non-immediacy	3.7.6.9.
	adults only	electrical, single application (method 2)	yes	ineffective stunning	3.7.6.11.
	adults only	electrical, single application, followed by killing (method 3)	yes	ineffective stunning; regaining of consciousness before death	3.7.6.11.
	all	CO_2 / air mixture Method 1 Method 2	 yes no	slow induction of unconsciousness, aversiveness of induction	3.7.6.12.

Summary of killing methods (contd)

Species (contd)	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
Poultry (contd)	all	nitrogen and/or inert gas mixed with CO_2	yes	slow induction of unconsciousness, aversiveness of induction	3.7.6.13.
	all	nitrogen and/or inert gases	yes	slow induction of unconsciousness	3.7.6.14.
	all	injection of barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	3.7.6.15.
	adults only	addition of anaesthetics to feed or water, followed by an appropriate killing method	no	ineffective or slow induction of unconsciousness	3.7.6.16

Article 3.7.6.6.

Free bullet

1. Introduction

   a) A free bullet is a projectile fired from a shotgun, rifle, handgun or purpose-made humane killer.

   b) The most commonly used firearms for close range use are:

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

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

      iii) rifles (.22 rimfire);

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

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

   d) A free bullet used from long range should be aimed to penetrate the skull or soft tissue at the top of the neck of the animal (high neck shot) and to cause irreversible concussion and death and should only be used by properly trained and competent marksmen.

2. Requirements for effective use

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

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

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

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

3. Advantages

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

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

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

4. Disadvantages

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

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

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

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

e) Legal requirements may preclude or restrict use.

f) There is a limited availability of competent personnel.

5. Conclusion

The method is suitable for cattle, sheep, goats and pigs, including large animals in open spaces.

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

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

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

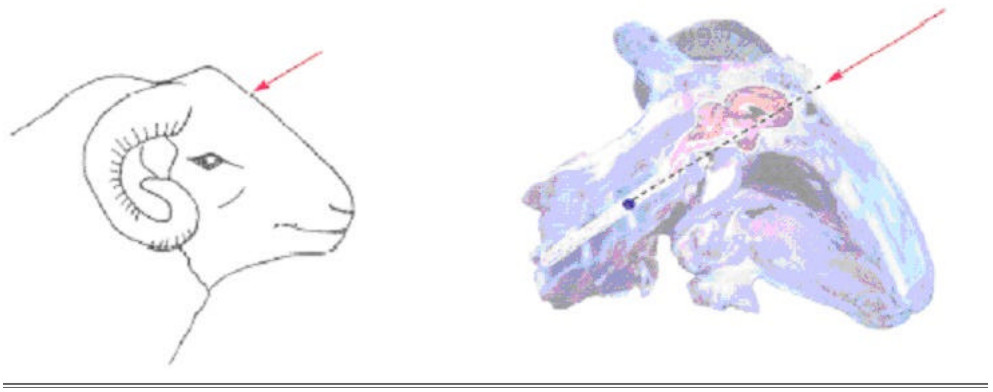


Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

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

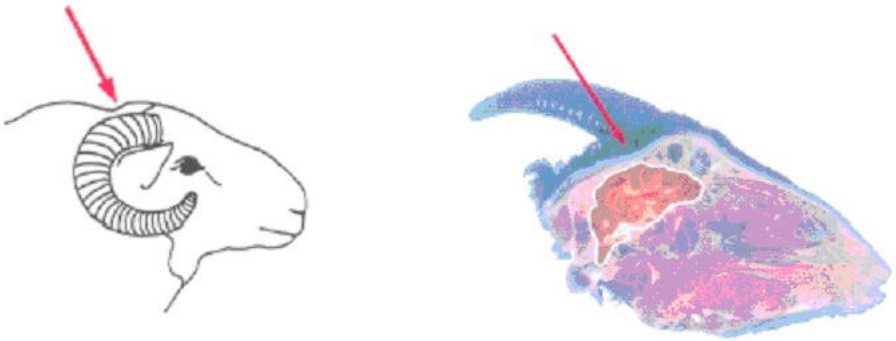


Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

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

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

Article 3.7.6.7.

Penetrating captive bolt

1. Introduction

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

The captive bolt should be aimed on the skull in a position to penetrate the cortex and mid-brain of the animal. The impact of the bolt on the skull produces unconsciousness. Physical damage to the brain caused by penetration of the bolt may result in death; however, pithing or bleeding should be performed as soon as possible after the shot to ensure the death of the animal.

2. Requirements for effective use

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

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

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

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

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

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

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

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

3. Advantages

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

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

4. Disadvantages

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

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

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

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

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

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

5. Conclusions

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

Article 3.7.6.8.

Non-penetrating captive bolt

1. Introduction

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

The gun should be placed on the front of the skull to deliver a percussive blow which produces unconsciousness in cattle (adults only), sheep, goats and pigs, and death in poultry and neonate sheep, goats and pigs. Bleeding should be performed as soon as possible after the blow to ensure the death of the animal.

2. Requirements for effective use

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

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

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

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

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

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

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

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

3. Advantages

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

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

4. Disadvantages

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

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

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

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

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

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

g) Bleeding may present a biosecurity risk.

5. Conclusions

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

Article 3.7.6.9.

Maceration

1. Introduction

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

2. Requirements

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

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

3. Advantages

a) Procedure results in immediate death.

b) Large numbers can be killed quickly.

4. Disadvantages

a) Specialised equipment is required.

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

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

5. Conclusion

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

Article 3.7.6.10.

Electrical – two-stage application

1. Introduction

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

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

2. Requirements for effective use

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

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

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

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

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

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

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

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

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

3. Advantages

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

b) Non-invasive technique minimises biosecurity risk.

4. Disadvantages

a) The method requires a reliable supply of electricity.

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

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

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

5. Conclusion

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

Figure 5 Scissor-type stunning tongs

Article 3.7.6.11.

Electrical – single application

1. Method 1

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

a) Requirements for effective use

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

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

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

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

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

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

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

b) Advantages

i) Method 1 stuns and kills simultaneously.

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

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

iv) Non-invasive technique minimises biosecurity risk.

c) Disadvantages

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

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

iii) Method 1 requires a reliable supply of electricity.

d) Conclusion

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

2. Method 2

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

a) Requirements for effective use

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

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

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

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

- Quails - 100 mA/bird
- Chickens – 160 mA/bird
- Duck & geese – 200 mA/bird
- Turkey – 250 mA/bird.

A higher current is required for wet birds.

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

b) Advantages

i) Method 2 stuns and kills simultaneously.

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

iii) This non-invasive technique minimises biosecurity risk.

c) Disadvantages

i) Method 2 requires a reliable supply of electricity.

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

d) Conclusion

Method 2 is suitable for large numbers of poultry.

3. Method 3

Method 3 comprises the single application of sufficient electrical current to the head of poultry in a position that spans the brain, causing unconsciousness; this is followed by a *killing* method (see Article 3.7.6.17.).

a) Requirements for effective use

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

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

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

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

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

b) Advantages

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

c) Disadvantages

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

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

iii) Birds must be individually restrained.

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

d) Conclusion

Method 3 is suitable for small numbers of poultry.

Article 3.7.6.12.

CO2 / air mixture (under study)

1. Introduction

Controlled atmosphere *killing* is performed by exposing animals to a predetermined gas mixture, either by placing them in a gas-filled container or apparatus (Method 1) or by the gas being introduced into a poultry house (Method 2). Method 2 should be used whenever possible, as it eliminates welfare issues resulting from the need to manually remove live birds.

Inhalation of carbon dioxide (CO_2) induces respiratory and metabolic acidosis and hence reduces the pH of cerebrospinal fluid (CSF) and neurones thereby causing unconsciousness and, after prolonged exposure, death.

2. Method 1

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

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

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

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

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

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

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

b) Advantages

i) CO_2 is readily available.

ii) Application methods are simple.

c) Disadvantages

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

ii) The aversive nature of high CO_2 concentrations.

iii) No immediate loss of consciousness.

iv) The risk of suffocation due to overcrowding.

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

d) Conclusion

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

3. Method 2

The gas is introduced into a poultry house.

a) Requirements for effective use in a poultry house

i) Prior to introduction of the CO_2, the poultry house should be appropriately sealed to allow control over the gas concentration.

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

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

b) Advantages

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

ii) CO_2 is readily available.

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

c) Disadvantages

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

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

d) Conclusion

Method 2 is suitable for use in poultry in closed-environment sheds.

Article 3.7.6.13.

Nitrogen and/or inert gas mixed with CO2

1. Introduction

CO_2 may be mixed in various proportions with nitrogen or an inert gas (e.g. argon), and the inhalation of such mixtures leads to hypercapnic-hypoxia and death when the oxygen concentration by volume is $\leq$2%. This method involves the introduction of animals into a *container* or apparatus containing the gases. Such mixtures do not induce immediate loss of consciousness, therefore the aversiveness of various gas mixtures containing high concentrations of CO_2 and the respiratory distress occurring during the induction phase, are important animal welfare considerations.

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

2. Requirements for effective use

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

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

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

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

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

3. Advantages

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

4. Disadvantages

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

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

c) There is no immediate loss of consciousness.

d) Exposure times required to kill are considerable.

5. Conclusion

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

Article 3.7.6.14.

Nitrogen and/or inert gases

1. Introduction

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

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

2. Requirements for effective use

a) *Containers* or apparatus should allow the required gas concentrations to be maintained, and the O_2 concentration accurately measured.

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

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

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

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

3. Advantages

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

4. Disadvantages

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

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

c) There is no immediate loss of consciousness.

d) Exposure times required to kill are considerable.

5. Conclusion

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

Article 3.7.6.15.

Lethal injection

1. Introduction

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

2. Requirements for effective use

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

b) Prior sedation may be necessary for some animals.

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

d) Animals should be restrained to allow effective administration.

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

3. Advantages

a) The method can be used in all species.

b) Death can be induced smoothly.

4. Disadvantages

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

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

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

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

5. Conclusion

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

Article 3.7.6.16.

Addition of anaesthetics to feed or water

1. Introduction

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

2. Requirements for effective use

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

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

c) Must be followed by *killing* (see Article 3.7.6.17.) if birds are anaesthetised only.

3. Advantages

a) Handling is not required until birds are anaesthetised.

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

4. Disadvantages

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

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

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

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

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

5. Conclusion

The method is suitable for *killing* large numbers of poultry in houses.

Article 3.7.6.17.

Cervical dislocation and decapitation

1. Cervical dislocation (manual and mechanical)

a) Introduction

Unconscious poultry may be killed by either manual cervical dislocation (stretching) or mechanical neck crushing with a pair of pliers. Both methods result in death from cerebral anoxia due to cessation of breathing and/or blood supply to the brain.

b) Requirements for effective use

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

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

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

c) Advantages

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

ii) It can be performed manually on small birds.

d) Disadvantages

i) Operator fatigue.

ii) The method is more difficult in larger birds.

iii) Requires trained personnel to perform humanely.

2. Decapitation

a) Introduction

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

b) Requirements for effective use

The required equipment should be kept in good working order.

c) Advantages

The technique is effective and does not require monitoring.

d) Disadvantages

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

Article 3.7.6.18.

Pithing and bleeding

1. Pithing

   a) Introduction

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

   b) Requirements for effective use

   i) Pithing cane or rod is required.

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

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

   c) Advantages

   The technique is effective in producing immediate death.

   d) Disadvantages

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

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

2. Bleeding

   a) Introduction

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

   b) Requirements for effective use

   i) A sharp knife is required.

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

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

   c) Advantages

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

   d) Disadvantages

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

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

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

SECTION 3.8.

GENERAL GUIDELINES AND SURVEILLANCE FOR SPECIFIC DISEASES

APPENDIX 3.8.1.

GENERAL GUIDELINES FOR ANIMAL HEALTH SURVEILLANCE

Article 3.8.1.1.

Introduction and objectives

1. In general, surveillance is aimed at demonstrating the absence of *disease* or *infection*, determining the occurrence or distribution of *disease* or *infection*, while also detecting as early as possible exotic or *emerging diseases*. The type of surveillance applied depends on the desired outputs needed to support decision-making. The following guidelines may be applied to all *diseases*, their agents and susceptible species as listed in the *Terrestrial Code*, and are designed to assist with the development of surveillance methodologies. Except where a specific surveillance method for a certain *disease* or *infection* is already described in the *Terrestrial Code*, the guidelines in this Appendix may be used to further refine the general approaches described for a specific *disease* or *infection*. Where detailed *disease/infection*-specific information is not available, suitable approaches should be based on the guidelines in this Appendix.

2. Animal health surveillance is an essential component necessary to detect *diseases*, to monitor disease trends, to control endemic and exotic diseases, to support claims for freedom from *disease* or *infection*, to provide data to support the risk analysis process, for both animal health and/or public health purposes, and to substantiate the rationale for sanitary measures. Surveillance data underpin the quality of disease status reports and should satisfy information requirements for accurate risk analysis both for *international trade* as well as for national decision-making.

3. Essential prerequisites to enable a Member Country to provide information for the evaluation of its animal health status are:

   a) that the particular Member Country complies with the provisions of Chapter 1.3.3. of the *Terrestrial Code* on the quality and evaluation of the *Veterinary Services*;

   b) that, where possible, surveillance data be complemented by other sources of information (e.g. scientific publications, research data, documented field observations and other non-survey data);

   c) that transparency in the planning and execution of surveillance activities and the analysis and availability of data and information, be maintained at all times, in accordance with Chapter 1.1.2. of the *Terrestrial Code*.

4. The objectives of this Appendix are to:

   a) provide guidance to the type of outputs that a surveillance system should generate;

   b) provide guidelines to assess the quality of disease surveillance systems.

Article 3.8.1.2.

Definitions

The following definitions apply for the purposes of this Appendix:

Bias: A tendency of an estimate to deviate in one direction from a true value.

Case definition: A case definition is a set of criteria used to classify an animal or *epidemiological unit* as a case.

Confidence: In the context of demonstrating freedom from *infection*, confidence is the probability that the type of surveillance applied would detect the presence of *infection* if the population were infected. The confidence depends on, among other parameters, the assumed level of *infection* in an infected population. The term refers to confidence in the ability of the surveillance applied to detect *disease*, and is equivalent to the sensitivity of the surveillance system.

Early detection system: A system for the timely detection and identification of an incursion or emergence of *disease / infection* in a country, *zone* or *compartment*. An early detection system should be under the control of the *Veterinary Services* and should include the following characteristics:

a) representative coverage of target animal populations by field services;

b) ability to undertake effective *disease* investigation and reporting;

c) access to laboratories capable of diagnosing and differentiating relevant diseases;

d) a training programme for *veterinarians*, *veterinary para-professionals* and others involved in handling animals for detecting and reporting unusual animal health incidents;

e) the legal obligation of private veterinarians in relation to the *Veterinary Authority*;

f) timely reporting system of the event to the *Veterinary Services*;

g) a national chain of command.

Outbreak definition: An outbreak definition is a set of criteria used to classify the occurrence of one or more cases in a group of animals or units as an outbreak.

Probability sampling: A sampling strategy in which every unit has a known non-zero probability of inclusion in the sample.

Sample: The group of elements (sampling units) drawn from a population, on which tests are performed or parameters measured to provide surveillance information.

Sampling units: The unit that is sampled, either in a random survey or in non-random surveillance. This may be an individual animal or a group of animals (e.g. an *epidemiological unit*). Together, they comprise the sampling frame.

Sensitivity: The proportion of truly positive units that are correctly identified as positive by a test.

Specificity: The proportion of truly negative units that are correctly identified as negative by a test.

Study population: The population from which surveillance data are derived. This may be the same as the target population or a subset of it.

Surveillance: The systematic ongoing collection, collation, and analysis of data, and the timely dissemination of information to those who need to know so that action can be taken.

Surveillance system: A method of surveillance that may involve one or more component activities that generates information on the health, disease or zoonosis status of animal populations.

Survey: An investigation in which information is systematically collected, usually carried out on a sample of a defined population group, within a defined time period.

Target population: The population about which conclusions are to be inferred.

Test: A procedure used to classify a unit as either positive, negative or suspect with respect to an *infection* or *disease*.

Test system: A combination of multiple tests and rules of interpretation which are used for the same purpose as a test.

Article 3.8.1.3.

Principles of surveillance

1. Types of surveillance

   a) Surveillance may be based on many different data sources and can be classified in a number of ways, including:

      i) the means by which data are collected (active versus passive surveillance);

      ii) the disease focus (pathogen-specific versus general surveillance); and

      iii) the way in which units for observation are selected (structured surveys versus non-random data sources).

   b) In this Appendix, surveillance activities are classified as being based on:

      EITHER

      i) structured population-based surveys, such as:

         - systematic sampling at slaughter;

         - random surveys;

      OR

      ii) structured non-random surveillance activities, such as:

         - disease reporting or notifications;

         - control programmes/health schemes;

         - targeted testing/screening;

         - ante-mortem and post-mortem inspections;

         - laboratory investigation records;

         - biological specimen banks;

         - sentinel units;

         - field observations;

         - farm production records.

   c) In addition, surveillance data should be supported by related information, such as:

      i) data on the epidemiology of the infection, including environmental, host population distribution, and climatic information;

      ii) data on animal movements and trading patterns for animals and animal products;

      iii) national animal health regulations, including information on compliance with them and their effectiveness;

      iv) history of imports of potentially infected material; and

      v) biosecurity measures in place.

   d) The sources of evidence should be fully described. In the case of a structured survey, this should include a description of the sampling strategy used for the selection of units for testing. For structured non-random data sources, a full description of the system is required including the source(s) of the data, when the data were collected, and a consideration of any biases that may be inherent in the system.

2. Critical elements

   In assessing the quality of a surveillance system, the following critical elements need to be addressed over and above quality of *Veterinary Services* (Chapter 1.3.3.).

a) Populations

Ideally, surveillance should be carried out in such a way as to take into account all animal species susceptible to the infection in a country, *zone* or *compartment*. The surveillance activity may cover all individuals in the population or part of them. When surveillance is conducted only on a *subpopulation*, care should be taken regarding the inferences made from the results.

Definitions of appropriate populations should be based on the specific recommendations of the disease chapters of the *Terrestrial Code*.

b) Epidemiological unit

The relevant *epidemiological unit* for the surveillance system should be defined and documented to ensure that it is representative of the population. Therefore, it should be chosen taking into account factors such as carriers, reservoirs, vectors, immune status, genetic resistance and age, sex, and other host criteria.

c) Clustering

Infection in a country, *zone* or *compartment* usually clusters rather than being uniformly or randomly distributed through a population. Clustering may occur at a number of different levels (e.g. a cluster of infected animals within a herd, a cluster of pens in a building, or a cluster of farms in a *compartment*). Clustering should be taken into account in the design of surveillance activities and the statistical analysis of surveillance data, at least at what is judged to be the most significant level of clustering for the particular animal population and infection.

d) Case and outbreak definitions

Clear and unambiguous case and outbreak definitions should be developed and documented for each pathogen under surveillance, using, where they exist, the standards in the *Terrestrial Code*.

e) Analytical methodologies

Surveillance data should be analysed using appropriate methodologies, and at the appropriate organisational levels to facilitate effective decision making, whether it be planning interventions or demonstrating status.

Methodologies for the analysis of surveillance data should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. Different methodologies may be needed to accommodate the relevant pathogens, varying production and surveillance systems, and types and amounts of data and information available.

The methodology used should be based on the best available information that is in accord with current scientific thinking. The methodology should be in accordance with this Appendix and fully documented, and supported by reference to the scientific literature and other sources, including expert opinion. Sophisticated mathematical or statistical analyses should only be carried out when justified by the proper amount and quality of field data.

Consistency in the application of different methodologies should be encouraged and transparency is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding. The uncertainties, assumptions made, and the effect of these on the final conclusions should be documented.

f) Testing

Surveillance involves the detection of *disease* or *infection* by the use of appropriate case definitions based on the results of one or more tests for evidence of infection or immune status. In this context, a test may range from detailed laboratory examinations to field observations and the analysis of production records. The performance of a test at the population level (including field observations) may be described in terms of its sensitivity and specificity and predictive values. Imperfect sensitivity and/or specificity will have an impact on the conclusions from surveillance. Therefore, these parameters should be taken into account in the design of surveillance systems and analysis of surveillance data.

The values of sensitivity and specificity for the tests used should be specified, and the method used to determine or estimate these values should be documented. Alternatively, where values for sensitivity and/or specificity for a particular test are specified in the *Terrestrial Manual*, these values may be used as a guide.

Samples from a number of animals or units may be pooled and subjected to a testing protocol. The results should be interpreted using sensitivity and specificity values that have been determined or estimated for that particular pool size and testing procedure.

g) Quality assurance

Surveillance systems should incorporate the principles of quality assurance and be subjected to periodic auditing to ensure that all components of the system function and provide verifiable documentation of procedures and basic checks to detect significant deviations of procedures from those documented in the design.

h) Validation

Results from animal health surveillance systems are subject to one or more potential biases. When assessing the results, care should be taken to identify potential biases that can inadvertently lead to an over-estimate or an under-estimate of the parameters of interest.

i) Data collection and management

The success of a surveillance system is dependent on a reliable process for data collection and management. The process may be based on paper records or computerised. Even where data are collected for non-survey purposes (e.g. during disease control interventions, inspections for movement control or during disease eradication schemes), the consistency and quality of data collection and event reporting in a format that facilitates analysis, is critical. Factors influencing the quality of collected data include:

- the distribution of, and communication between, those involved in generating and transferring data from the field to a centralised location;
- the ability of the data processing system to detect missing, inconsistent or inaccurate data, and to address these problems;
- maintenance of disaggregated data rather than the compilation of summary data;
- minimisation of transcription errors during data processing and communication.

Article 3.8.1.4.

Structured population-based surveys

In addition to the principles for surveillance discussed above, the following guidelines should be used when planning, implementing and analysing surveys.

1. Types of surveys

Surveys may be conducted on the entire target population (i.e. a census) or on a sample. A sample may be selected in either of the two following ways:

a) non-probability based sampling methods, such as:

i) convenience;

ii) expert choice;

iii) quota;

b) probability based sampling methods, such as:

i) simple random selection;

ii) cluster sampling;

iii) stratified sampling;

iv) systematic sampling.

Non-probability based sampling methods will not be discussed further.

Periodic or repeated surveys conducted in order to document disease freedom should be done using probability based sampling methods so that data from the study population can be extrapolated to the target population in a statistically valid manner.

The sources of information should be fully described and should include a detailed description of the sampling strategy used for the selection of units for testing. Also, consideration should be made of any biases that may be inherent in the survey design.

2. Survey design

The population of *epidemiological units* should first be clearly defined; hereafter sampling units appropriate for each stage, depending on the design of the survey, should be defined.

The design of the survey will depend on the size and structure of the population being studied, the epidemiology of the infection and the resources available.

3. Sampling

The objective of sampling from a population is to select a subset of units from the population that is representative of the population with respect to the object of the study such as the presence or absence of infection. Sampling should be carried out in such a way as to provide the best likelihood that the sample will be representative of the population, within the practical constraints imposed by different environments and production systems. In order to detect the presence of an infection in a population of unknown disease status, targeted sampling methods that optimise the detection of infection can be used. In such cases, care should be taken regarding the inferences made from the results.

4. Sampling methods

When selecting *epidemiological units* from within a population, probability sampling (e.g. simple random selection) should be used. When this is not possible, sampling should provide the best practical chance of generating a sample that is representative of the target population.

In any case, the sampling method used at all stages should be fully documented and justified.

5. Sample size

In general, surveys are conducted either to demonstrate the presence or absence of a factor (e.g. infection) or to estimate a parameter (e.g. the prevalence of infection). The method used to calculate sample size for surveys depends on the purpose of the survey, the expected prevalence, the level of confidence desired of the survey results and the performance of the tests used.

Article 3.8.1.5.

Structured non-random surveillance

Surveillance systems routinely use structured non-random data, either alone or in combination with surveys.

1. Common non-random surveillance sources

A wide variety of non-random surveillance sources may be available. These vary in their primary purpose and the type of surveillance information they are able to provide. Some surveillance systems are primarily established as early detection systems, but may also provide valuable information to demonstrate freedom from infection. Other systems provide cross-sectional information suitable for prevalence estimation, either

once or repeatedly, while yet others provide continuous information, suitable for the estimate of incidence data (e.g. disease reporting systems, sentinel sites, testing schemes). Surveillance systems routinely use structured non-random data, either alone or in combination with surveys.

a) Disease reporting or notification systems

Data derived from disease reporting systems can be used in combination with other data sources to substantiate claims of animal health status, to generate data for risk analysis, or for early detection. Effective laboratory support is an important component of any reporting system. Reporting systems relying on laboratory confirmation of suspect clinical cases should use tests that have a high specificity. Reports should be released by the laboratory in a timely manner, with the amount of time from disease detection to report generation minimized (to hours in the case of introduction of a foreign animal disease).

b) Control programmes / health schemes

Animal disease control programmes or health schemes, while focusing on the control or eradication of specific diseases, should be planned and structured in such a manner as to generate data that are scientifically verifiable and contribute to structured surveillance.

c) Targeted testing / screening

This may involve testing targeted to selected sections of the population (subpopulations), in which disease is more likely to be introduced or found. Examples include testing culled and dead animals, swill fed animals, those exhibiting clinical signs, animals located in a defined geographic area and specific age or commodity group.

d) Ante-mortem and post-mortem inspections

Inspections of animals at abattoirs may provide valuable surveillance data. The sensitivity and specificity of the particular slaughterhouse inspection system for detecting the presence of infectious agents of surveillance interest under the particular inspection arrangements applying in a country should be pre-determined by the *Competent Authority* if the data is to be fully utilised. The accuracy of the inspection system will be influenced by:

i) the level of training and experience of the staff doing the inspections, and the ratio of staff of different levels of training;

ii) the involvement of the *Competent Authorities* in the supervision of ante-mortem and post-mortem inspections;

iii) the quality of construction of the abattoir, speed of the slaughter chain, lighting quality, etc.; and

iv) staff morale/motivation for accurate and efficient performance.

Abattoir inspections are likely to provide good coverage only for particular age groups and geographical areas. Abattoir surveillance data are subject to obvious biases in relation to target and study populations (e.g. only animals of a particular class and age may be slaughtered for human consumption in significant numbers). Such biases need to be recognized when analysing surveillance data.

Both for traceback in the event of detection of disease and for analysis of spatial and herd-level coverage, there should be, if possible, an effective identification system that relates each animal in the abattoir to its locality of origin.

e) Laboratory investigation records

Analysis of laboratory investigation records may provide useful surveillance information. The coverage of the system will be increased if analysis is able to incorporate records from national, accredited, university and private sector laboratories. Valid analysis of data from different laboratories depends on the existence of standardised diagnostic procedures and standardised methods for interpretation and data recording. As with abattoir inspections, there needs to be a mechanism to relate specimens to the farm of origin.

f) Biological specimen banks

Specimen banks consist of stored specimens, gathered either through representative sampling or opportunistic collection or both. Specimen banks may contribute to retrospective studies, including providing support for claims of historical freedom from infection, and may allow certain studies to be conducted more quickly and at lower cost than alternative approaches.

g) Sentinel units

Sentinel units/sites involve the identification and regular testing of one or more of animals of known health/immune status in a specified geographical location to detect the occurrence of disease (usually serologically). They are particularly useful for surveillance of diseases with a strong spatial component, such as vector-borne diseases. Sentinel units provide the opportunity to target surveillance depending on the likelihood of infection (related to vector habitats and host population distribution), cost and other practical constraints. Sentinel units may provide evidence of freedom from infection, or provide data on prevalence and incidence as well as the distribution of disease.

h) Field observations

Clinical observations of animals in the field are an important source of surveillance data. The sensitivity and specificity of field observations may be relatively low, but these can be more easily determined and controlled if a clear, unambiguous and easy to apply standardised case definition is applied. Education of potential field observers in application of the case definition and reporting is an important component. Ideally, both the number of positive observations and the total number of observations should be recorded.

i) Farm production records

Systematic analysis of farm production records may be used as an indicator of the presence or absence of disease at the herd or flock level. In general, the sensitivity of this approach may be quite high (depending on the disease), but the specificity is often quite low.

2. Critical elements for structured non-random surveillance

There is a number of critical factors which should be taken into account when using structured non-random surveillance data such as coverage of the population, duplication of data, and sensitivity and specificity of tests that may give rise to difficulties in the interpretation of data. Surveillance data from non-random data sources may increase the level of confidence or be able to detect a lower level of prevalence with the same level of confidence compared to structured surveys.

3. Analytical methodologies

Different methodologies may be used for the analysis of non-random surveillance data.

Different scientifically valid methodologies may be used for the analysis of non-random surveillance data. Where no data are available, estimates based on expert opinions, gathered and combined using a formal, documented and scientifically valid methodology may be used.

4. Combination of multiple sources of data

The methodology used to combine the evidence from multiple data sources should be scientifically valid, and fully documented including references to published material.

Surveillance information gathered from the same country, *zone* or *compartment* at different times may provide cumulative evidence of animal health status. Such evidence gathered over time may be combined to provide an overall level of confidence. For instance, repeated annual surveys may be analysed to provide a cumulative level of confidence. However, a single larger survey, or the combination of data collected during the same time period from multiple random or non-random sources, may be able to achieve the same level of confidence in just one year.

Analysis of surveillance information gathered intermittently or continuously over time should, where possible, incorporate the time of collection of the information to take the decreased value of older information into account. The sensitivity, specificity and completeness of data from each source should also be taken into account for the final overall confidence level estimation.

Article 3.8.1.6.

Surveillance to demonstrate freedom from disease / infection

1. Requirements to declare a country, zone or compartment free from disease / infection without pathogen specific surveillance

This Article provides general principles for declaring a country, *zone* or *compartment* free from *disease / infection* in relation to the time of last occurrence and in particular for the recognition of historical freedom.

The provisions of this Article are based on the principles described in Article 3.8.1.3. of this Appendix and the following premises:

- in the absence of disease and vaccination, the animal population would become susceptible over a period of time;
- the disease agents to which these provisions apply are likely to produce identifiable clinical signs in susceptible animals;
- competent and effective *Veterinary Services* will be able to investigate, diagnose and report disease, if present;
- the absence of *disease / infection* over a long period of time in a susceptible population can be substantiated by effective disease investigation and reporting by a Member Country.

a) Historically free

Unless otherwise specified in the relevant disease chapter, a country, *zone* or *compartment* may be recognised free from infection without formally applying a pathogen-specific surveillance programme when:

i) there has never been occurrence of disease, or

ii) eradication has been achieved or the *disease / infection* has ceased to occur for at least 25 years,

provided that for at least the past 10 years:

iii) it has been a notifiable disease;

iv) an early detection system has been in place;

v) measures to prevent *disease / infection* introduction have been in place; no vaccination against the disease has been carried out unless otherwise provided in the *Terrestrial Code*;

vi) infection is not known to be established in wildlife within the country or *zone* intended to be declared free. (A country or *zone* cannot apply for historical freedom if there is any evidence of infection in wildlife. However, specific surveillance in wildlife is not necessary.)

b) Last occurrence within the previous 25 years

Countries, *zones* or *compartments* that have achieved eradication (or in which the *disease / infection* has ceased to occur) within the previous 25 years, should follow the pathogen-specific surveillance requirements in the *Terrestrial Code* if they exist. In the absence of specific requirements for surveillance in the *Terrestrial Code*, countries should follow the general guidelines for surveillance to demonstrate animal health status outlined in this Appendix provided that 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 *disease / infection* introduction have been in place;

iv) no vaccination against the disease has been carried out unless otherwise provided in the *Terrestrial Code*;

v) infection is not known to be established in wildlife within the country or *zone* intended to be declared free. (A country or *zone* cannot apply for freedom if there is any evidence of infection in wildlife. However, specific surveillance in wildlife is not necessary.)

2. Guidelines for the discontinuation of pathogen-specific screening after recognition of freedom from infection

   A country, *zone* or *compartment* that has been recognised as free from infection following the provisions of the *Terrestrial Code* may discontinue pathogen-specific screening while maintaining the infection-free status provided that:

   a) it is a *notifiable disease*;

   b) an early detection system is in place;

   c) measures to prevent *disease/infection* introduction are in place;

   d) vaccination against the disease is not applied;

   e) infection is known not to be established in wildlife. (Specific surveillance in wildlife has demonstrated the absence of infection.)

3. International recognition of disease/infection free status

   For diseases for which procedures exist whereby the OIE can officially recognise the existence of a *disease/infection* free country, *zone* or *compartment*, a Member Country wishing to apply for recognition of this status shall, via its Permanent Delegate, send to the OIE all the relevant documentation relating to the country, *zone* or *compartment* concerned. Such documentation should be presented according to guidelines prescribed by the OIE for the appropriate animal diseases.

4. Demonstration of freedom from infection

   A surveillance system to demonstrate freedom from infection should meet the following requirements in addition to the general requirements for surveillance outlined in Article 3.8.1.3. of this Appendix.

   Freedom from infection implies the absence of the pathogenic agent in the country, *zone* or *compartment*. Scientific methods cannot provide absolute certainty of the absence of infection. Demonstrating freedom from infection involves providing sufficient evidence to demonstrate (to a level of confidence acceptable to Member Countries) that infection with a specified pathogen is not present in a population. In practice, it is not possible to prove (i.e., be 100% confident) that a population is free from infection (unless every member of the population is examined simultaneously with a perfect test with both sensitivity and specificity equal to 100%). Instead, the aim is to provide adequate evidence (to an acceptable level of confidence), that infection, if present, is present in less than a specified proportion of the population.

   However, finding evidence of infection at any level in the target population automatically invalidates any freedom from infection claim unless otherwise stated in the relevant disease Chapter.

   Evidence from targeted, random or non-random data sources, as stated before, may increase the level of confidence or be able to detect a lower level of prevalence with the same level of confidence compared to structured surveys.

Article 3.8.1.7.

Surveillance for distribution and occurrence of infection

Surveillance to determine distribution and occurrence of infection or of other relevant health related events is widely used to assess progress in the control or eradication of selected diseases and pathogens and as an aid to decision making. It has, however, relevance for the international movement of animals and products when movement occurs among infected countries.

In contrast to surveillance to demonstrate freedom from infection, surveillance used to assess progress in control or eradication of selected diseases and pathogens is usually designed to collect data about a number of variables of animal health relevance, for example:

1. prevalence or incidence of infection;
2. morbidity and mortality rates;
3. frequency of *disease/infection* risk factors and their quantification;
4. frequency distribution of herd sizes or the sizes of other *epidemiological units*;
5. frequency distribution of antibody titres;

6. proportion of immunised animals after a vaccination campaign;
7. frequency distribution of the number of days elapsing between suspicion of infection and laboratory confirmation of the diagnosis and/or to the adoption of control measures;
8. farm production records, etc.

APPENDIX 3.8.2.

GUIDELINES FOR THE SURVEILLANCE OF RINDERPEST

Article 3.8.2.1.

Purposes of the document

In order to receive OIE recognition of rinderpest freedom, a country's national authority must present for consideration a dossier of information relating to its livestock production systems, rinderpest vaccination and eradication history and the functioning of its *Veterinary Services*. The dossier must contain convincing evidence derived from an animal disease surveillance system that sufficient evidence has accrued to demonstrate that the presence of rinderpest virus would have been disclosed were it to be present. Guidelines for the structure and the functioning of *Veterinary Services* and diagnostic support services are provided in Chapters 1.3.3. and 1.3.4. of the *Terrestrial Code*. A Member Country must also be in compliance with its OIE reporting obligations (Chapter 1.1.2. of the *Terrestrial Code*).

Article 3.8.2.2.

Definitions

1. Rinderpest

   For the purpose of this Appendix, rinderpest is defined as an infection of large ruminants (cattle, buffaloes, yaks, etc.), small ruminants, pigs and various wildlife species within the order Artiodactyla, caused by rinderpest virus. In small ruminants and various species of wildlife, particularly antelopes, infection generally passes without the development of frank clinical signs. Characteristic clinical signs and pathological lesions are described in Chapter 2.1.4. of the *Terrestrial Manual*.

   Outbreaks of rinderpest in cattle may be graded as per-acute, acute or sub-acute. Differing clinical presentations reflect variations in levels of innate host resistance (*Bos indicus* breeds being more resistant than *Bos taurus*), and variations in the virulence of the attacking strain. It is generally accepted that unvaccinated populations of cattle are likely to promote the emergence of virulent strains and associated epidemics while partially vaccinated populations favour the emergence of mild strains associated with endemic situations. In the case of per-acute cases the presenting sign may be sudden death. In the case of sub-acute (mild) cases, clinical signs are irregularly displayed and difficult to detect.

   Freedom from rinderpest means freedom from rinderpest virus infection.

2. Rinderpest vaccines

   For the purpose of this Appendix and the *Terrestrial Code*, OIE-recognised rinderpest vaccines currently in use, or likely to become so in the forseeable future, are considered to be commercial modified live vaccines produced from attenuated rinderpest virus (referred to as 'rinderpest vaccine') produced in accordance with Chapter 2.1.4. of the *Terrestrial Manual*.

Article 3.8.2.3.

Rinderpest surveillance

General guidelines on animal disease surveillance are outlined in Appendix 3.8.1. of the *Terrestrial Code*.

Rinderpest must be a *notifiable disease* i.e. notification of *outbreaks* of rinderpest as soon as detected or suspected must be brought to the attention of the *Veterinary Authority*.

The precise surveillance information required for establishing freedom will differ from country to country depending on factors such as the former rinderpest status of the country, the regional rinderpest situation and

accreditation status, the time elapsing since the last occurrence of rinderpest, livestock husbandry systems (e.g. extensive pastoralism, nomadism and transhumance versus sedentary agropastoralism) and trading patterns.

Evidence of efficiency of the surveillance system can be provided by the use of performance indicators.

Surveillance results presented will be expected to have accrued from a combination of surveillance activities including some or all of the following:

1. A routine national animal disease reporting system supported by evidence of its efficiency and follow-up - an on-going, statutory, centrally organised system of reporting

   Ideally disease reports should be expressed in a Geographical Information System environment and analysed for clustering of observations and followed up.

2. Emergency disease reporting systems and investigation of epidemiologically significant events ('stomatitis-enteritis syndrome')

   Emergency reporting systems can be devised to short-circuit normal passive reporting systems to bring suspicious events to the fore and lead to rapid investigation and tracing. All such investigations should be well documented for presentation as an outcome of the surveillance system.

3. Detection and thorough investigation of epidemiologically significant events ('stomatitis-enteritis syndrome') which raise suspicion of rinderpest supported by evidence of efficiency of the system

   Laboratory examination undertaken to confirm or rule out rinderpest is given extra credibility if it is accompanied by the results of differential diagnostic examinations.

4. Searching for evidence of clinical rinderpest

   Active search for disease might include participatory disease searching combined with village disease searching, tracing backwards and forwards, follow-up and investigation.

5. Serosurveillance

   a) Randomised serosurveys

      Statistically selected samples from relevant strata within the host populations are examined to detect serological evidence of possible virus circulation.

      A sampling unit for the purposes of disease investigation and surveillance is defined as a group of animals in sufficiently close contact that individuals within the group are at approximately equal risk of coming in contact with the virus if there should be an infectious animal within the group. In most circumstances, the sampling unit will be a herd which is managed as a unit by an individual or a community, but it may also be other epidemiologically appropriate groupings which are subject to regular mixing, such as all animals belonging to residents of a village. In the areas where nomadic or transhumant movements exist, the sampling unit can be the permanent bore holes, wells or water points. Sampling units should normally be defined so that their size is generally between 50 and 1,000 animals.

      i) Criteria for stratification of host populations

         Strata are homogeneously mixing sub-populations of livestock. Any disease surveillance activities must be conducted on populations stratified according to the management system, and by herd size where this is variable. Herds, or other sampling units, should be selected by proper random statistical selection procedures from each stratum.

      ii) Field procedures and sample sizes

         Annual sample sizes shall be sufficient to provide 95% probability of detecting evidence of rinderpest if present at a prevalence of 1% of herds or other sampling units and 5% within herds or other sampling units. This can typically be achieved by examining 300 herds per stratum per year, but procedures for sampling should be in accordance with the "Guide to Epidemiological Surveillance for Rinderpest"[1], or another procedure that would achieve the same probability of detection.

         Where the sampling frame of herds is known, herds shall be selected for examination by the use of random number tables. Otherwise, samples of herds can be selected by taking the nearest herd to a randomly selected map reference, provided that the herds are evenly distributed. Failing this, any herd(s) within a fixed radius of randomly selected map references should be sampled. It must be compulsory for any selected herd to be examined or tested as required.

In carrying out clinical surveillance for evidence of rinderpest, all animals in selected herds or sampling units will be examined by a *veterinarian* for signs of the disease, especially mouth lesions. Any positive result shall be evaluated using epidemiological and laboratory methods to confirm or refute the suspicion of rinderpest virus activity. All animals born after the cessation of vaccination and more than one year old will be eligible for serological testing.

Where operational considerations require it, the number of eligible animals tested within each sampled herd may be reduced. This will reduce the probability of within-herd detection and there must be at least a compensatory increase in the number of herds sampled, so that the required 95% probability of detectin 1% between-herd prevalence is maintained.

b) Risk-focussed serosurveillance

Risk-focussed serosurveillance differs from randomised serosurveillance in that it increases detection sensitivity by obtaining samples from areas/populations determined to be at higher risk of infection, so as to detect serological evidence of possible virus circulation. The operational modalities for risk-based focussing of surveillance require definition (randomisation within defined focus, high risk animals, etc.). The extent to which randomisation needs to be retained in the generation of risk-focussed serosurveillance data needs to be established.

Focussing can be achieved by reference to some or all of the following:

i) Historical disease patterns (prior probability mapping) – clinical, participatory and laboratory-based

ii) Critical population size, structure and density

iii) Livestock husbandry and farming systems

iv) Movement and contact patterns – markets and other trade-related movements

v) Transmission parameters (e.g. virulence of the strain, animal movements)

vi) Wildlife and other species demography.

Article 3.8.2.4.

Selection of cattle and buffaloes for serosurveillance

Ageing cattle and Asian buffaloes for the purpose of serosurveillance:

Mis-ageing of cattle selected for serosurveillance is the most common source of error. Colostral immunity can persist almost up to one year of age when measured by the H c-ELISA. Thus, it is essential to exclude from sampling buffaloes and cattle less than one year of age. In addition, it is frequently necessary to be able to exclude those which are older than a certain age, for example, to select only those born after cessation of vaccination.

Accounts of the ages for eruption of the incisor teeth vary markedly and are clearly dependent on species, breed, nutritional status and nature of the feed.

Pragmatically, and solely for the purposes of serosurveillance, it can be accepted that:

a) cattle having only one pair of erupted permanent central incisor teeth are aged between 21 and 36 months (Asian buffaloes 24-48 months);

b) cattle having only two pairs of erupted permanent central incisor teeth are aged between 30 and 48 months (Asian buffaloes 48-60 months).

Thus selecting a cohort of cattle possessing only one pair of permanent incisors will preclude any interference from maternal immunity derived from earlier vaccination or infection and ensure that vaccinated cattle are not included if vaccination ceased 3 years or more previously (for Asian buffaloes 4 years or more).

Although it is stressed here that animals with milk teeth only are not suitable for surveillance based on serology, they are of particular interest and importance in surveillance for clinical disease. After the loss of colostral immunity, by about one year of age, these are the animals which are most likely to suffer the more severe disease form and in which to look for lesions indicative of rinderpest.

Article 3.8.2.5.

Wildlife surveillance where a significant susceptible wildlife population exists

There are some key wildlife populations, especially African buffaloes, which act as sentinels for rinderpest infection. Where a significant population of a susceptible wildlife species exists, serosurveillance data are required to support absence of infection. These populations should be monitored purposively to support the dossiers to be submitted for freedom from rinderpest virus infection. Detection of virus circulation in wildlife can be undertaken indirectly by sampling contiguous livestock populations.

Obtaining meaningful data from wildlife surveillance can be enhanced by close coordination of activities in the regions and countries. Both purposive and opportunistic samplings are used to obtain material for analysis in national and reference laboratories. The latter are required because most countries are unable to perform the full testing protocol for detecting rinderpest antibodies in wildlife sera.

Purposive sampling is the preferred method to provide wildlife data to evaluate the status of rinderpest infection. In reality, the capacity to perform purposive work in the majority of countries remains minimal. Opportunistic sampling (hunting) is feasible and it provides useful background information.

Wildlife form transboundary populations; therefore, any data from the population could be used to represent the result for the ecosystem and be submitted by more than one country in a dossier (even if the sampling was not obtained in the country submitting). It is therefore recommended that the countries represented in a particular ecosystem should coordinate their sampling programmes.

The standards for serosurveillance are different from that set for cattle because the serological tests are not fully validated for wildlife species and financial and logistic constraints of sampling prevent collection of large numbers of samples.

From the collective experience of the laboratories and experts over the years, an appropriate test protocol is based on the high expected sero-prevalence in a previously infected buffalo herd (99% seroconversion of eligible animals within a herd), which is detected using a test, which is 100% sensitive. No single test can achieve this; however, combining H c-ELISA to VNT raises sensitivity close to 100%.

In the order of 1-2% of a herd of African buffaloes must be sampled to ensure that no positive case is missed. For example in a herd of 300 buffaloes, five animals should be sampled and the above multiple test protocol followed. Where the serological history of the herd is known from previous work (as might be the case for a sentinel herd), repeat sampling need only focus on the untested age groups, born since the last known infection. Appropriate sampling fraction for other wildlife species are less well defined, as social organization (herd structure, likely contact rates, etc.) vary. The sample needs to be taken according to the known epidemiology of the disease in a given species. Opportunistic samples, which are positive, should not be interpreted without a purposive survey to confirm the validity of these results. Opportunistic sampling cannot follow a defined protocol and therefore can only provide background information.

Article 3.8.2.6.

Evaluation of applications for accreditation of freedom from rinderpest

Evaluation of applications for the status of freedom from rinderpest will be the responsibility of the OIE Scientific Commission for Animal Diseases which can request the Director General if the OIE to appoint an ad hoc group in order to assist in reaching an informed decision to present to the OIE International Committee for approval.

The composition and method of selection of the ad hoc group shall be such as to ensure both a high level of expertise in evaluating the evidence and total independence of the group in reaching conclusions concerning the disease status of a particular country.

Article 3.8.2.7.

Steps to be taken to declare a country to be free from rinderpest

Recognition of the status 'free from rinderpest' is given to a Member Country. Where traditionally managed livestock move freely across international borders, groups of Member Countries may usefully associate themselves into a group for the purposes of obtaining data to be used for mutually supportive applications for individual country accreditation.

For the purpose of this Appendix, the following assumptions are made:

a) that within most previously infected countries, rinderpest vaccine will have been used to control the rate of infection;

b) that within an endemically infected population there will be a large number of immune hosts (both vaccinees and recovered animals);

c) that the presence of a proportion of immune hosts within a vaccinated population could have led to a slowing of the rate of virus transmission and possibly the concomitant emergence of strains of reduced virulence, difficult to detect clinically;

d) that the virulence of the virus (and therefore the ease of clinical detection) may or may not increase as the herd immunity declines following withdrawal of vaccination; however, continuing transmission will generate serological evidence of their persistence.

Before accreditation can be considered, countries which have controlled the disease by the use of rinderpest vaccine must wait until an unvaccinated cohort is available to allow meaningful serological surveillance to be conducted.

The OIE has concluded that the majority of countries have stopped vaccinating for a sufficient length of time for it now to be feasible that a single submission of evidence gained over 2 years of appropriate surveillance shall be sufficient to gain rinderpest free accreditation.

A Member Country accredited as free from rinderpest must thereafter submit annual statements to the Director General of the OIE indicating that surveillance has failed to disclose the presence of rinderpest, and that all other criteria continue to be met.

A country previously infected with rinderpest which has not employed rinderpest vaccine for at least 25 years and has throughout that period detected no evidence of rinderpest virus disease or infection may be accredited as free from rinderpest by the OIE based on historical grounds, provided that the country:

- has had throughout at least the last 10 years and maintains permanently an adequate animal disease surveillance system along with the other requirements outlined in Article 3.8.1.6.;
- is in compliance with OIE reporting obligations (Chapter 1.1.2.).

The *Veterinary Authorities* of the Member Country must submit a dossier containing evidence supporting their claim to be free from rinderpest on a historical basis to the Director General of the OIE for evaluation by the OIE Scientific Commission for Animal Diseases and accreditation by the OIE International Committee. The dossier should contain at least the following information:

- a description of livestock populations, including wildlife;
- the history of rinderpest occurrence in the country and its control;
- an affirmation that rinderpest has not occurred for 25 years, that vaccine has not been used during that time, and that rinderpest is a *notifiable disease*;
- evidence that in the last 10 years the disease situation throughout the Member Country has been constantly monitored by a competent and effective veterinary infrastructure that has operated a national animal disease reporting system submitting regular (monthly) disease occurrence reports to the *Veterinary Authority*;
- the structure and functioning of the *Veterinary Services*;
- the Member Country operates a reliable system of risk analysis based importation of livestock and livestock products.

Evidence in support of these criteria must accompany the Member Country's accreditation application dossier. In the event that satisfactory evidence is not forthcoming, the OIE may seek clarification or refer the dossier back to

the originators, giving its reasons for so doing. Under such circumstances a fresh dossier would be entertained in due course.

OR

A Member Country having eradicated rinderpest within the last 25 years, wishing to be accredited free from rinderpest and having ended rinderpest vaccination must initiate a two-year surveillance programme to demonstrate freedom from rinderpest whilst banning further use of rinderpest vaccine. The step of accreditation as free from rinderpest is subject to meeting stringent criteria with international verification under the auspices of the OIE.

A country historically infected with rinderpest but which has convincing evidence that the disease has been excluded for at least two years and is not likely to return, may apply to OIE to be accredited as free from rinderpest. The conditions which apply include that an adequate animal disease surveillance system has been maintained throughout at least that period.

The *Veterinary Authority* of the Member Country must submit a dossier containing evidence supporting their claim to be free from rinderpest to the Director General of the OIE for evaluation by the OIE Scientific Commission for Animal Diseases and accreditation by the OIE International Committee showing that they comply with:

- the provisions outlined in Chapter 2.2.12. of the *Terrestrial Code*;
- OIE reporting obligations outlined in Chapter 1.1.2. of the *Terrestrial Code*.

Other conditions that apply are:

- The Member Country affirms that rinderpest has not occurred for at least 2 years, that vaccine has not been used during that time, and that rinderpest is a *notifiable disease*.
- The *Veterinary Authority* has issued orders curtailing the distribution and use of rinderpest vaccine in livestock.
- The *Veterinary Authority* has issued orders for the recall and destruction of rinderpest vaccine already issued.
- The *Veterinary Authority* has issued orders restricting the importation of rinderpest vaccine into, or the further manufacture of rinderpest vaccine within, the territory under his jurisdiction. An exception can be made for establishing a safeguarded rinderpest emergency vaccine bank under the control of the Chief Veterinary Officer who can demonstrate that no calls have been made on that vaccine bank.
- The *Veterinary Authority* has set in place a rinderpest contingency plan.
- Over the previous 2 years at least, the disease situation throughout the Member Country has been constantly monitored by a competent and effective infrastructure that has operated a national animal disease reporting system submitting regular (monthly) disease occurrence reports to the *Veterinary Authority*.
- All *outbreaks of disease* with a clinical resemblance to rinderpest have been thoroughly investigated and routinely subjected to laboratory testing by an OIE recognised rinderpest-specific test within the national rinderpest laboratory or at a recognised reference laboratory.

The dossier shall contain:

- the results of a continuous surveillance programme, including appropriate serological surveys conducted during at least the last 24 months, providing convincing evidence for the absence of rinderpest virus circulation;
- a description of livestock populations including wildlife;
- the history of rinderpest occurrence in the country and its control;
- an affirmation that rinderpest has not occurred for at least 2 years, that vaccine has not been used during that time, and that rinderpest is a *notifiable disease*;
- evidence that in the last 2 years the disease situation throughout the Member Country has been constantly monitored by a competent and effective veterinary infrastructure that has operated a national animal disease reporting system submitting regular (monthly) disease occurrence reports to the *Veterinary Authority*;
- the structure and functioning of the *Veterinary Services*;
- the Member Country operates a reliable system of risk analysis based importation of livestock and livestock products.

In the event that satisfactory evidence in support of the application is not forthcoming, the OIE may seek clarification or refer the dossier back to the originators, giving its reasons for so doing. Under such circumstances a fresh dossier would be entertained in due course.

Article 3.8.2.8.

Rinderpest outbreaks after the accreditation process and recovery of rinderpest free status

Should there be an *outbreak*, or *outbreaks*, of rinderpest in a Member Country at any time after recognition of rinderpest freedom, the origin of the virus strain must be thoroughly investigated. In particular it is important to determine if this is due to the re-introduction of virus or re-emergence from an undetected focus of infection. The virus must be isolated and compared with historical strains from the same area as well as those representatives of other possible sources. The *outbreak* itself must be contained with the utmost rapidity using the resources and methods outlined in the Contingency Plan.

After elimination of the *outbreak*, a Member Country wishing to regain the status 'free from rinderpest' must undertake serosurveillance to determine the extent of virus spread.

If investigations show the *outbreak* virus originated from outside the country, provided the *outbreak* was localised, rapidly contained and speedily eliminated, and provided there was no serological evidence of virus spread outside the index infected area, accreditation of freedom could proceed rapidly. The country must satisfy the OIE Scientific Commission for Animal Diseases that the *outbreaks* were contained, eliminated and did not represent endemic infection.

An application to regain the status free from rinderpest shall not generally be accepted until both clinical and serological evidence shows that there has been no virus transmission for at least 3 or 6 months, depending on whether or not stamping-out or vaccination respectively has been applied.

1 JAMES A.D. (1998). Guide to epidemiological surveillance for rinderpest. *Rev. Sci. Tech.* 17 **(3)**, 796–824.

APPENDIX 3.8.3.

SURVEILLANCE FOR CONTAGIOUS BOVINE PLEUROPNEUMONIA

1. Introduction

The Ad hoc Group on Contagious Bovine Pleuropneumonia (CBPP) Surveillance Systems held a meeting on 7-9 June 1993 with the purpose of formulating these standards, which describe surveillance systems suited to the declaration of countries and zones free of disease and free of infection. Background information is contained in the report of the meeting. In order to write these standards, the Group reviewed the following:

a) epidemiological and non-disease factors influencing the choice of CBPP surveillance systems;

b) sampling and surveillance strategies;

c) diagnostic methods applicable to CBPP surveillance systems;

d) the implications of CBPP vaccination for surveillance systems.

This last point was the subject of lengthy discussions during the meeting of the OIE Committee in May 1994. A revised text was submitted at the following meeting of the Committee (May 1995), which requested that a small group of experts formulate revised proposals. The present text is the product of their consensus.

2. Definition and purposes of surveillance

Disease surveillance is necessary to provide evidence that a country or zone is free from a disease or infection.

Disease surveillance should be implemented by both:

a) a system of reporting any signs of disease activity which come to the notice of Veterinary Services or livestock owners; and

b) an active programme of examination of statistically selected samples from host populations in order to detect clinical signs or other indications of the occurrence of disease or transmission of infection.

In either case, suspicion of disease activity should be followed by quarantine, confirmatory diagnostic work and any necessary disease control measures. Surveillance thus implies that official action will follow from the discovery of evidence of disease or infection. It can be contrasted with monitoring, in which the gathering of data from the field takes place similarly, but no official action based on the findings is implied in the data-gathering activity.

Within the context of pleuropneumonia, specific measures need to be implemented, such as an exhaustive inspection of all lungs of bovines throughout the country or zone.

3. Steps to be taken to declare a country free from contagious bovine pleuropneumonia

The current goal in CBPP control is to achieve freedom from disease in particular countries and later of entire world regions, with the ultimate aim of achieving global eradication. It is therefore necessary to institute a system for verifying the steps towards these short and long-term aims, and to assist countries which wish to trade in livestock or livestock products, but face difficulties due to the presence or past occurrence of CBPP.

In conformity with the general principles for assessing disease status developed by the OIE, a four-stage process should be applied:

- intention to eradicate pleuropneumonia: the longest phase, depending on prevalence of the disease in the country or zone, geographical, socio-economic and administrative conditions, and the capacity of the animal health infrastructure;
- once a country is free from CBPP and that disease is unlikely to be re-introduced, the country can declare itself provisionally free from disease, provided it meets the criteria listed below;
- declaration of freedom from clinical CBPP, after international verification carried out under the auspices of the OIE;

- declaration of freedom from CBPP, where a country meets more stringent surveillance and control criteria.

The last three stages are strictly covered by the epidemiological surveillance methods of the OIE.

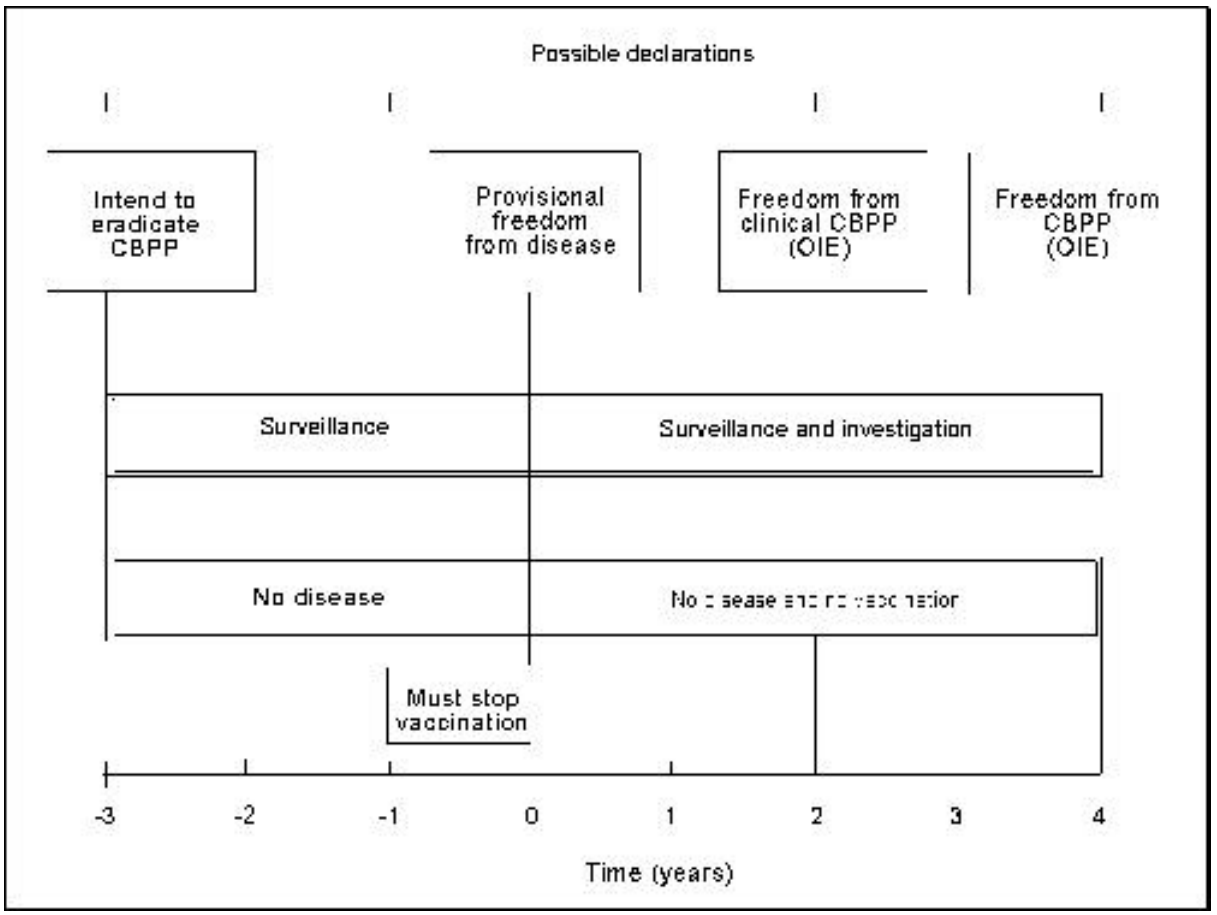
The sequence of operations differs both in terms of tactics and duration depending on whether or not the country wishing to eradicate CBPP practises vaccination.

'Disease' in the context of declaration of freedom means that the particular pathogenic agent is present and causes significant pathological effects on animals which become infected with the agent. Thus 'freedom from disease' means that there is no evidence in animals within the country or zone of any pathological effects occurring (including clinical signs) due to the presence of the agent, and from all the evidence pathogenic strains of the particular agent have been eliminated.

COUNTRIES PRACTISING VACCINATION

The process is summarised in the following chart:

Fig. 1. ***Requirements for the declaration of freedom from disease and freedom from CBPP***



The specific criteria proposed for each stage of this process are as follows:

a) Provisional freedom from disease

For a country to declare the whole or a zone of its territory provisionally free from disease, it must fulfil certain conditions, which are:

i) no clinical or pathological evidence of CBPP should have been detected for at least 3 years;

ii) there is an effective Veterinary Service which is able to monitor the animal health situation in the country;

iii) there is effective meat inspection at *approved abattoirs*, and effective surveillance of populations in which significant numbers of slaughtered susceptible livestock are not subject to meat inspection;

iv) all evidence suggestive of CBPP is investigated by field and laboratory methods (including serological and microbiological assessment) to refute a possible diagnosis of CBPP;

v) there is an effective reporting system, both from the field to the central veterinary authority, and by that body to the OIE;

vi) there is an effective system to prevent the introduction of infection, including appropriate border control, quarantine etc.;

vii) if vaccination has been used, all vaccination against CBPP has ceased by the date of declaration; the OIE and neighbouring countries having been notified in writing, giving the date from which vaccination was discontinued.

b) Freedom from clinical CBPP

A country which has declared itself or a zone to be provisionally free from disease may be declared by the OIE free from clinical CBPP, provided that the following criteria are met:

i) no clinical or pathological evidence of CBPP has been detected for at least 5 years;

ii) no CBPP vaccination has taken place for at least 2 years;

iii) the country operates surveillance and disease reporting systems for CBPP adequate to detect disease if it were present, and ensures that veterinary staff are adequately trained in the recognition of CBPP;

iv) all susceptible livestock at recognised abattoirs are subject to meat inspection procedures adequate to detect lung lesions, with diagnostic procedures to refute a possible diagnosis of CBPP;

v) there has been a programme of surveillance (using serological, pathological and microbiological techniques) for at least 2 years on any populations of susceptible domestic livestock where more than 10% of slaughtering is not subject to adequate meat inspection procedures;

vi) all evidence suggestive of CBPP is investigated by field and laboratory methods (including serological and microbiological assessment) to refute a possible diagnosis of CBPP;

vii) there are effective measures in force to prevent re-introduction of the disease.

On meeting these criteria, a country may apply to the OIE for all, or a zone, of its territory to be declared free from clinical CBPP.

An Expert Panel for the Verification of Disease Status of the OIE will evaluate the application and decide whether or not to approve it. In coming to its decision, the Expert Panel will consider evidence presented by the country and will gather information on the extent to which the criteria are met. This information-gathering will usually include sending members of the Panel to make a field visit to the country. The Expert Panel will report its findings to the OIE Scientific Commission for Animal Diseases. The Commission will report its conclusions annually to the International Committee for endorsement.

To maintain this status, a country must continue to meet these requirements until it is declared free from CBPP, and must report to the OIE an annual summary of developments.

Should there be a localised temporary outbreak of disease due to re-introduction of CBPP to a country which has met, or is within 2 years of meeting, the requirements for a declaration of freedom from clinical CBPP, that country should implement a stamping-out policy, which may be supported by intensive perifocal vaccination, to eradicate the outbreak. In such circumstances if no vaccination was carried out, it will then require at least one year from the date of the last case before the country becomes eligible to apply for a declaration of freedom from clinical CBPP. If vaccination was used, this period is extended to 2 years from the date of the last case or the last vaccination (whichever occurs later). In making an application under these special circumstances, it must be shown that the outbreak did not represent endemic infection, and that the disease has been eradicated by the actions taken.

The declaration of zones to be free from clinical CBPP will not remove the requirement for the country subsequently to meet the criteria for declaration of freedom from clinical CBPP for the country as a whole; if it wishes to achieve that status, it will have to meet all of the requirements specified above before it can apply for a declaration of freedom from clinical CBPP for the entire country.

c) Freedom from CBPP

A country or a zone of its territory which has within the last 10 years either vaccinated against CBPP, or found clinical or pathological evidence of CBPP, may be declared by the OIE to be free from CBPP if the following criteria are met:

i) it has been declared free from clinical CBPP at least 2 years earlier, and continues to meet the requirements for this status;

ii) there has been effective abattoir surveillance for at least 4 years, covering all susceptible domestic livestock;

iii) use has been made of diagnostic procedures capable of differentiating *Mycoplasma mycoides* from other bovine *Mycoplasma* infections in the investigation of respiratory disease, and the findings are consistent with freedom from *M. mycoides* infection;

iv) there has been a programme of surveillance, including serological, pathological and microbiological components, for at least 3 years on any populations of susceptible domestic livestock where more than 10% of slaughter stock are not subject to adequate meat inspection procedures.

On satisfying these criteria, a country may apply to the OIE to be declared free from CBPP.

An Expert Panel for the Verification of Disease Status of the OIE will evaluate the application and decide whether or not to approve it. In coming to its decision, the Expert Panel will consider evidence presented by the country and will gather information on the extent to which the criteria are met. This information-gathering will usually include sending members of the Panel to make a field visit to the country.

The Expert Panel will report its findings to the OIE Scientific Commission for Animal Diseases. The Commission will report its conclusions annually to the International Committee for endorsement.

In the special case of a country or zone which has been considered to be continuously free from CBPP for at least 10 years, and meets all of the following requirements:

v) has not vaccinated against CBPP for at least 10 years;

vi) throughout that period found no clinical or pathological evidence of CBPP infection;

vii) had throughout that period, and undertakes to maintain permanently, an adequate disease surveillance and reporting system, covering all susceptible domestic livestock;

viii) in appropriate circumstances, made use of diagnostic procedures capable of differentiating *Mycoplasma mycoides*; from other bovine *Mycoplasma* infections in the investigation of respiratory disease, with findings consistent with freedom from *M. mycoides* infection;

the country or zone may be declared by the OIE to be free from CBPP without the necessity to proceed through the normal intermediate steps. This declaration will be based on the conclusions of the Expert Panel for the Verification of Disease Status.

Declaration of freedom from CBPP can be made for the country as a whole, or for zones within a country.

Should there be a localised temporary outbreak of disease due to re-introduction of CBPP to a country which has met, or is within one year of meeting, the requirements for a declaration of freedom from CBPP, that country may take special measures (excluding the use of vaccination) to eradicate the outbreak. In such circumstances, it will then require at least 2 years from the date of the last case before the country becomes eligible to apply for a declaration of freedom from CBPP. In making an application under these special circumstances, the country must demonstrate that the outbreak did not represent endemic infection, and that the disease has been eradicated by the actions taken.

In order to maintain this status, the country must continue to operate an efficient disease surveillance and reporting system, which would detect CBPP if it occurred.

COUNTRIES NOT PRACTISING VACCINATION

These are generally countries with a solid animal health infrastructure (with a system for individually identifying animals) where CBPP has been accidentally introduced.

The specific criteria proposed for each stage of this process are as follows:

a) Provisional freedom from disease

A country may declare the whole or a zone of its territory provisionally free from disease one year after the last infected herds and in-contact herds have been slaughtered, on condition that:

i) there has been no vaccination in the country or zone for at least 2 years;

ii) all treatment against CBPP is prohibited for sick animals or suspected cases;

iii) a stamping-out policy is implemented after any CBPP outbreaks. Within the framework of the declaration, a minimum period of 12 months will be required after the last sick or in-contact herd has been slaughtered;

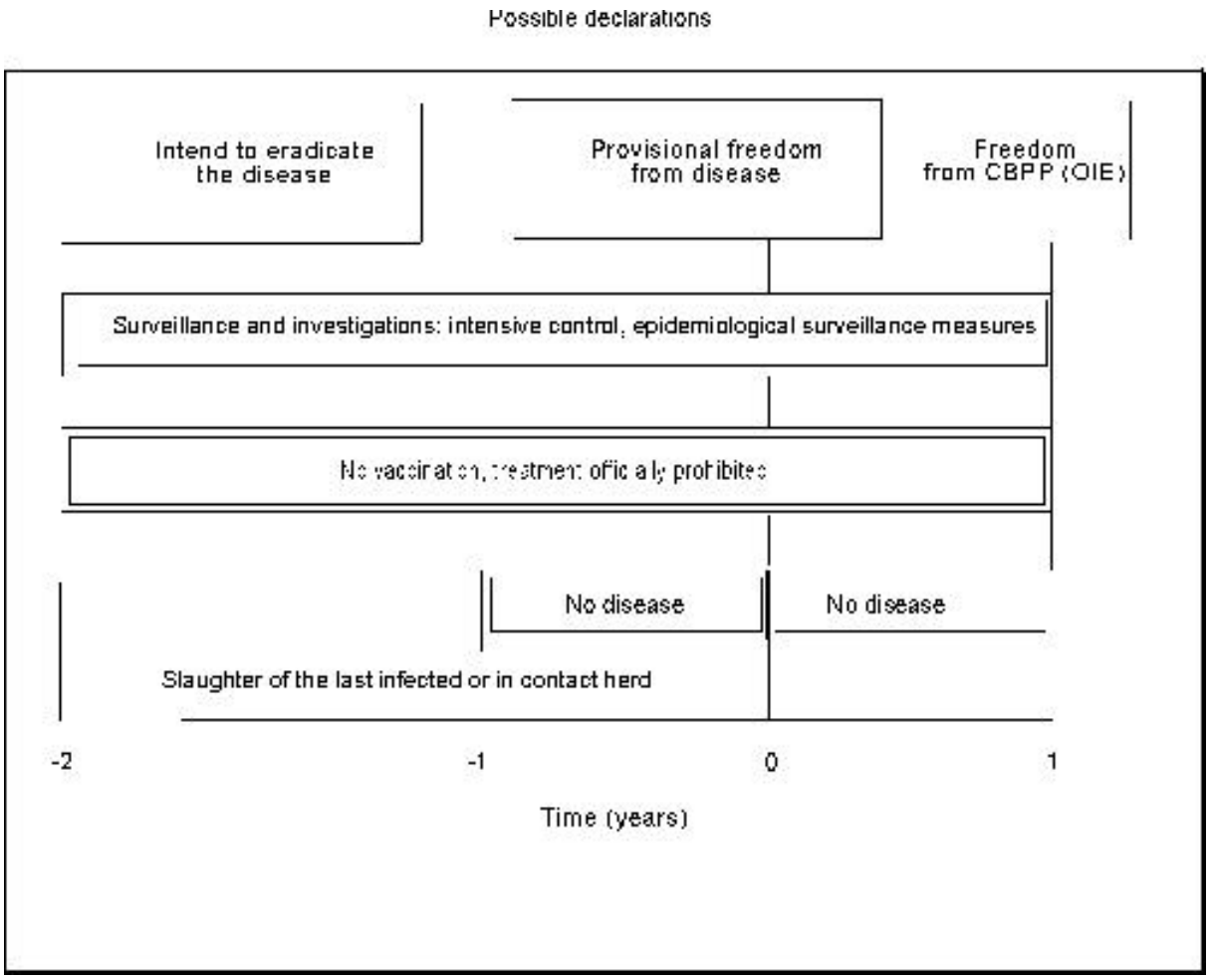
iv) an epidemiological investigation, including serological tests, has been carried out to determine the prevalence of the disease in the country or infected zone. Special attention should be given to screening animals transported into or out of the infected herds during the 6 months preceding detection of the outbreak(s);

v) a system of livestock identification and movement control has been set up in the country or zone for the purposes of CBPP control and surveillance as follows:

- all herds are officially registered and all animals of susceptible species aged over 12 months are individually identified;

- before being moved, other than for immediate slaughter, all animals of susceptible species are to be clinically inspected and serologically tested for CBPP;

Fig. 2. ***Summary of the accelerated eradication process***



vi) all animals of susceptible species in herds or *establishments* within a 3-km radius of an outbreak, and any animals with a possible epidemiological link, are individually identified, placed in quarantine for at least 6 months, and

- all animals of susceptible species in the aforementioned herds or *establishments* are serological tested on two occasions at an interval of 2 to 8 weeks; microbiological investigations are to be carried out on any serologically positive animal;
- during the quarantine period, animals in the aforementioned herds or *establishments* are not to be moved other than to an officially approved abattoir, where they are to be immediately slaughtered and subjected to sanitary inspection after slaughter;
- microbiological tests should be carried out on animals presenting lesions suggestive of CBPP;

vii) surveillance is carried out in abattoirs in the contaminated country. Any lesion suggestive of CBPP should be examined microbiologically and, if the result is positive, the herd of origin must be found and subjected to serological testing;

viii) the diagnostic tests used in the country or zone comply with OIE standards and are conducted in a nationally approved laboratory.

b) Freedom from contagious bovine pleuropneumonia

A country or zone may be declared by the OIE to be free from CBPP 2 years after the last infected and in-contact herds have been slaughtered if the conditions listed in paragraphs a)i) to a)viii) continue to be met.

4. Epidemiological methods

a) Surveillance systems

In demonstrating that a country or zone is free of disease, it is necessary to conduct a surveillance programme which would have a very high probability of detecting the disease if it were present. Surveillance for CBPP will include a combination of clinical, pathological, serological and microbiological methods, built around an epidemiological surveillance approach. The mix of procedures used will depend on the specific circumstances of the country or zone.

The most efficient means of detecting CBPP is through effective meat inspection procedures at abattoirs followed by laboratory examination of suspect lesions. Where a very high proportion of susceptible domestic livestock are slaughtered in controlled abattoirs, this will provide a very sensitive surveillance system covering the whole population. It is possible that structured investigation of a statistical sample of carcasses might be used to augment the routine meat inspection procedures.

Where large numbers of susceptible livestock are exported for slaughter, it may be necessary to obtain meat inspection data from the importing country.

Where a significant proportion of susceptible domestic livestock are not subject to meat inspection at the abattoir, then it will be necessary to use alternative surveillance methods based on the examination of samples of herds so as to achieve a standard probability of detection. Animals in sampled herds would be subjected to clinical examination for signs of CBPP, but not all infected animals exhibit clinical signs. Serological testing can be useful in identifying infected herds, but due to the limitations of the currently available serological tests, and the possibility that the disease may be present at very low prevalence, such surveillance systems are not very efficient in proving freedom from disease, and require large numbers of herds to be sampled.

b) Definition of sampling units

A sampling unit for the purposes of disease investigation and surveillance is defined as a group of animals in sufficiently close contact that individuals in the group would be at approximately equal risk of coming into contact with the disease agent if there were an infectious animal within the group. In most circumstances, the sampling unit would be a herd which is managed as a unit by an individual or a community, but there may be other epidemiologically appropriate groupings which are subject to regular mixing, such as all the animals belonging to residents of a village. Sampling units should normally be defined so that the majority of units contain between 50 and 1,000 animals.

c) Criteria for the stratification and sampling of host populations

'Serological surveillance would only be adopted for CBPP in circumstances where the preferred slaughterhouse surveillance system described in item 3(c) of this document could not be carried out on an adequate scale because too low a proportion of animals was slaughtered in a slaughterhouse. Thus the following system would be used as an exceptional case, rather than as the usual procedure'.

Any disease surveillance activities must be conducted on populations stratified according to disease risk, which depends principally upon the environment and management system. The cattle production systems of most countries would be categorised into between two and six strata.

Annual sample sizes must be sufficient to provide 95% probability of detecting evidence of CBPP if it were present at a prevalence of 1% of herds or other sampling units. Given perfect sensitivity of the within-herd testing procedure, this would require the examination of 300 herds from each stratum per year. However, the currently available serological tests have rather low sensitivity. The sensitivity of the test procedure at herd level is further reduced when only a sample of the herd is tested. It is possible to compensate for lower sensitivity by increasing the numbers of herds examined. The required sample size is determined by adjusting the prevalence to allow for the lack of sensitivity. For example, if there was 50% probability of detecting a sampled infected herd (sensitivity 0.5), then a true disease prevalence of 1% of herds would result in a detectable prevalence of 0.5%, and this detectable prevalence would be used to determine the required sample size.

Herds, or other sampling units, must be selected from each stratum by proper random methods, which are described in the *Guide to Epidemiological Surveillance for Rinderpest* published by the OIE. Any randomly selected herd must be examined in order to achieve the required probability of detection. However, this probability can often be increased by an important but unquantifiable margin by sampling additional herds based on subjective assessment of risk, or information gained during field work.

5. Contagious bovine pleuropneumonia vaccines

T1 strain (and its streptomycin-resistant variant) is the recommended vaccine, and the following facts are relevant to disease surveillance activities:

Current vaccines do not induce life-long immunity; the duration of protection after vaccination is about one year.

A significant proportion of vaccinated animals do not develop a serological response detectable by currently used techniques, although such animals may be protected against challenge. Where the serological response to vaccination is detectable by the complement fixation test, it usually persists for less than 3 months.

As their immunity wanes, vaccinated cattle are more likely to develop chronic lesions (sequestra) after infection.

6. Diagnostic methods

The diagnosis of CBPP depends on:

a) clinical signs in the live animal;

b) gross pathological findings;

c) serological tests;

d) culture and identification of the causative organism.

e) Clinical diagnosis

The clinical signs of CBPP may be slight or non-existent. Furthermore, the use of anti-microbial or anti-inflammatory drugs can mask the clinical expression of the disease. For these reasons, clinical signs are an unreliable indicator of the presence of the disease. However, if respiratory disease is observed in a livestock population, then the diagnosis of CBPP should be considered and confirmed or rejected on the basis of further pathological, microbiological or serological investigations.

f) Gross pathology

The lung lesions of CBPP are distinctive. Consequently, abattoir meat inspection is the most practical single method for maintaining CBPP surveillance. The pleura and lungs should be examined by palpation and section. A mixture of acute lesions and chronic lesions (sequestra) may be found in the same herd or even the same animal. In case of chronic infection, post-mortem diagnosis may be the only way of detecting asymptomatic animals, which may not react to serological tests.

g) Serological diagnosis

The serological test of choice is the complement fixation test (CFT). The specificity of this test can be as high as 99.5%, but the frequency of false positive reactions may temporarily be higher in certain herds. The sensitivity of the test is limited, and it may fail to identify four classes of animals:

i) animals in the very early stages of the disease;

ii) animals in the very late stages of the disease (the CFT appears to fail to detect 30% of animals containing sequestra);

iii) animals with massive lesions, where the antibodies produced are overwhelmed by the antigen;

iv) animals which have been treated in the early stages of the disease may fail to develop a detectable serological response.

Despite these limitations, the CFT is a useful herd test.

The CFT reaction after vaccination is inconstant and short-lived (generally less than 3 months).

An indirect enzyme linked immunosorbent assay (ELISA) is under field evaluation in several countries. It is at least as sensitive as the CFT, but as with other ELISA systems, increased sensitivity can only be achieved at the expense of specificity, and vice versa. It is a useful tool to measure the efficacy of vaccination programmes, as the detectable response is more reliable than the CFT, and may persist for as long as one year after vaccination.

Monoclonal and competitive ELISA systems are being developed and should offer higher specificity.

The passive haemagglutination test, while not used routinely, may have a place in serological diagnosis. It is more sensitive than the CFT in early and late stages of disease, but the specificity is lower. It has a potential role as a screening test.

The slide agglutination test is simple to perform and could be used as a pen-side test. It is more sensitive than the CFT in the early stages of the disease, but it lacks specificity.

h) Culture and identification of the causative organism

It is desirable that all diagnoses are confirmed by isolation of the causative organism. It may prove difficult to isolate *Mycoplasma* from chronic lesions and also after animals have been treated with anti-microbial drugs.

The causative organism is normally identified by growth inhibition tests and/or the immunofluorescence test. Closely related *Mycoplasma* may cause cross-reactions in these tests. Several new techniques which may overcome this problem are being developed, and these include immunobinding, immunoperoxidase and polymerase chain reaction (PCR) tests. These need further evaluation.

i) Testing imported animals

In formulating its recommendations for a system of declaration of freedom, the Group acknowledged that existing serological tests for CBPP are quite variable in sensitivity and specificity. Hence serological methods alone are unlikely to prevent the introduction of infection if live animals are imported from CBPP-infected countries. The chronic course of the disease may mean that diagnosis following introduction of CBPP may be delayed by a number of years. In the longer term there is a need for more sensitive and specific diagnostic tests. Pending the development of such tests, serological methods are necessary, but not sufficient to prevent introduction of the disease in live animals.

APPENDIX 3.8.4.

SURVEILLANCE FOR BOVINE SPONGIFORM ENCEPHALOPATHY

Article 3.8.4.1.

Introduction

1. Depending on the risk category of a country, *zone* or *compartment* with regard to bovine spongiform encephalopathy (BSE), surveillance for BSE may have one or more goals:

   a) detecting BSE, to a pre-determined design prevalence, in a country, *zone* or *compartment*;

   b) monitoring the evolution of BSE in a country, *zone* or *compartment*;

   c) monitoring the effectiveness of a feed ban and/or other risk mitigation measures, in conjunction with auditing;

   d) supporting a claimed BSE status;

   e) gaining or regaining a higher BSE status.

2. When the BSE agent is present in a country or *zone*, the cattle population will comprise the following sectors, in order of decreasing size:

   a) cattle not exposed to the infective agent;

   b) cattle exposed but not infected;

   c) infected cattle, which may lie within one of three stages in the progress of BSE:

      i) the majority will die or be killed before reaching a stage at which BSE is detectable by current methods;

      ii) some will progress to a stage at which BSE is detectable by testing before clinical signs appear;

      iii) the smallest number will show clinical signs.

3. The BSE status of a country, *zone* or *compartment* cannot be determined only on the basis of a surveillance programme but should be determined in accordance with all the factors listed in Article 2.3.13.2. The surveillance programme should take into account the diagnostic limitations associated with the above sectors and the relative distributions of infected cattle among them.

4. With respect to the distribution and expression of the BSE agent within the sectors described above, the following four subpopulations of cattle have been identified for surveillance purposes:

   a) cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects);

   b) cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency slaughter or condemned at ante-mortem inspection (casualty or emergency slaughter or downer cattle);

   c) cattle over 30 months of age which are found dead or killed on farm, during transport or at an *abattoir* (fallen stock);

   d) cattle over 36 months of age at routine slaughter.

5. A gradient is used to describe the relative value of surveillance applied to each subpopulation. Surveillance should focus on the first subpopulation, but investigation of other subpopulations will help to provide an accurate assessment of the BSE situation in the country, *zone* or *compartment*. This approach is consistent with Appendix 3.8.1. on general guidelines for animal health surveillance.

6. When establishing a surveillance strategy, authorities need to take into account the inherent difficulties of obtaining samples on farm, and overcome them. These difficulties include higher cost, the necessity to educate and motivate owners, and counteracting potentially negative socio-economic implications.

Article 3.8.4.2.

Description of cattle subpopulations

1. Cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects)

   Cattle affected by illnesses that are refractory to treatment, and displaying progressive behavioural changes such as excitability, persistent kicking when milked, changes in herd hierarchical status, hesitation at doors, gates and barriers, as well as those displaying progressive neurological signs without signs of infectious illness are candidates for examination. These behavioural changes, being very subtle, are best identified by those who handle animals on a daily basis. Since BSE causes no pathognomonic clinical signs, all countries with cattle populations will observe individual animals displaying clinical signs consistent with BSE. It should be recognised that cases may display only some of these signs, which may also vary in severity, and such animals should still be investigated as potential BSE affected animals. The rate at which such suspicious cases are likely to occur will differ among epidemiological situations and cannot therefore be predicted reliably.

   This subpopulation is the one exhibiting the highest prevalence. The accurate recognition, reporting and classification of such animals will depend on the ongoing owner/veterinarian awareness programme. This and the quality of the investigation and laboratory examination systems (Article 2.3.13.2.), implemented by the *Veterinary Services*, are essential for the credibility of the surveillance system.

2. Cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency slaughter or condemned at ante-mortem inspection (casualty or emergency slaughter, or downer cattle)

   These cattle may have exhibited some of the clinical signs listed above which were not recognised as being consistent with BSE. Experience in countries where BSE has been identified indicates that this subpopulation is the one demonstrating the second highest prevalence. For that reason, it is the second most appropriate population to target in order to detect BSE.

3. Cattle over 30 months of age which are found dead or killed on farm, during transport or at an abattoir (fallen stock)

   These cattle may have exhibited some of the clinical signs listed above prior to death, but were not recognised as being consistent with BSE. Experience in countries where BSE has been identified indicates that this subpopulation is the one demonstrating the third highest prevalence.

4. Cattle over 36 months of age at routine slaughter

   Experience in countries where BSE has been identified indicates that this subpopulation is the one demonstrating the lowest prevalence. For that reason, it is the least appropriate population to target in order to detect BSE. However, sampling in this subpopulation may be an aide in monitoring the progress of the epizootic and the efficacy of control measures applied, because it offers continuous access to a cattle population of known class, age structure and geographical origin. Testing of routine slaughter cattle 36 months of age or less is of relatively very little value (Table 2).

Article 3.8.4.3.

Implementation of surveillance

In order to implement efficiently a surveillance strategy for BSE, a country must use documented records or reliable estimates of the age distribution of the adult cattle population and the number of cattle tested for BSE stratified by age and by subpopulation within the country, *zone* or *compartment*.

The approach assigns ‘point values’ to each sample, based on the subpopulation from which it was collected and the likelihood of detecting infected cattle in that subpopulation. The number of points a sample is assigned is

determined by the subpopulation from which the sample is collected and the age of the animal sampled. The total points accumulation is then periodically compared to the target number of points for a country, *zone* or *compartment*.

A surveillance strategy should be designed to ensure that samples are representative of the herd of the country, *zone* or *compartment*, and include consideration of demographic factors such as production type and geographic location, and the potential influence of culturally unique husbandry practices. The approach used and the assumptions made should be fully documented, and the documentation retained for 7 years.

The points targets and surveillance point values in this Appendix were obtained by applying the following factors to a statistical model:

a) the design prevalence for Type A or Type B surveillance;

b) a confidence level of 95%;

c) the pathogenesis, and pathological and clinical expression of BSE:

   i) sensitivity of diagnostic methods used;

   ii) relative frequency of expression by age;

   iii) relative frequency of expression within each subpopulation;

   iv) interval between pathological change and clinical expression;

d) demographics of the cattle population, including age distribution;

e) influence of BSE on culling or attrition of animals from the cattle population via the four subpopulations;

f) percentage of infected animals in the cattle population which are not detected.

Although the procedure accepts very basic information about a cattle population, and can be used with estimates and less precise data, careful collection and documentation of the data significantly enhance their value. Since samples from clinical suspect animals provide many times more information than samples from healthy or dead-of-unknown-cause animals, careful attention to the input data can substantially decrease the procedure's cost and the number of samples needed. The essential input data are:

g) cattle population numbers stratified by age;

h) the number of cattle tested for BSE stratified by age and by subpopulation.

This Appendix utilises Tables 1 and 2 to determine a desired surveillance points target and the point values of surveillance samples collected.

Within each of the subpopulations above in a country, *zone* or *compartment*, a country may wish to target cattle identifiable as imported from countries or *zones* not free from BSE and cattle which have consumed potentially contaminated feedstuffs from countries or *zones* not free from BSE.

All clinical suspects should be investigated, regardless of the number of points accumulated. In addition, animals from the other subpopulations should be tested.

1. Type A surveillance

   The application of Type A surveillance will allow the detection of BSE around a design prevalence of at least one case per 100,000 in the adult cattle population in the country, *zone* or *compartment* of concern, at a confidence level of 95%.

2. Type B surveillance

   The application of Type B surveillance will allow the detection of BSE around a design prevalence of at least one case per 50,000 in the adult cattle population in the country, *zone* or *compartment* of concern, at a confidence level of 95%.

   Type B surveillance may be carried out by countries, *zones* or *compartments* of negligible BSE risk status (Article 2.3.13.13.) to confirm the conclusions of the risk assessment, for example by demonstrating the effectiveness of the measures mitigating any risk factors identified, through surveillance targeted to maximise the likelihood of identifying failures of such measures.

   Type B surveillance may also be carried out by countries, *zones* or *compartments* of controlled BSE risk status (Article 2.3.13.4.), following the achievement of the relevant points target using Type A surveillance, to maintain confidence in the knowledge gained through Type A surveillance.

Article 3.8.4.4.

1. Selecting the points target

The surveillance points target should be selected from Table 1, which shows target points for adult cattle populations of different sizes. The size of the adult cattle population of a country, *zone* or *compartment* may be estimated or may be set at one million because, for statistical reasons, one million is the point beyond which sample size does not further increase with population size.

Table 1. ***Points targets for different adult cattle population sizes in a country, zone or compartment***

Points targets for country, zone or compartment		
Adult cattle population size (24 months and older)	**Type A surveillance**	**Type B surveillance**
≥1,000,000	300,000	150,000
800,000-1,000,000	240,000	120,000
600,000-800,000	180,000	90,000
400,000-600,000	120,000	60,000
200,000-400,000	60,000	30,000
100,000-200,000	30,000	15,000
50,000-100,000	15,000	7,500

2. Determining the point values of samples collected

Table 2 can be used to determine the point values of the surveillance samples collected. The approach assigns point values to each sample according to the likelihood of detecting infection based on the subpopulation from which the sample was collected and the age of the animal sampled. This approach takes into account the general principles of surveillance described in Appendix 3.8.1. and the epidemiology of BSE.

Because precise aging of the animals that are sampled may not be possible, Table 2 combines point values into five age categories. The point estimates for each category were determined as an average for the age range comprising the group. The age groups were selected on their relative likelihoods of expressing BSE according to scientific knowledge of the incubation of the disease and the world BSE experience. Samples may be collected from any combination of subpopulations and ages but should reflect the demographics of the cattle herd of the country, *zone* or *compartment*. In addition, countries should sample at least three of the four subpopulations.

If a country, *zone* or *compartment* determines, based on the demographics and epidemiological characteristics of its cattle population, that precise classification of the subpopulations 'casualty or emergency slaughter, or downer cattle' and 'fallen stock' is not possible, these subpopulations may be combined. In such a case, the surveillance point values accorded to the combined subpopulation would be that of 'fallen stock'.

The total points for samples collected may be accumulated over a period of a maximum of 7 consecutive years to achieve the target number of points determined in Table 1.

Table 2. ***Surveillance point values for samples collected from animals in the given subpopulation and age category***

Surveillance subpopulation			
Routine slaughter[2]	**Fallen stock[3]**	**Casualty slaughter[4]**	**Clinical suspect[5]**
Age ≥1 year and <2years			
0.01	0.2	0.4	N/A
Age ≥2 years and <4 years (young adult)			
0.1	0.2	0.4	260
Age ≥4 years and <7 years (middle adult)			

Table 2. ***Surveillance point values for samples collected from animals in the given subpopulation and age category (contd)***

0.2	0.9	1.6	750
Age ≥7 years and <9 years (older adult)			
0.1	0.4	0.7	220
Age ≥9 years (aged)			
0.0	0.1	0.2	45

Surveillance points remain valid for 7 years (the 95th percentile of the incubation period).

1 DP (design prevalence) is used to determine the size of a testing survey expressed in terms of target points. If the actual prevalence is greater than the selected design prevalence, the survey is highly likely to detect disease.

2 See point 4) of Article 3.8.4.2.

3 See point 3) of Article 3.8.4.2.

4 See point 2) of Article 3.8.4.2.

5 See point 1) of Article 3.8.4.2.

APPENDIX 3.8.5.

FACTORS TO CONSIDER IN CONDUCTING THE BOVINE SPONGIFORM ENCEPHALOPATHY RISK ASSESSMENT RECOMMENDED IN CHAPTER 2.3.13.

Article 3.8.5.1.

Introduction

The first step in determining the bovine spongiform encephalopathy (BSE) risk status of the cattle population of a country or *zone* is to conduct a *risk assessment* (reviewed annually), based on Section 1.3. of this *Terrestrial Code*, identifying all potential factors for BSE occurrence and their historic perspective.

1. Release assessment

   Release assessment consists of assessing the likelihood that a transmissible spongiform encephalopathy (TSE) agent has been introduced via the importation of the following commodities potentially contaminated with a TSE agent:

   a) *meat-and-bone meal* or *greaves*;

   b) live animals;

   c) animal feed and feed ingredients;

   d) products of animal origin for human consumption.

2. Exposure assessment

   Exposure assessment consists of assessing the likelihood of exposure of the BSE agent to cattle, through a consideration of the following:

   a) epidemiological situation concerning all animal TSE agents in the country or *zone*;

   b) recycling and amplification of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;

   c) the origin and use of ruminant carcasses (including fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;

   d) implementation and enforcement of feed bans, including measures to prevent cross-contamination of animal feed.

The following guidelines are intended to assist *Veterinary Services* in conducting such a *risk assessment*.

Article 3.8.5.2.

The potential for the release of the BSE agent through importation of meat-and-bone meal or greaves

This point is irrelevant if the exposure assessment outlined below in Article 3.8.5.5. indicates that *meat-and-bone meal* or *greaves* has not been fed, either deliberately or accidentally, in the past 8 years. Nevertheless, documentation should be provided on the control systems (including relevant legislation) in place to ensure that *meat-and-bone meal* or *greaves* has not been fed to ruminants.

Assumption: That *meat-and-bone meal* or *greaves* of ruminant origin plays the only significant role in BSE transmission.

Question to be answered: Has *meat-and-bone meal*, *greaves*, or feedstuffs containing either been imported within the past 8 years? If so, where from and in what quantities?

Rationale: Knowledge of the origin of *meat-and-bone meal*, *greaves* or feedstuffs containing either *meat-and-bone meal* or *greaves*, is necessary to assess the risk of release of BSE agent. *Meat-and-bone meal* and *greaves* originating in countries

of high BSE risk pose a higher release risk than that from low risk countries. *Meat-and-bone meal* and *greaves* originating in countries of unknown BSE risk pose an unknown release risk.

Evidence required:

- Documentation to support claims that *meat-and-bone meal*, *greaves* or feedstuffs containing either *meat-and-bone meal* or *greaves* have not been imported, OR
- Where *meat-and-bone meal*, *greaves* or feedstuffs containing them have been imported, documentation of country of origin and, if different, the country of export.
- Documentation on annual volume, by country of origin, of *meat*, *greaves* or feedstuffs containing them imported during the past 8 years.
- Documentation describing the composition (on a species and class of stock basis) of the imported *meat-and-bone meal*, *greaves* or feedstuffs containing them.
- Documentation, from the country of production, supporting why the rendering processes used to produce *meat-and-bone meal*, *greaves* or feedstuffs containing them would have inactivated, or significantly reduced the titre of TSE agent, should it be present.
- Documentation describing the fate of imported *meat-and-bone meal* and *greaves*.

Article 3.8.5.3.

The potential for the release of the BSE agent through the importation of live animals potentially infected with a TSE

Assumptions:

- Countries which have imported ruminants from countries infected with animal TSEs are more likely to experience BSE.
- Cattle pose the only known risk although other species are under stud.
- Animals imported for breeding may pose a greater risk than animals imported for slaughter because of the hypothetical risk of maternal transmission and because they are kept to a greater age than animals imported for slaughter.
- Risk is influenced by the date at which imports occurred, relative to the BSE status of the country of origin.
- Risk is proportional to volume of imports (Article 1.3.2.3.).

Question to be answered: Have live animals been imported within the past 7 years?

Rationale: The release risks are dependent on:

- country of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical disease, or following active surveillance, or assessment of geographical BSE risk;
- feeding and management of the animals in the country of origin;
- use to which the commodity has been put as apart from representing risk of developing clinical disease, the slaughter, rendering and recycling in *meat-and-bone meal* of imported animals represents a potential route of exposure of indigenous livestock even if *meat-and-bone meal* and *greaves*, or feedstuffs containing them, have not been imported;
- species;
- dairy versus meat breeds, where there are differences in exposure in the country of origin because feeding practices result in greater exposure of one category;
- age at slaughter.

Evidence required:

- Documentation on the country of origin of imports. This should identify the country of breeding of animals, the length of time they lived in that country and of any other country in which they have resided during their lifetime.

- Documentation describing origins, species and volume of imports.

- Documentation describing the fate of imported animals, including their age at slaughter.

- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Article 3.8.5.4.

The potential for the release of the BSE agent through the importation of products of animal origin potentially infected with a TSE

Assumptions:

- Semen, embryos, hides and skins or milk are not considered to play a role in the transmission of BSE.

- Countries which have imported products of animal origin from countries with animal TSEs are more likely to experience BSE.

- Risk is influenced by the date at which imports occurred, relative to the animal TSE status of the country of origin.

- Risk is proportional to volume of imports (Article 1.3.2.3.).

Question to be answered: What products of animal origin have been imported within the past 7 years?

Rationale: The release risks are dependent on:

- the species of origin of the animal products and whether these products contain tissues known to contain BSE infectivity (Article 2.3.13.13.);

- country of origin and its animal TSE status, which will change as more data become available; this may result from the detection of clinical disease, or following active surveillance, or assessment of geographical BSE risk;

- feeding and management of the animals in the country of origin;

- use to which the commodity has been put as apart from representing risk of developing clinical disease, the slaughter, rendering and recycling in *meat-and-bone meal* of imported animals represents a potential route of exposure of indigenous livestock even if *meat-and-bone meal* and *greaves*, or feedstuffs containing them, have not been imported;

- species;

- dairy versus meat breeds, where there are differences in exposure in the country of origin because feeding practices result in greater exposure of one category;

- age at slaughter.

Evidence required:

- Documentation on the country of origin of imports. This should identify the country of breeding of animals, the length of time they lived in that country and of any other country in which they have resided during their lifetime.

- Documentation describing origins, species and volume of imports.

- Documentation describing the end use of imported animal products, and the disposal of waste.

- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Article 3.8.5.5.

The potential for the exposure of cattle to the BSE agent through consumption of meat-and-bone meal or greaves of ruminant origin

Assumptions:

- That the consumption by bovines of *meat-and-bone meal* or *greaves* of ruminant origin plays the only significant role in BSE transmission.
- That commercially-available products of animal origin used in animal feeds may contain *meat-and-bone meal* or *greaves* of ruminant origin.
- Milk and blood are not considered to play a role in the transmission of BSE.

Question to be answered: Has *meat-and-bone meal* or *greaves* of ruminant origin been fed to cattle within the past 8 years (Articles 2.3.13.3. and 2.3.13.4. in the *Terrestrial Code*)?

Rationale: If cattle have not been fed products of animal origin (other than milk or blood) potentially containing *meat-and-bone meal* or *greaves* of ruminant origin within the past 8 years, *meat-and-bone meal* and *greaves* can be dismissed as a risk.

Article 3.8.5.6.

Epidemiological situation concerning all animal TSE in the country or zone

Assumptions:

- BSE may have originated from scrapie of sheep. Countries with scrapie may be at greater risk than those which have demonstrated scrapie freedom.
- Theoretically, scrapie in small ruminants might mask the presence of BSE and no field methods are available to differentiate between different TSEs.
- Available evidence suggests there is no link between chronic wasting disease of cervids and BSE.
- It has been suggested that transmissible mink encephalopathy may be an indicator of a hitherto undefined and hypothetical TSE of cattle.
- If a hypothetical 'spontaneous' TSE of cattle is assumed to occur, it must also be assumed to occur in all countries at a similar rate.

Question to be answered: Have other animal TSEs been identified in the country? What surveillance is there for TSEs?

Rationale: Surveillance programmes generate a picture of the epidemiological situation of animal TSE. The greater the surveillance effort, the greater the power of the information. Adequately targeted surveillance for BSE, such as described in Appendix 3.8.4., provides more powerful information than generic animal disease surveillance.

Evidence required: Documentation on awareness and surveillance programmes targeting all TSEs of livestock, their legal basis, scale, duration, and data generated.

Article 3.8.5.7.

The origin of animal waste, the parameters of the rendering processes and the methods of animal feed production

Assumptions:

- TSE of livestock have long *incubation periods* and insidious onset of signs, so cases may escape detection.
- Pre-clinical TSE cannot be detected by any method and may enter rendering, in particular if specified risk materials are not removed.
- Tissues most likely to contain high titres of TSE infectivity (brain, spinal cord, eyes) may not be harvested for human consumption and may be rendered.

- TSE of livestock may manifest in sudden death, chronic disease, or recumbency, and may be presented as fallen stock or materials condemned as unfit for human consumption.

- TSE agent survival in rendering is affected by the method of processing. Adequate rendering processes are described in Appendix 3.6.3.

- TSE agent is present at much higher titres in central nervous system and reticulo-endothelial tissues (so-called 'Specified Risk Materials', or SRM).

Question to be answered: How has animal waste been processed over the past 8 years?

Rationale: If potentially infected animals or contaminated materials are rendered, there is a risk that the resulting *meat-and-bone meal* could retain TSE infectivity.

Where *meat-and-bone meal* is utilized in the production of any animal feeds, the risk of cross-contamination exists.

Evidence required:

- Documentation describing the collection and disposal of fallen stock and materials condemned as unfit for human consumption.

- Documentation describing the definition and disposal of specified risk material, if any.

- Documentation describing the rendering process and parameters used to produce *meat-and-bone meal* and *greaves.*

- Documentation describing methods of animal feed production, including details of ingredients used, the extent of use of *meat-and-bone meal* in any livestock feed, and measures that prevent cross-contamination of cattle feed with ingredients used in monogastric feed.

- Documentation describing monitoring and enforcement of the above.

Article 3.8.5.8.

The overall risk of BSE in the cattle population of a country or *zone* is proportional to the level of known or potential exposure to BSE infectivity and the potential for recycling and amplification of the infectivity through livestock feeding practices. For the *risk assessment* to conclude that the cattle population of a country or *zone* is free from BSE risk, it must have demonstrated that appropriate measures have been taken to manage any risks identified.

APPENDIX 3.8.6.

PRINCIPLES FOR RECOGNISING A COUNTRY OR ZONE HISTORICALLY FREE FROM SCRAPIE

Article 3.8.6.1.

Introduction

This Appendix outlines principles for declaring a country or *zone* free from scrapie.

An essential prerequisite to provide the guarantees required for the recognition of freedom from *disease/infection* is that the *Veterinary Services* of the Member Country comply with the provisions of Chapter 1.3.3. on evaluation of *Veterinary Services*, and, if relevant, with the provisions of Chapter 1.3.5. on zoning and compartmentalisation.

The provisions of this Appendix are based on the principles developed in Appendix 3.8.1. and the following premises:

1. the sheep population of the country or *zone* includes a range of genotypes known to be susceptible to scrapie;

2. the *Veterinary Services* have the competence, capacity and mandate to investigate, diagnose and report scrapie, if present;

3. the absence of scrapie over a long period of time can be substantiated by effective *disease* investigation and reporting by the *Veterinary Services* of an OIE Member Country.

Article 3.8.6.2.

Requirements to declare a country or zone free from scrapie

1. Historically free

   A country or *zone* may be recognised free from scrapie without having applied the requirements of Article 2.4.8.3. when:

   a) scrapie has been notifiable for at least 25 years, and

   b) a formal programme of targeted surveillance and monitoring can be documented as having been in place for at least 10 years, and

   c) the presence of a range of scrapie susceptible genotypes in this sheep population can be documented, and

   d) appropriate measures to prevent scrapie introduction can be documented as having been in place for at least 25 years, and

      i) either scrapie has never been reported; or

      ii) no *case* of scrapie has been reported for at least 25 years.

APPENDIX 3.8.7.

GUIDELINES FOR THE SURVEILLANCE OF FOOT AND MOUTH DISEASE

Article 3.8.7.1.

Introduction

This Appendix defines the principles and provides a guide for the surveillance of foot and mouth disease (FMD) in accordance with Appendix 3.8.1. applicable to countries seeking recognition from the OIE for freedom from FMD, either with or without the use of vaccination. This may be for the entire country or a *zone* within the country. Guidance for countries seeking reestablishment of freedom from FMD for the whole country or a *zone* within the country, either with or without vaccination, following an *outbreak*, as well as guidelines for the maintenance of FMD status are provided. These guidelines are intended to expand on and explain the requirements of Chapter 2.2.10. Applications to the OIE for recognition of freedom should follow the format and answer all the questions posed by the "Questionnaire on FMD" available from the OIE *Central Bureau.*

The impact and epidemiology of FMD differ widely in different regions of the world and therefore it is impossible to provide specific guidelines for all situations. It is axiomatic that the surveillance strategies employed for demonstrating freedom from FMD at an acceptable level of confidence will need to be adapted to the local situation. For example, the approach to proving freedom from FMD following an *outbreak* caused by a pig-adapted strain of FMD virus (FMDV) should differ significantly from an application designed to prove freedom from FMD for a country or *zone* where African buffaloes (*Syncerus caffer*) provide a potential reservoir of infection. It is incumbent upon the applicant country to submit a dossier to the OIE in support of its application that not only explains the epidemiology of FMD in the region concerned but also demonstrates how all the risk factors are managed. This should include provision of scientifically-based supporting data. There is therefore considerable latitude available to Member Countries to provide a well-reasoned argument to prove that the absence of FMDV infection (in non-vaccinated populations) or circulation (in vaccinated populations) is assured at an acceptable level of confidence.

Surveillance for FMD should be in the form of a continuing programme designed to establish that the whole territory or part of it is free from FMDV infection/circulation.

For the purposes of this Appendix, virus circulation means transmission of FMDV as demonstrated by clinical signs, serological evidence or virus isolation.

Article 3.8.7.2.

General conditions and methods

1. A surveillance system in accordance with Appendix 3.8.1. should be under the responsibility of the *Veterinary Authority*. A procedure should be in place for the rapid collection and transport of samples from suspect cases of FMD to a laboratory for FMD diagnoses as described in the *Terrestrial Manual*.

2. The FMD 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 FMD. They should be supported directly or indirectly (e.g. through private veterinarians or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All suspect cases of FMD should be investigated immediately. Where suspicion cannot be resolved by epidemiological and clinical investigation, samples should be taken and submitted to an *approved laboratory*. This requires that sampling kits and other equipment are available for those responsible for surveillance. Personnel responsible for surveillance should be able to call for assistance from a team with expertise in FMD diagnosis and control;

b) implement, when relevant, regular and frequent clinical inspection and serological testing of high-risk groups of animals, such as those adjacent to an FMD infected country or zone (for example, bordering a game park in which infected wildlife 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 FMDV. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from FMDV infection/circulation should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of laboratory testing and the control measures to which the animals concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 3.8.7.3.

Surveillance strategies

1. Introduction

The target population for surveillance aimed at identifying *disease* and *infection* should cover all the susceptible species within the country or *zone* to be recognised as free from FMDV infection/circulation.

The strategy employed may be based on randomised sampling requiring surveillance consistent with demonstrating the absence of FMDV infection/circulation at an acceptable level of statistical confidence. The frequency of sampling should be dependent on the epidemiological situation. Targeted surveillance (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. The applicant country should justify the surveillance strategy chosen as adequate to detect the presence of FMDV infection/circulation in accordance with Appendix 3.8.1. and the epidemiological situation. It may, for example, be appropriate to target clinical surveillance at particular species likely to exhibit clear clinical signs (e.g. cattle and pigs). If a Member Country wishes to apply for recognition of a specific *zone* within the country as being free from FMDV infection/circulation, the design of the survey and the basis for the sampling process would need to be aimed at the population within the *zone*.

For random surveys, the design of the sampling strategy will need to incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect infection/circulation if it were to occur at a predetermined minimum rate. The sample size and expected disease prevalence determine the level of confidence in the results of the survey. The applicant country must justify the choice of design prevalence and confidence level based on the objectives of surveillance and the epidemiological situation, in accordance with Appendix 3.8.1. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.

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

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

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

2. Clinical surveillance

Clinical surveillance aims at detecting clinical signs of FMD by close physical examination of susceptible animals. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, surveillance based on clinical inspection should not be underrated. It may be able to provide a high level of confidence of detection of disease if a sufficiently large number of clinically susceptible animals is examined.

Clinical surveillance and laboratory testing should always be applied in series to clarify the status of FMD suspects detected by either of these complementary diagnostic approaches. Laboratory testing may confirm clinical suspicion, while clinical surveillance may contribute to confirmation of positive serology. Any sampling unit within which suspicious animals are detected should be classified as infected until contrary evidence is produced.

A number of issues must be considered in clinical surveillance for FMD. The often underestimated labour intensity and the logistical difficulties involved in conducting clinical examinations should not be underestimated and should be taken into account.

Identification of clinical cases is fundamental to FMD surveillance. Establishment of the molecular, antigenic and other biological characteristics of the causative virus, as well as its source, is dependent upon disclosure of such animals. It is essential that FMDV isolates are sent regularly to the regional reference laboratory for genetic and antigenic characterization.

3. Virological surveillance

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

a) to monitor at risk populations;

b) to confirm clinically suspect cases;

c) to follow up positive serological results;

d) to test "normal" daily mortality, to ensure early detection of infection in the face of vaccination or in *establishments* epidemiologically linked to an *outbreak*.

4. Serological surveillance

Serological surveillance aims at detecting antibodies against FMDV. Positive FMDV antibody test results can have four possible causes:

a) natural infection with FMDV;

b) vaccination against FMD;

c) maternal antibodies derived from an immune dam (maternal antibodies in cattle are usually found only up to 6 months of age but in some individuals and in some species, maternal antibodies can be detected for considerably longer periods);

d) heterophile (cross) reactions.

It is important that serological tests, where applicable, contain antigens appropriate for detecting antibodies against viral variants (types, subtypes, lineages, topotypes, etc.) that have recently occurred in the region concerned. Where the probable identity of FMDVs is unknown or where exotic viruses are suspected to be present, tests able to detect representatives of all serotypes should be employed (e.g. tests based on nonstructural viral proteins – see below).

It may be possible to use serum collected for other survey purposes for FMD surveillance. However, the principles of survey design described in this Appendix and the requirement for a statistically valid survey for the presence of FMDV should not be compromised.

The discovery of clustering of seropositive reactions should be foreseen. It may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of field strain infection. As clustering may signal field strain infection, the investigation of all instances must be incorporated in the survey design. If vaccination cannot be excluded as the cause of positive serological reactions, diagnostic methods should be employed that detect the presence of antibodies to nonstructural proteins (NSPs) of FMDVs as described in the *Terrestrial Manual.*

The results of random or targeted serological surveys are important in providing reliable evidence that FMDV infection is not present in a country or zone. It is therefore essential that the survey be thoroughly documented.

Article 3.8.7.4.

Countries applying for freedom from FMD for the whole country or a zone where vaccination is not practised

In addition to the general conditions described in Chapter 2.2.10., a Member Country applying for recognition of FMD freedom for the country or a *zone* where vaccination is not practised should provide evidence for the existence of an effective surveillance programme. The strategy and design of the surveillance programme will depend on the prevailing epidemiological circumstances and will be planned and implemented according to general conditions and methods in this Appendix, to demonstrate absence of FMDV infection, during the preceding 12 months in susceptible populations. This requires the support of a national or other laboratory able to undertake identification of FMDV infection through virus/antigen/genome detection and antibody tests described in the *Terrestrial Manual.*

Article 3.8.7.5.

Countries or zones applying for freedom from FMD where vaccination is practised

In addition to the general conditions described in Chapter 2.2.10., a Member Country applying for recognition of country or *zone* freedom from FMD with vaccination should show evidence of an effective surveillance programme planned and implemented according to general conditions and methods in this Appendix. Absence of clinical disease in the country or *zone* for the past 2 years should be demonstrated. Furthermore, surveillance should demonstrate that FMDV has not been circulating in any susceptible population during the past 12 months. This will require serological surveillance incorporating tests able to detect antibodies to NSPs as described in the *Terrestrial Manual.* Vaccination to prevent the transmission of FMDV may be part of a disease control programme. The level of herd immunity required to prevent transmission will depend on the size, composition (e.g. species) and density of the susceptible population. It is therefore impossible to be prescriptive. However, the aim should, in general, be to vaccinate at least 80% of the susceptible population. The vaccine must comply with the *Terrestrial Manual.* Based on the epidemiology of FMD in the country or *zone*, it may be that a decision is reached to vaccinate only certain species or other subsets of the total susceptible population. In that case, the rationale should be contained within the dossier accompanying the application to the OIE for recognition of status.

Evidence to show the effectiveness of the vaccination programme should be provided.

Article 3.8.7.6.

Countries or zones re-applying for freedom from FMD where vaccination is either practised or not practised, following an outbreak

In addition to the general conditions described in Chapter 2.2.10., a country re-applying for country or *zone* freedom from FMD where vaccination is practised or not practised should show evidence of an active surveillance programme for FMD as well as absence of FMDV infection/circulation. This will require serological surveillance

incorporating, in the case of a country or a *zone* practising vaccination, tests able to detect antibodies to NSPs as described in the *Terrestrial Manual*.

Four strategies are recognised by the OIE in a programme to eradicate FMDV infection following an *outbreak*:

1. slaughter of all clinically affected and in-contact susceptible animals;
2. slaughter of all clinically affected and in-contact susceptible animals and vaccination of at-risk animals, with subsequent slaughter of vaccinated animals;
3. slaughter of all clinically affected and in-contact susceptible animals and vaccination of at-risk animals, without subsequent slaughter of vaccinated animals;
4. vaccination used without slaughter of affected animals or subsequent slaughter of vaccinated animals.

The time periods before which an application can be made for re-instatement of freedom from FMD depends on which of these alternatives is followed. The time periods are prescribed in Article 2.2.10.7.

In all circumstances, a Member Country re-applying for country or *zone* freedom from FMD with vaccination or without vaccination should report the results of an active surveillance programme implemented according to general conditions and methods in this Appendix.

Article 3.8.7.7.

The use and interpretation of serological tests (see Figure 1)

The recommended serological tests for FMD surveillance are described in the *Terrestrial Manual*.

Animals infected with FMDV produce antibodies to both the structural proteins (SP) and the nonstructural proteins (NSP) of the virus. Tests for SP antibodies to include SP-ELISAs and the virus neutralisation test (VNT). The SP tests are serotype specific and for optimal sensitivity should utilise an antigen or virus closely related to the field strain against which antibodies are being sought. Tests for NSP antibodies include NSP I-ELISA 3ABC and the electro-immunotransfer blotting technique (EITB) as recommended in the *Terrestrial Manual* or equivalent validated tests. In contrast to SP tests, NSP tests can detect antibodies to all serotypes of FMD virus. Animals vaccinated and subsequently infected with FMD virus develop antibodies to NSPs, but in some, the titre may be lower than that found in infected animals that have not been vaccinated. Both the NSP I-ELISA 3ABC and EITB tests have been extensively used in cattle. Validation in other species is ongoing. Vaccines used should comply with the standards of the *Terrestrial Manual* insofar as purity is concerned to avoid interference with NSP antibody testing.

Serological testing is a suitable tool for FMD surveillance. The choice of a serosurveillance system will depend on, amongst other things, the vaccination status of the country. A country, which is free from FMD without vaccination, may choose serosurveillance of high-risk subpopulations (e.g. based on geographical risk for exposure to FMDV). SP tests may be used in such situations for screening sera for evidence of FMDV infection/circulation if a particular virus of serious threat has been identified and is well characterised. In other cases, NSP testing is recommended in order to cover a broader range of strains and even serotypes. In both cases, serological testing can provide additional support to clinical surveillance. Regardless of whether SP or NSP tests are used in countries that do not vaccinate, a diagnostic follow-up protocol should be in place to resolve any presumptive positive serological test results.

In areas where animals have been vaccinated, SP antibody tests may be used to monitor the serological response to the vaccination. However, NSP antibody tests should be used to monitor for FMDV infection/circulation. NSP-ELISAs may be used for screening sera for evidence of infection/circulation irrespective of the vaccination status of the animal. All herds with seropositive reactors should be investigated. Epidemiological and supplementary laboratory investigation results should document the status of FMDV infection/circulation for each positive herd. Tests used for confirmation should be of high diagnostic specificity to eliminate as many false positive screening test reactors as possible. The diagnostic sensitivity of the confirmatory test should approach that of the screening test. The EITB or another OIE-accepted test should be used for confirmation.

Information should be provided on the protocols, reagents, performance characteristics and validation of all tests used.

1. <u>The follow-up procedure in case of positive test results if no vaccination is used in order to establish or re-establish FMD free status without vaccination</u>

   Any positive test result (regardless of whether SP or NSP tests were used) should be followed up immediately using appropriate clinical, epidemiological, serological and, where possible, virological investigations of the reactor animal at hand, of susceptible animals of the same epidemiological unit and of susceptible animals that have been in contact or otherwise epidemiologically associated with the reactor animal. If the follow-up investigations provide no evidence for FMDV infection, the reactor animal shall be classified as FMD negative. In all other cases, including the absence of such follow-up investigations, the reactor animal should be classified as FMD positive.

2. <u>The follow-up procedure in case of positive test results if vaccination is used in order to establish or re-establish FMD free status with vaccination</u>

   In case of vaccinated populations, one has to exclude that positive test results are indicative of virus circulation. To this end, the following procedure should be followed in the investigation of positive serological test results derived from surveillance conducted on FMD vaccinated populations.

   The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated, and the results should be collated in the final report.

   It is suggested that in the primary sampling units where at least one animal reacts positive to the NSP test, the following strategy(ies) should be applied:

   a) Following clinical examination, a second serum sample should be taken from the animals tested in the initial survey after an adequate interval of time has lapsed, on the condition that they are individually identified, accessible and have not been vaccinated during this period. Antibody titres against NSP at the time of retest should be statistically either equal to or lower than those observed in the initial test if virus is not circulating.

      The animals sampled should remain in the holding pending test results and should be clearly identifiable. If the three conditions for retesting mentioned above cannot be met, a new serological survey should be carried out in the holding after an adequate period of time, repeating the application of the primary survey design and ensuring that all animals tested are individually identified. These animals should remain in the holding and should not be vaccinated, so that they can be retested after an adequate period of time.

   b) Following clinical examination, serum samples should be collected from representative numbers of cattle that were in physical contact with the primary sampling unit. The magnitude and prevalence of antibody reactivity observed should not differ in a statistically significant manner from that of the primary sample if virus is not circulating.

c) Following clinical examination, epidemiologically linked herds should be serologically tested and satisfactory results should be achieved if virus is not circulating.

d) Sentinel animals can also be used. These can be young, unvaccinated animals or animals in which maternally conferred immunity has lapsed and belonging to the same species resident within the positive initial sampling units. They should be serologically negative if virus is not circulating. If other susceptible, unvaccinated ruminants (sheep, goats) are present, they could act as sentinels to provide additional serological evidence.

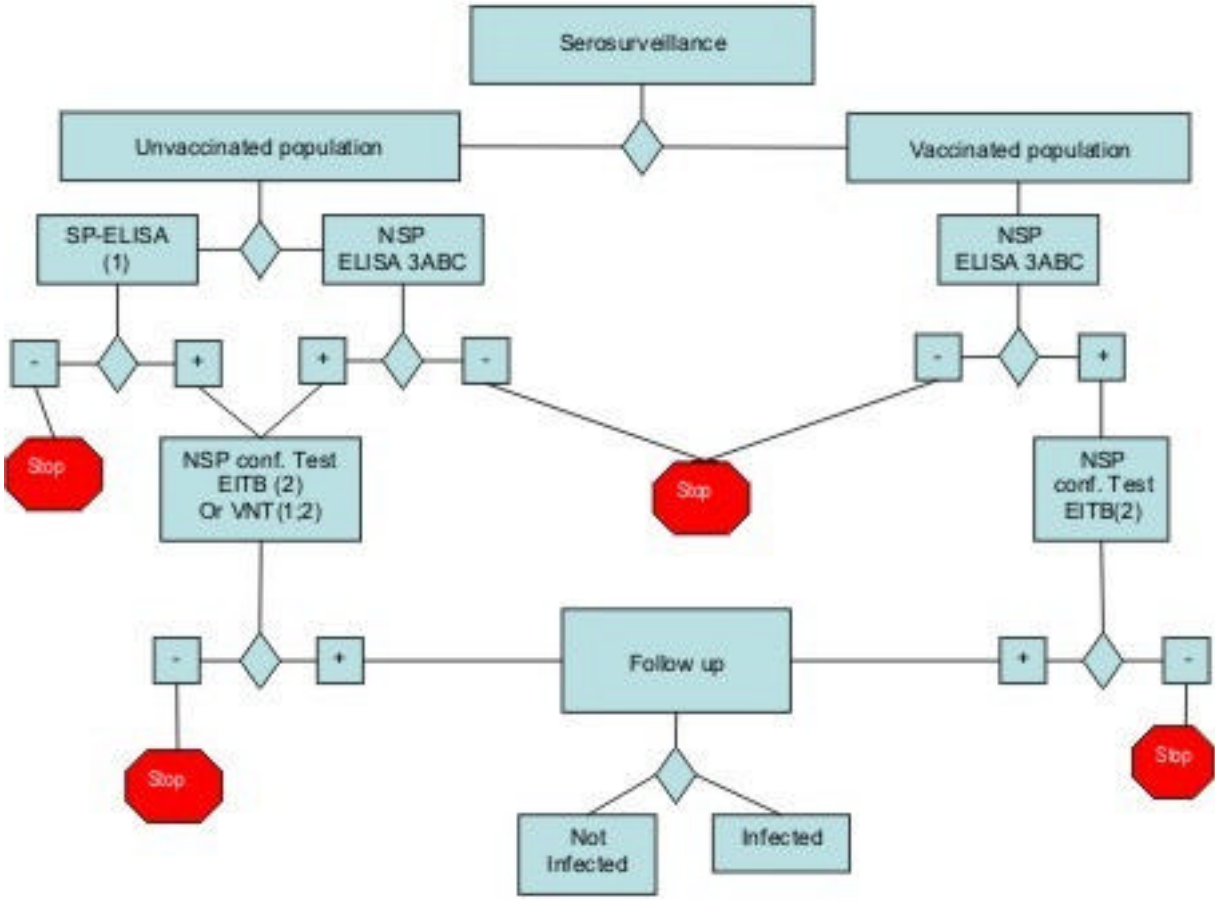
Laboratory results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral circulation includes but is not limited to:

- characterization of the existing production systems;
- results of clinical surveillance of the suspects and their cohorts;
- quantification of vaccinations performed on the affected sites;
- sanitary protocol and history of the *establishments* with positive reactors;
- control of animal identification and movements;
- other parameters of regional significance in historic FMDV transmission.

The entire investigative process should be documented as standard operating procedure within the surveillance programme.

Key:	
ELISA	Enzyme-linked immunosorbent assay
VNT	Virus neutralisation test
NSP	Nonstructural protein(s) of foot and mouth disease virus (FMDV)
3ABC	NSP antibody test
EITB	Electro-immuno transfer blotting technique (Western blot for NSP antibodies of FMDV)
SP	Structural protein test
S	No evidence of FMDV

Fig. 1. ***Schematic representation of laboratory tests for determining evidence of FMDV infection through or following serological surveys***



APPENDIX 3.8.8.

GUIDELINES FOR THE SURVEILLANCE OF CLASSICAL SWINE FEVER

Article 3.8.8.1.

Introduction

This Appendix defines the principles and provides a guide for the surveillance of classical swine fever (CSF) in accordance with Appendix 3.8.1., applicable to countries seeking recognition of freedom from CSF. This may be for the entire country or a *zone* within the country. Guidance for countries seeking reestablishment of freedom from CSF for the whole country or a *zone*, following an *outbreak*, as well as guidelines for demonstrating the maintenance of CSF free status are also provided. This Appendix complements Chapter 2.6.7.

The impact and epidemiology of CSF differ widely in different regions of the world, and it is, therefore, impossible to provide specific guidelines for all situations. It is axiomatic that 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 must 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 must 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 Member Countries 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 the whole country or a *zone* within the country is free from CSFV infection. 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 Appendix, 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 3.8.8.2.

General conditions and methods

1. A surveillance system in accordance with Appendix 3.8.1. should be under the responsibility of the *Veterinary Authority*. A procedure should be in place for the rapid collection and transport of samples to an accredited laboratory as described in the *Terrestrial Manual*.

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 stand-still orders, etc.).

Article 3.8.8.3.

Surveillance strategies

1. Introduction

The target population for surveillance aimed at identifying *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.

Depending on the local epidemiological situation, targeted surveillance could be considered as more effective than a randomized surveillance strategy. Surveillance is targeted to the pig population which presents the highest risk of infection (for example, swill fed farms, pigs reared outdoors or farms in proximity to infected wild pigs). Each country will need to identify its individual risk factors. 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 country should justify the surveillance strategy chosen as adequate to detect the presence of CSFV infection in accordance with Appendix 3.8.1. 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 Country wishes to apply for recognition by other Member Countries 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*.

For random surveys, the design of the sampling strategy will need to incorporate epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect infection if it were to occur at a predetermined minimum rate. The sample size and expected disease prevalence determine the level of confidence in the results of the survey. The country must justify the choice of design prevalence and confidence level based on the objectives of surveillance and the epidemiological situation, in accordance with Appendix 3.8.1. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.

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

Irrespective of the testing system employed, 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.

One element of clinical surveillance involves the detection of clinical signs of CSF by close physical examination of susceptible animals. 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. Nevertheless, clinical presentation should not be ignored as a tool 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 infections involving low virulence strains, high mortality may only be seen in young animals.

In the past, clinical identification of cases was the cornerstone of early detection of CSF. However, emergence of low virulence strains of CSF, as well as new diseases - in particular 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. In *zones* or countries where such diseases exist, careful clinical and virological surveillance of such cases should be applied.

Clinical signs and pathology of CSF infection will also vary considerably, depending on the strain of virus as well as host factors, such as age, nutrition and health status. These factors, along with the compounding effects of concurrent infections and disease caused by ruminant pestiviruses, dictate the need for laboratory testing in order to clarify the status of CSF suspects detected by clinical monitoring. 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 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.

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.

3. 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. Chronically infected pigs may have undetectable or fluctuating antibody levels.

It may be possible to use sera collected for other survey purposes for CSF surveillance. However, the principles of survey design described in this Appendix 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 must 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. Targeted serosurveillance of young stock will indicate whether newly circulating virus is present, although the presence of maternal antibody will also need to be considered. 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.

Vaccines also exist which, when used in conjunction with dedicated serological tests, may allow discrimination between vaccinal antibody and that induced by field 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, serosurveillance using 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.

Article 3.8.8.4.

Country or zone free of CSF in domestic and wild pigs

1. Historically free status

The free status should be reviewed whenever evidence emerges to indicate that changes which may alter the underlying assumption of continuing historical freedom, has occurred. Such changes include but are not limited to:

a) an emergence or an increase in the prevalence of CSF in countries or *zones* from which live pigs or products are imported;

b) an increase in the volume of imports or a change in their country or *zone* of origin;

c) an increase in the prevalence of CSF in the domestic or wild pigs of adjacent countries or *zones*;

d) an increased entry from, or exposure to, wild pig populations of adjacent countries or *zones*.

2. Free status as a result of an eradication programme

In addition to the general conditions described in Chapter 2.6.7., a Member Country 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 and will be planned and implemented according to the general conditions and methods described in this Appendix, to demonstrate the absence of CSFV infection in domestic and wild pig populations. 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*.

Article 3.8.8.5.

Countries, zones or compartments applying for freedom from CSF where vaccination is practised

1. In addition to the general conditions described in Chapter 2.6.7., a Member Country 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 and will be planned and implemented according to the general conditions and methods described in this Appendix, to demonstrate the absence of CSFV infection in domestic and wild pig populations. 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. The objective of surveillance in this instance is to demonstrate that the two subpopulations are effectively separated by measures that ensure the biosecurity of domestic pigs. To this end, a biosecurity programme which includes but is not limited to the following provisions should be implemented:

   a) a programme for the management of CSF in wild pigs;

   b) delineation of CSF wild pig control areas around every CSF case reported in wild pigs;

   c) assessment of the presence and mitigative role of natural boundaries;

   d) documentation of the ecology of the wild pig population;

   e) proper containment of domestic pigs;

   f) control of movement of *vehicles* with cleaning and *disinfection* as appropriate;

   g) control of personnel entering into the *establishments* and awareness of risk of fomite spread;

   h) prohibition of introduction to the *establishments* of hunted animals and products;

   i) registry of animal movements into and out of *establishments*;

   j) information and training programmes for farmers, hunters, processors, veterinarians, etc.

3. The biosecurity programme implemented would also require internal and external monitoring by the *Veterinary Authority*. These elements should include but are not limited to:

   a) periodic clinical and serological monitoring of herds in the country or *zone*, and adjacent wild pig populations following these guidelines;

   b) herd registration;

   c) official accreditation of biosecurity programme;

   d) periodic monitoring and review.

4. Monitoring the CSF status of wild populations will be of value in assessing the degree of risk they pose to the CSF free domestic population. 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 occurrence of CSF in

wild pigs may vary considerably among countries. Surveillance design should be scientifically based, and the Member Country must justify its choice of design prevalence and level of confidence based on Appendix 3.8.1.

5. 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 wildlife 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 3.8.8.6.

Recovery of free status

1. Countries or zones seeking reestablishment of freedom from CSF following an outbreak

In addition to the general conditions described in Chapter 2.6.7., a country seeking reestablishment of country or *zone* freedom from CSF should show evidence of an active surveillance programme for CSF as well as absence of CSFV infection.

Populations under this surveillance programme should include, but not be limited to:

a) *establishments* in the area 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 pig populations in the area of the *outbreak*.

In all circumstances, a Member Country seeking reestablishment of country or *zone* freedom from CSF with vaccination or without vaccination should report the results of an active and passive surveillance programme in which the pig population undergoes regular clinical, pathological, virological, and/or serological examination, planned and implemented according to the general conditions and methods described in these guidelines. The surveillance should be based on a statistically representative sample of the populations at risk.

2. Country or zone free of CSF in wild pigs

While the same principles apply, surveillance in wild 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 pig population;

b) assessment of the possible presence of CSF within the population;

c) determination of the practicability of establishing *zone*.

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 may include wildlife conservation organisations, hunter associations and other available sources. The objective of a surveillance programme is to determine the geographic distribution and estimation of target population.

Estimates of wild pig population can be made using advanced methods (radio tracking, linear transect method, capture/recapture) or traditional methods based on the number of animals that can be hunted to allow for natural restocking (hunting bags).

For implementation of the monitoring programme, it will be necessary to define the limits of the territory over which wild pigs range in order to delineate the epidemiological units within the monitoring programme. It is often difficult to define epidemiological units for wild animals. The most practical approach is based on natural and artificial barriers.

The monitoring programme should also include animals found dead, road kills, animals showing abnormal behaviour or exhibiting gross lesions during dressing.

There may be situations where a more targeted surveillance programme can provide additional assurance. The criteria to define high risk areas for targeted surveillance can be:

- areas with past history of CSF;
- sub-regions with high wild pig density;
- border regions with CSF affected countries or *zones*;
- areas of contact between sub-populations;
- picnic and camping areas;
- around farms with free-ranging pigs;
- special risk areas determined by local *Veterinary Authorities*;
- garbage dumps.

APPENDIX 3.8.9.

GUIDELINES FOR THE SURVEILLANCE OF AVIAN INFLUENZA

Article 3.8.9.1.

Introduction

This Appendix defines the principles and provides a guide for the surveillance of notifiable avian influenza (NAI) in accordance with Appendix 3.8.1., applicable to countries seeking recognition for a declared NAI status, with or without the use of vaccination. This may be for the entire country, *zone* or *compartment*. Guidance for countries seeking free status following an *outbreak* and for the maintenance of NAI status are provided. This Appendix complements Chapter 2.7.12.

The presence of avian influenza viruses in wild birds creates a particular problem. In essence, no country can declare itself free from avian influenza (AI) in wild birds. However, the definition of NAI in Chapter 2.7.12. refers to the infection in poultry only, and this Appendix was developed under this definition.

The impact and epidemiology of NAI differ widely in different regions of the world and therefore it is impossible to provide specific guidelines for all situations. It is axiomatic that the surveillance strategies employed for demonstrating freedom from NAI at an acceptable level of confidence will need to be adapted to the local situation. Variables such as the frequency of contacts of poultry with wild birds, different biosecurity levels and production systems and the commingling of different susceptible species including domestic waterfowl require specific surveillance strategies to address each specific situation. It is incumbent upon the country to provide scientific data that explains the epidemiology of NAI in the region concerned and also demonstrates how all the risk factors are managed. There is therefore considerable latitude available to Member Countries to provide a well-reasoned argument to prove that absence of NAI virus (NAIV) infection is assured at an acceptable level of confidence.

Surveillance for NAI should be in the form of a continuing programme designed to establish that the country, *zone* or *compartment*, for which application is made, is free from NAIV infection.

Article 3.8.9.2.

General conditions and methods

1. A surveillance system in accordance with Appendix 3.8.1. should be under the responsibility of the *Veterinary Authority*. In particular:

   a) a formal and ongoing system for detecting and investigating *outbreaks of disease* or NAI *infection* should be in place;

   b) a procedure should be in place for the rapid collection and transport of samples from suspect cases of NAI to a laboratory for NAI 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 NAI surveillance programme should:

   a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers, who have day-to-day contact with poultry, as well as diagnosticians, should report promptly any suspicion of NAI to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private veterinarians or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All suspected cases of NAI should be investigated immediately. As suspicion cannot be resolved by epidemiological and clinical investigation alone, samples should be taken and submitted to an *approved laboratory*. This requires that sampling kits and other equipment are available for those responsible for surveillance. Personnel responsible for

surveillance should be able to call for assistance from a team with expertise in NAI diagnosis and control. In cases where potential public health implications are suspected, notification to the appropriate public health authorities is essential;

b) implement, when relevant, regular and frequent clinical inspection, serological and virological testing of high-risk groups of animals, such as those adjacent to an NAI infected country, *zone* or *compartment*, places where birds and poultry of different origins are mixed, such as live bird markets, poultry in close proximity to waterfowl or other sources of NAIV.

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 NAIV. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from NAIV infection should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of laboratory testing and the control measures to which the animals concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 3.8.9.3.

Surveillance strategies

1. Introduction

The target population for surveillance aimed at identification of *disease* and *infection* should cover all the susceptible poultry species within the country, *zone* or *compartment*. Active and passive surveillance for NAI should be ongoing. The frequency of active surveillance should be at least every 6 months. Surveillance should be composed of random and targeted approaches using virological, serological and clinical methods.

The strategy employed may be based on randomised sampling requiring surveillance consistent with demonstrating the absence of NAIV 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 should be followed up with virological methods.

Targeted surveillance (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. Virological and serological methods should be used concurrently to define the NAI status of high risk populations.

A country should justify the surveillance strategy chosen as adequate to detect the presence of NAIV infection in accordance with Appendix 3.8.1. and the prevailing epidemiological situation, including *cases* of HPNAI detected in any birds. It may, for example, be appropriate to target clinical surveillance at particular species likely to exhibit clear clinical signs (e.g. chickens). Similarly, virological and serological testing could be targeted to species that may not show clinical signs (e.g. ducks).

If a Member Country wishes to declare freedom from NAIV infection in a specific *zone* or *compartment*, the design of the survey and the basis for the sampling process would need to be aimed at the population within the *zone* or *compartment*.

For random surveys, the design of the sampling strategy will need to incorporate epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect *infection* if it were to occur at a predetermined minimum rate. The sample size and expected disease prevalence determine the level of confidence in the results of the survey. The applicant country must justify the choice of design prevalence and confidence level based on the objectives of surveillance and the epidemiological situation, in accordance with Appendix 3.8.1. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.

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

Irrespective of the testing system employed, surveillance system design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following up

positives to ultimately determine with a high level of confidence, whether they are indicative of infection or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as flocks which may be epidemiologically linked to it.

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

2. Clinical surveillance

Clinical surveillance aims at the detection of clinical signs of NAI at the flock level. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, surveillance based on clinical inspection should not be underrated. Monitoring of production parameters, such as increased mortality, reduced feed and water consumption, presence of clinical signs of a respiratory disease or a drop in egg production, is important for the early detection of NAIV infection. In some cases, the only indication of LPNAIV infection may be a drop in feed consumption or egg production.

Clinical surveillance and laboratory testing should always be applied in series to clarify the status of NAI suspects detected by either of these complementary diagnostic approaches. Laboratory testing may confirm clinical suspicion, while clinical surveillance may contribute to confirmation of positive serology. Any sampling unit within which suspicious animals are detected should be classified as infected until evidence to the contrary is produced.

Identification of suspect flocks is vital to the identification of sources of NAIV and to enable the molecular, antigenic and other biological characteristics of the virus to be determined. It is essential that NAIV isolates are sent regularly to the regional Reference Laboratory for genetic and antigenic characterization.

3. Virological surveillance

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

a) to monitor at risk populations;

b) to confirm clinically suspect cases;

c) to follow up positive serological results;

d) to test 'normal' daily mortality, to ensure early detection of infection in the face of vaccination or in *establishments* epidemiologically linked to an *outbreak*.

4. Serological surveillance

Serological surveillance aims at the detection of antibodies against NAIV. Positive NAIV antibody test results can have four possible causes:

a) natural infection with NAIV;

b) vaccination against NAI;

c) maternal antibodies derived from a vaccinated or infected parent flock are usually found in the yolk and can persist in progeny for up to 4 weeks;

d) false positive results due to the lack of specificity of the test.

It may be possible to use serum collected for other survey purposes for NAI surveillance. However, the principles of survey design described in these guidelines and the requirement for a statistically valid survey for the presence of NAIV should not be compromised.

The discovery of clusters of seropositive flocks may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or infection. As clustering may signal infection, the investigation of all instances must be incorporated in the survey design. Clustering of positive flocks is always epidemiologically significant and therefore should be investigated.

If vaccination cannot be excluded as the cause of positive serological reactions, diagnostic methods to differentiate antibodies due to infection or vaccination should be employed.

The results of random or targeted serological surveys are important in providing reliable evidence that no NAIV infection is present in a country, *zone* or *compartment*. It is therefore essential that the survey be thoroughly documented.

5. Virological and serological surveillance in vaccinated populations

The surveillance strategy is dependent on the type of vaccine used. The protection against AI is haemagglutinin subtype specific. Therefore, two broad vaccination strategies exist: 1) inactivated whole AI viruses, and 2) haemagglutinin expression-based vaccines.

In the case of vaccinated populations, the surveillance strategy should be based on virological and/or serological methods and clinical surveillance. It may be appropriate to use sentinel birds for this purpose. These birds should be unvaccinated, AI virus antibody free birds and clearly and permanently identified. The interpretation of serological results in the presence of vaccination is described in Article 3.8.9.7.

Article 3.8.9.4.

Documentation of NAI or HPNAI free status

1. Countries declaring freedom from NAI or HPNAI for the country, zone or compartment

In addition to the general conditions described in the *Terrestrial Code*, a Member Country declaring freedom from NAI or highly pathogenic notifiable avian influenza (HPNAI) for the entire country, or a *zone* or a *compartment* 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 Appendix, to demonstrate absence of NAIV or HPNAIV infection, during the preceding 12 months in susceptible poultry populations (vaccinated and non-vaccinated). This requires the support of a laboratory able to undertake identification of NAIV or HPNAIV infection through virus detection and antibody tests described in the *Terrestrial Manual*. This surveillance may be targeted to poultry population at specific risks linked to the types of production, possible direct or indirect contact with wild birds, multi-age flocks, local trade patterns including live bird markets, use of possibly contaminated surface water, and the presence of more than one species on the holding and poor biosecurity measures in place.

2. Additional requirements for countries, zones or compartments that practise vaccination

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

In all vaccinated flocks there is a need to perform virological and serological tests to ensure the absence of virus circulation. The use of sentinel poultry may provide further confidence of the absence of virus circulation. The tests have to be repeated at least every 6 months or at shorter intervals according to the risk in the country, *zone* or *compartment*.

Evidence to show the effectiveness of the vaccination programme should also be provided.

Article 3.8.9.5.

Countries, zones or compartments declaring that they have regained freedom from NAI or HPNAI following an outbreak

In addition to the general conditions described in Chapter 2.7.12., a country declaring that it has regained country, *zone* or *compartment* freedom from NAI or HPNAI virus infection should show evidence of an active surveillance programme depending on the epidemiological circumstances of the *outbreak* to demonstrate the absence of the infection. This will require surveillance incorporating virus detection and antibody tests described in the *Terrestrial Manual*. The use of sentinel birds may facilitate the interpretation of surveillance results.

A Member Country declaring freedom of country, *zone* or *compartment* after an *outbreak* of NAI or HPNAI (with or without vaccination) should report the results of an active surveillance programme in which the NAI or HPNAI susceptible poultry population undergoes regular clinical examination and active surveillance planned and implemented according to the general conditions and methods described in these guidelines. The surveillance should at least give the confidence that can be given by a randomized representative sample of the populations at risk.

Article 3.8.9.6.

NAI free establishments within HPNAI free compartments

The declaration of NAI free *establishments* requires the demonstration of absence of NAIV infection. Birds in these *establishments* should be randomly tested using virus detection or isolation tests, and serological methods, following the general conditions of these guidelines. The frequency of testing should be based on the risk of infection and at a maximum interval of 21 days.

Article 3.8.9.7.

The use and interpretation of serological and virus detection tests

Poultry infected with NAI virus produce antibodies to haemagglutinin (HA), neuraminidase (NA), nonstructural proteins (NSPs), nucleoprotein/matrix (NP/M) and the polymerase complex proteins. Detection of antibodies against the polymerase complex proteins will not be covered in this Appendix. Tests for NP/M antibodies include direct and blocking ELISA, and agar gel immunodiffusion (AGID) tests. Tests for antibodies against NA include the neuraminidase inhibition (NI), indirect fluorescent antibody and direct ELISA tests. For the HA, antibodies are detected in haemagglutination inhibition (HI) and neutralization (SN) tests. The HI test is reliable in avian species but not in mammals. The SN test can be used to detect subtype specific antibodies to the haemagglutinin and is the preferred test for mammals and some avian species. The AGID test is reliable for detection of NP/M antibodies in chickens and turkeys, but not in other avian species. As an alternative, blocking ELISA tests have been developed to detect NP/M antibodies in all avian species.

The HI and NI tests can be used to subtype AI viruses into 16 haemagglutinin and 9 neuraminidase subtypes. Such information is helpful for epidemiological investigations and in categorization of AI viruses.

Poultry can be vaccinated with a variety of AI vaccines including inactivated whole AI virus vaccines, and haemagglutinin expression-based vaccines. Antibodies to the haemagglutinin confer subtype specific protection. Various strategies can be used to differentiate vaccinated from infected birds including serosurveillance in unvaccinated sentinel birds or specific serological tests in the vaccinated birds.

AI virus infection of unvaccinated birds including sentinels is detected by antibodies to the NP/M, subtype specific HA or NA proteins, or NSP. Poultry vaccinated with inactivated whole AI vaccines containing an influenza virus of the same H sub-type but with a different neuraminidase may be tested for field exposure by applying serological tests directed to the detection of antibodies to the NA of the field virus. For example, birds vaccinated with H7N3 in the face of a H7N1 epidemic may be differentiated from infected birds (DIVA) by detection of subtype specific NA antibodies of the N1 protein of the field virus. Alternatively, in the absence of DIVA, inactivated vaccines may induce low titres of antibodies to NSP and the titre in infected birds would be markedly higher. Encouraging results have been obtained experimentally with this system, but it has not yet been validated in the field. In poultry vaccinated with haemagglutinin expression-based vaccines, antibodies are detected to the specific HA, but not any of the other AI viral proteins. Infection is evident by antibodies to the NP/M or NSP, or the specific NA protein of the field virus. Vaccines used should comply with the standards of the *Terrestrial Manual*.

All flocks with seropositive results should be investigated. Epidemiological and supplementary laboratory investigation results should document the status of NAI infection/circulation for each positive flock.

A confirmatory test should have a higher specificity than the screening test and sensitivity at least equivalent than that of the screening test.

Information should be provided on the performance characteristics and validation of tests used.

1. The follow-up procedure in case of positive test results if vaccination is used

   In case of vaccinated populations, one has to exclude the likelihood that positive test results are indicative of virus circulation. To this end, the following procedure should be followed in the investigation of positive serological test results derived from surveillance conducted on NAI-vaccinated poultry. The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated, and the results should be collated in the final report.

   Knowledge of the type of vaccine used is crucial in developing a serological based strategy to differentiate infected from vaccinated animals.

   a) Inactivated whole AI virus vaccines can use either homologous or heterologous neuraminidase subtypes between the vaccine and field strains. If poultry in the population have antibodies to NP/M and were vaccinated with inactivated whole AI virus vaccine, the following strategies should be applied:

      i) sentinel birds should remain NP/M antibody negative. If positive for NP/M antibodies, indicating AI virus infection, specific HI tests should be performed to identify H5 or H7 AI virus infection;

      ii) if vaccinated with inactivated whole AI virus vaccine containing homologous NA to field virus, the presence of antibodies to NSP could be indicative of infection. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins;

      iii) if vaccinated with inactivated whole AI virus vaccine containing heterologous NA to field virus, presence of antibodies to the field virus NA or NSP would be indicative of infection. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins.

   b) Haemagglutinin expression-based vaccines contain the HA protein or gene homologous to the HA of the field virus. Sentinel birds as described above can be used to detect AI infection. In vaccinated or sentinel birds, the presence of antibodies against NP/M, NSP or field virus NA is indicative of infection. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins.

2. The follow-up procedure in case of positive test results indicative of infection for determination of infection due to HPNAI or LPNAI virus

   The detection of antibodies indicative of a NAI virus infection as indicated in point a)i) above will result in the initiation of epidemiological and virological investigations to determine if the infections are due to HPNAI or LPNAI viruses.

   Virological testing should be initiated in all antibody-positive and at risk populations. The samples should be evaluated for the presence of AI virus, by virus isolation and identification, and/or detection of influenza A specific proteins or nucleic acids (Figure 2). Virus isolation is the gold standard for detecting infection by AI virus and the method is described in the *Terrestrial Manual*. All AI virus isolates should be tested to determine HA and NA subtypes, and *in vivo* tested in chickens and/or sequencing of HA proteolytic cleavage site of H5 and H7 subtypes for determination of classification as HPNAI, LPNAI or LPAI (not notifiable) viruses. As an alternative, nucleic acid detection tests have been developed and validated; these tests have the sensitivity of virus isolation, but with the advantage of providing results within a few hours. Samples with detection of H5 and H7 HA subtypes by nucleic acid detection methods should either be submitted for virus isolation, identification, and *in vivo* testing in chickens, or sequencing of nucleic acids for determination of proteolytic cleavage site as HPNAI or LPNAI viruses. The antigen detection systems, because of low sensitivity, are best suited for screening clinical field cases for infection by Type A influenza virus looking for NP/M proteins. NP/M positive samples should be submitted for virus isolation, identification and pathogenicity determination.

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

   a) characterization of the existing production systems;

   b) results of clinical surveillance of the suspects and their cohorts;

   c) quantification of vaccinations performed on the affected sites;

d) sanitary protocol and history of the affected *establishments*;

e) control of animal identification and movements;

f) other parameters of regional significance in historic NAIV transmission.

The entire investigative process should be documented as standard operating procedure within the epidemiological surveillance programme.

Fig. 1. ***Schematic representation of laboratory tests for determining evidence of NAI infection through or following serological surveys***

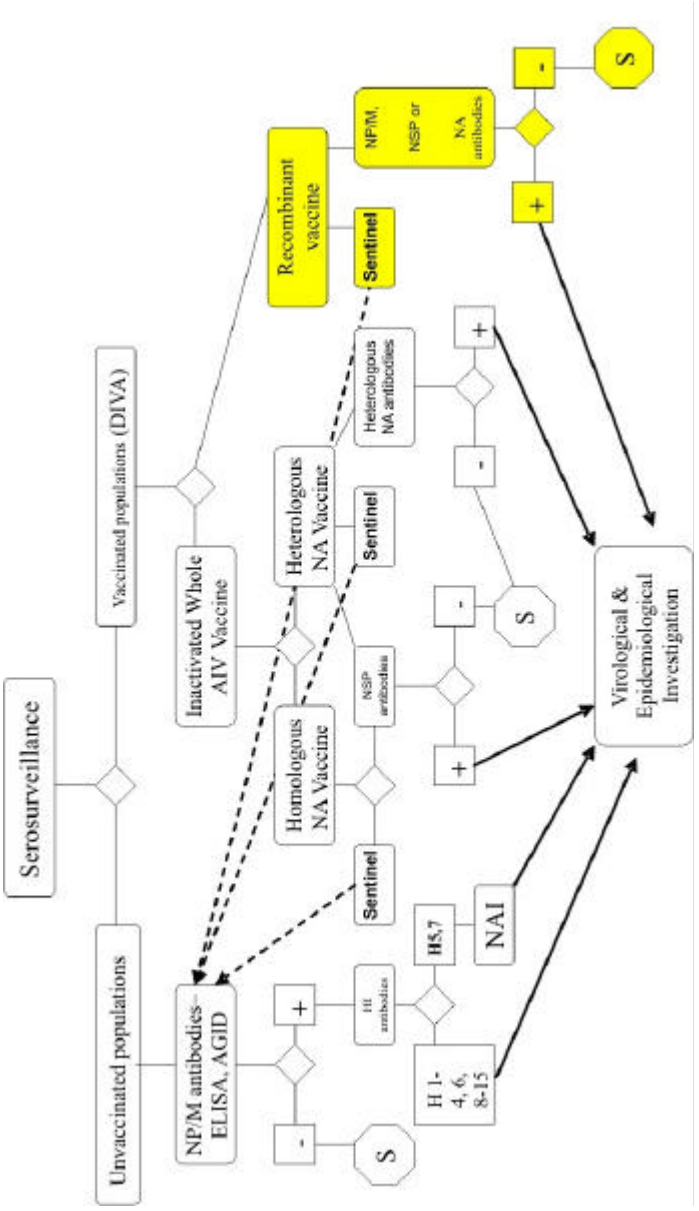
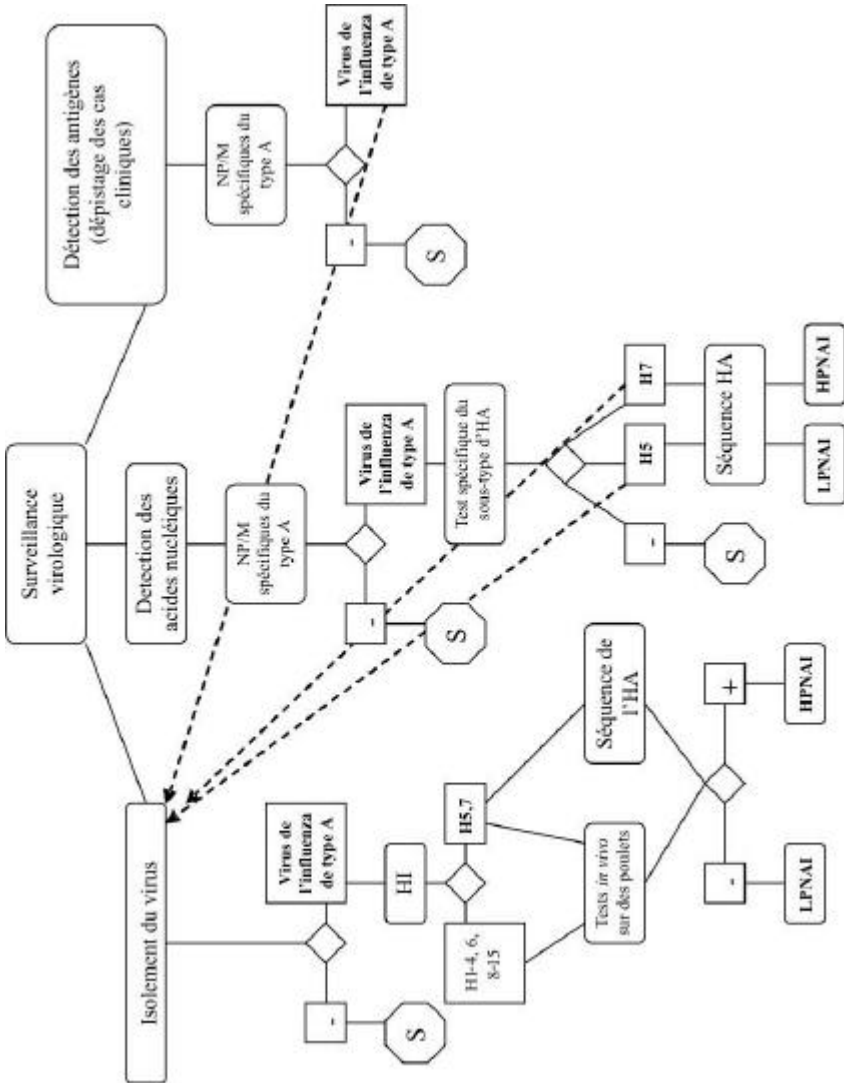


Fig. 2. ***Schematic representation of laboratory tests for determining evidence of NAI infection using virological methods***



The above diagra indicates the tests which are recommended for use in the investigation of poultry flocks.

Key:	
AGID	Agar gel immunodiffusion
DIVA	Differentiating infected from vaccinated animals
ELISA	Enzyme-linked immunosorbant assay
HA	Haemagglutinin
HI	Haemagglutination inhibition
NA	Neuraminidase
NP/M	Nucleoprotein and matrix protein
NSP	Nonstructural protein
S	No evidence of NAIV

APPENDIX 3.8.10.

GUIDELINES FOR THE SURVEILLANCE OF BLUETONGUE

Article 3.8.10.1.

Introduction

This Appendix defines the principles and provides a guide on the surveillance for bluetongue (BT) in accordance with Appendix 3.8.1., applicable to countries seeking recognition for a declared BT status, with or without the use of vaccination. This may be for the entire country or *zone*. Guidance for countries seeking free status following an *outbreak* and for the maintenance of BT status is also provided. This Appendix complements Chapter 2.2.13.

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.

Susceptible wild ruminant populations should be included in surveillance when these animals are intended for trade.

The impact and epidemiology of BT differ widely in different regions of the world and therefore it is impossible to provide specific guidelines for all situations. It is incumbent upon Member Countries 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 Member Countries to justify their infection status at an acceptable level of confidence.

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

Article 3.8.10.2.

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 must be made between a *case* as defined below and an animal that is potentially infectious to vectors. The conditions for trade are defined in Chapter 2.2.13. of the *Terrestrial Code*.

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

The following defines the occurrence of BTV infection:

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

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

Article 3.8.10.3.

General conditions and methods

1. A surveillance system in accordance with Appendix 3.8.1. 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 day-to-day 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 an *approved 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 like *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 2.2.13.11. and 2.2.13.15.

Article 3.8.10.4.

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 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*.

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 country should justify the surveillance strategy chosen as being adequate to detect the presence of BTV infection in accordance with Appendix 3.8.1. and the prevailing epidemiological situation. It may, for example, be appropriate to target clinical surveillance at particular species likely to exhibit clinical signs (e.g. sheep). Similarly, virological and serological testing may be targeted to species that rarely show clinical signs (e.g. cattle).

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

If a Member Country wishes to declare freedom from BTV infection 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 applicant country must justify the choice of design prevalence and confidence level based on the objectives of surveillance and the epidemiological situation, in accordance with Appendix 3.8.1. 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 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 influenc 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 must be individually identifiable), or a combination of methods.

   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 guidelines 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 surveillance *zone* within a free country or *zone* should separate it from a potentially infected country or *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 *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 confirme 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 confounding factors, 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 infection. 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 define 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 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 3.8.10.5.

Documentation of BTV infection free status

1. Countries declaring freedom from BTV infection for the country or zone

In addition to the general conditions described in Chapter 2.2.13. of the *Terrestrial Code*, a Member Country 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 Appendix, 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 vaccinatio

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 must 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 th 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 3.8.10.6.

The use and interpretation of serological and virus detection tests

1. Serological testing

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

2. Virus detection

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

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

a) The nested PCR assay detects BTV nucleic acid in ruminants long after the clearance of infectious virus. Thus positive PCR results do not necessarily coincide with active infection of ruminants. Furthermore, the nested PCR assay is especially prone to template contamination, thus there is considerable risk of false positive results.

b) PCR procedures other than real time PCR allow sequence analysis of viral amplicons from ruminant tissues, insect vectors or virus isolates. These sequence data are useful for creating data bases to facilitate important epidemiological studies, including the possible distinction of field and vaccine virus strains of BTV, genotype characterization of field strains of BTV, and potential genetic divergence of BTV relevant to vaccine and diagnostic testing strategies.

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

Fig. 1. Application of laboratory tests in serological surveillance

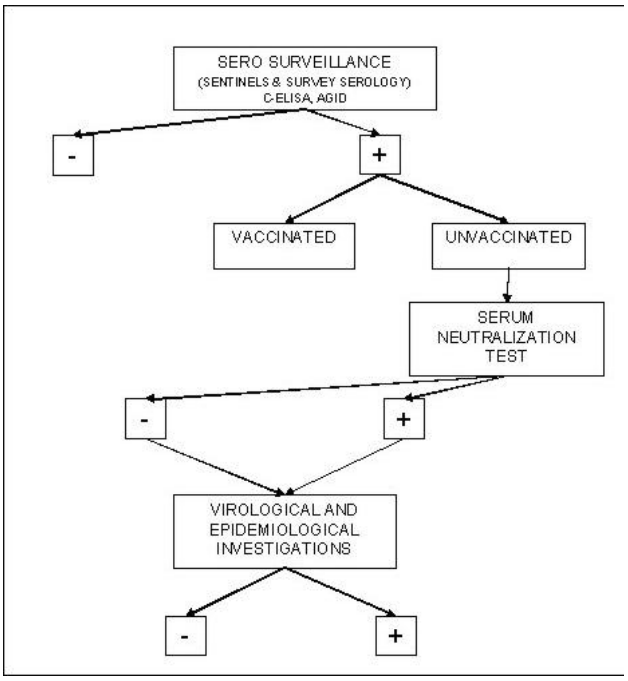
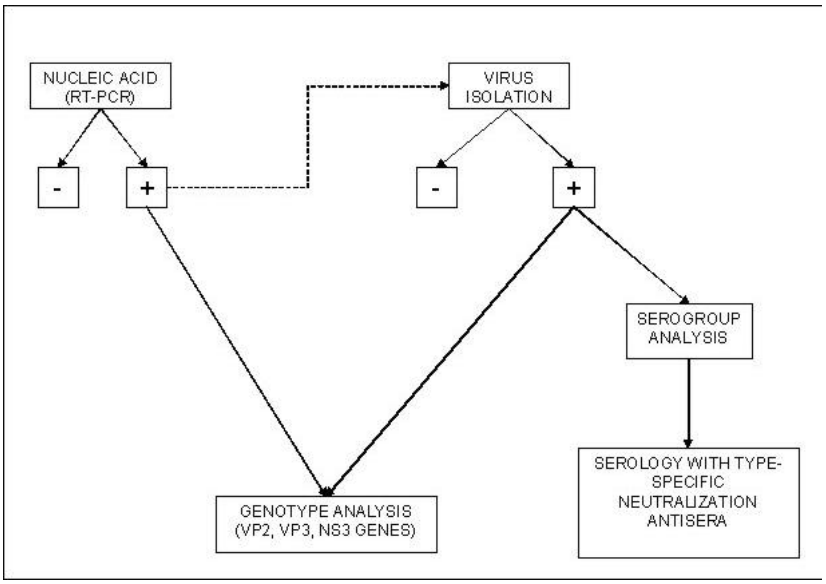


Fig. 2. Application of laboratory tests in virological surveillance



SECTION 3.9.

ANTIMICROBIAL RESISTANCE

APPENDIX 3.9.1.

GUIDELINES FOR THE HARMONISATION OF NATIONAL ANTIMICROBIAL RESISTANCE SURVEILLANCE AND MONITORING PROGRAMMES

Article 3.9.1.1.

Objective

This Appendix provides criteria for the:

1. development of national antimicrobial resistance surveillance and monitoring programmes,
2. harmonisation of existing national surveillance and monitoring programmes,

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

Article 3.9.1.2.

Purpose of surveillance and monitoring

1. Surveillance and monitoring of antimicrobial resistance is necessary to:
   a) follow trends in antimicrobial resistance in bacteria;
   b) detect the emergence of new antimicrobial resistance mechanisms;
   c) provide the data necessary for conducting risk analyses with relevance for human and animal health;
   d) provide a basis for policy recommendations for animal and public health;
   e) provide information for prescribing practices and prudent use recommendations.
2. National antimicrobial resistance monitoring and surveillance programmes may include the following components:
   a) scientifically based surveys (including statistically based programmes);
   b) routine sampling and testing of animals on the farm, at market or at slaughter;
   c) an organised sentinel programme, sampling animals, herds, flocks, and vectors;
   d) analysis of veterinary practice and diagnostic laboratory records.
3. Countries should conduct active surveillance and monitoring. Passive surveillance and monitoring may offer additional information.
4. Targeted surveillance is conducted through an active sampling scheme designed to meet programme objectives. Passive surveillance is conducted when samples are submitted to a laboratory for testing from sources outside the programme.

Article 3.9.1.3.

The development of antimicrobial resistance surveillance and monitoring programmes

1. General aspects

Surveillance of antimicrobial resistance at regular intervals or ongoing monitoring of prevalence changes of resistant bacteria of animal, food, environmental and human origin, constitutes a critical part of a strategy aimed at limiting the spread of antimicrobial resistance and optimising the choice of antimicrobials used in therapy.

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

2. Sampling strategies

a) General

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

- the sample representativeness of the population of interest;
- the robustness of the sampling method.

ii) The following criteria are to be considered:

- sample size;
- sample source (animal, food, animal feed);
- animal species;
- category of animal within species (age group, production type);
- stratification within category;
- health status of the animals (healthy, diseased);
- random sample (targeted, systematic);
- sample specimens (faecal, carcass, processed food).

b) Sample size

The sample size should be:

i) large enough to allow detection of existing resistance,

ii) not excessively large to avoid waste of resources.

Details are provided in table 1. Sampling fall follow standard operating procedures.

3. Sample sources

a) Animals

Each Member Country should examine its livestock production systems and decide, after risk analysis, the relative importance of antimicrobial resistance and its impact on animal and human health.

Categories of livestock that should be considered for sampling include cattle and calves, slaughter pigs, broiler chickens, layer hens and/or other poultry and farmed fish.

b) Food and animal feed

Contaminated food is commonly considered to be the principal route for the transfer of antimicrobial resistance from animals to humans. Plants and vegetables of different types may be exposed to manure or sewage from livestock and may thereby become contaminated with resistant bacteria of animal origin. Animal feed, including imported feed, may also be considered in surveillance and monitoring programmes.

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

	Level of confidence					
Expected prevalence	**90% Desired precision**			**95% Desired precision**		
	10%	**5%**	**1%**	**10%**	**5%**	**1%**
10%	24	97	2.429	35	138	3.445
20%	43	173	4.310	61	246	6.109
30%	57	227	5.650	81	323	8.003
40%	65	260	6.451	92	369	9.135
50%	68	270	6.718	96	384	9.512
60%	65	260	6.451	92	369	9.135
70%	57	227	5.650	81	323	8.003
¨80%	43	173	4.310	61	246	6.109
90%	24	97	2.429	35	138	3.445

Calculations based on Epi Info v6.04b to c Upgrade, October 1997, Centers for Disease Control (public domain software available at hpp://www.cdc.gov/epo/epi/epiinfo.htm)

4. Sample specimens to be collected

Faecal samples should be collected from livestock, and whole caeca should be collected from poultry. In cattle and pigs, a faecal sample size at least of 5 g provides a sufficient sample for isolation of the bacteria of concern.

Sampling of the carcasses at the abattoir provides information on slaughter practices, slaughter hygiene and the level of faecal contamination of meat during the slaughter process. Further sampling from the retail chain provides information on prevalence changes before the food reaches the consumer.

Existing food processing microbiological monitoring and 'hazard analysis and critical control points' (HACCP) programmes may provide useful samples for surveillance and monitoring of resistance in the food chain after slaughter.

5. Bacterial isolates

The following categories of bacteria could be monitored:

a) Animal bacterial pathogens

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

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

ii) guide veterinarians in their prescribing decisions.

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

b) Zoonotic bacteria

i) *Salmonella*

Salmonella should be sampled from cattle, pigs, broilers and other poultry. For the purpose of facilitating sampling and reducing the concurrent costs, samples should preferably be taken at the abattoir. Surveillance and monitoring programmes may also use bacterial isolates from designated national laboratories originating from other sources.

Isolation and identification of bacteria and bacterial strains should follow internationally accepted procedures.

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

All *Salmonella* isolates should be serotyped and, where appropriate, phage-typed according to standard methods used at the nationally designated laboratories.

Validated methods should be used.

ii) *Campylobacter*

Campylobacter jejuni and *C. coli* can be isolated from the same samples as commensal bacteria. Isolation and identification of these bacteria should follow internationally accepted procedures. *Campylobacter* isolates should be identified to the species level.

Agar or broth micro-dilution methods are recommended for *Campylobacter* susceptibility testing. Internal and external quality control programmes should be strictly adhered to.

Validated methods with appropriate reference strains are expected to become available in the near future.

iii) Enterohaemorrhagic *Escherichia coli*

Enterohaemorrhagic *Escherichia coli* (EHEC), such as the serotype O157, which is pathogenic to humans but not to animals, may be included in resistance surveillance and monitoring programmes.

c) Commensal bacteria

Escherichia coli and *enterococci* are common commensal bacteria. These bacteria are considered to constitute a reservoir of antimicrobial resistance genes, which may be transferred to pathogenic bacteria causing disease in animals or humans. It is considered that these bacteria should be isolated from healthy animals, preferably at the abattoir, and be monitored for antimicrobial resistance.

Validated methods should be used.

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

Source	Sample type	Outcome	Additional information required / additional stratification
Herd of origin		Prevalence of resistance in bacteria originating from animal populations (of different production types) Relationship resistance - antibiotic use	Per age categories, production types, etc. Antibiotic use over time
Abattoir	Faecal	Prevalence of resistance in bacterial populations originating from animals at slaughter age	
	Intestine	As above	
	Carcass	Hygiene, contamination during slaughter	
Processing, packing	Meat products	Hygiene, contamination during processing and handling	
Retail	Meat products	Prevalence of resistance in bacteria originating from food, exposure data for consumers	
	Vegetables	Prevalence of resistance in bacteria originating from vegetables, exposure data for consumers	
Various origin	Animal feed	Prevalence of resistance in bacteria originating from animal feed, exposure data for animals	

6. Storage of bacterial strains

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

7. Antimicrobials to be used in susceptibility testing

Clinically important antimicrobial classes used in human and veterinary medicine should be monitored. However, the number of tested antimicrobials may have to be limited according to the financial resources of the country.

8. Type of data to be recorded and stored

Data on antimicrobial susceptibility should be reported quantitatively.

Appropriate validated methods should be used in accordance with Chapter I.1.10. of the *Terrestrial Manual* concerning laboratory methodologies for bacterial antimicrobial susceptibility testing.

9. Recording, storage and interpretation of results

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

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

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

i) as distribution of minimum inhibitory concentrations (MICs) in milligrams per litre;

ii) or inhibition zone diameters in millimetres.

d) The information to be recorded should include at least the following aspects:

i) sampling programme;

ii) sampling date;

iii) animal species/livestock category;

iv) type of sample;

v) purpose of sampling;

vi) geographical origin of herd, flock or animal;

vii) age of animal.

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

i) identity of laboratory,

ii) isolation date,

iii) reporting date,

iv) bacterial species,

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

v) serovar,

vi) phage-type,

vii) antimicrobial susceptibility result/resistance phenotype.

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

g) In the clinical setting, breakpoints are used to categorise bacterial strains as susceptible, intermediate susceptible or resistant. These breakpoints, often referred to as clinical or pharmacological breakpoints, are elaborated on a national basis and vary between countries.

h) The system of reference used should be recorded.

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

j) If available, the phenotype of the isolates (resistance pattern) should be recorded.

10. Reference laboratory and annual reports

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

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

ii) collect information at a central location within the country;

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

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

i) raw data;

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

iii) proficiency testing results;

iv) information on the structure of the monitoring system;

v) information on the chosen laboratory methods.

Table 3. ***Examples of animal bacterial pathogens that may be included in resistance surveillance and monitoring***

Target animals	Respiratory pathogens	Enteric pathogens	Udder pathogens	Other pathogens
Cattle	*Pasteurella* spp.	*Escherichia coli*	*Staphylococcus aureus*	
	Haemophilus somnus	*Salmonella* spp.	*Streptococcus* spp.	
Pigs	*Actinobacillus pleuropneumoniae*	*Escherichia coli*		*Streptococcus suis*
		Brachyspira spp.		
		Salmonella spp.		
Poultry				*Escherichia coli* *Vibrio* spp.
Fish				*Aeromonas* spp.

APPENDIX 3.9.2.

GUIDELINES FOR THE MONITORING OF THE QUANTITIES OF ANTIMICROBIALS USED IN ANIMAL HUSBANDRY

Article 3.9.2.1.

Purpose

The purpose of these guidelines is to describe an approach to the monitoring of quantities of antimicrobials used in animal husbandry.

These guidelines are intended for use by OIE Member Countries to collect objective and quantitative information to evaluate usage patterns by animal species, antimicrobial class, potency and type of use in order to evaluate antimicrobial exposure.

Article 3.9.2.2.

Objectives

The information provided in these guidelines is essential for risk analyses and planning, can be helpful in interpreting resistance surveillance data and can assist in the ability to respond to problems of antimicrobial resistance in a precise and targeted way. This information may also assist in evaluating the effectiveness of efforts to ensure prudent use and mitigation strategies (for example, by identifying changes in prescribing practices for veterinarians) and to indicate where alteration of antimicrobial prescribing practices might be appropriate, or if changes in prescription practice have altered the pattern of antimicrobial use.

The continued collection of this basic information will also help give an indication of trends in the use of animal antimicrobials over time and the role of these trends in the development of antimicrobial resistance in animals.

For all OIE Member Countries, the minimum basic information collected should be the annual weight in kilograms of the active ingredient of the antimicrobial(s) used in food animal production. In addition, the type of use (therapeutic or growth promotion) and route of administration (parenteral or oral administration) should be recorded.

Member Countries may wish to consider, for reasons of cost and administrative efficiency, collecting medical, food animal, agricultural and other antimicrobial use data in a single programme. A consolidated programme would also facilitate comparisons of animal use with human use data for relative risk analysis and help to promote optimal usage of antimicrobials.

Article 3.9.2.3.

Development and standardisation of monitoring systems

Systems to monitor antimicrobial usage consist of the following elements:

1. Sources of antimicrobial data

   a) Basic sources

   Sources of data will vary from country to country. Such sources may include customs, import and export data, manufacturing and manufacturing sales data.

   b) Direct sources

   Data from animal drug registration, wholesalers, retailers, pharmacists, veterinarians, feed stores, feed mills and organised industry associations in these countries might be efficient and practical sources. A possible mechanism for the collection of this information is to make the provision of appropriate information by manufacturers to the regulatory authority one of the requirements of antimicrobial registration.

   c) End-use sources (veterinarians and food animal producers)

   This may be appropriate when basic or direct sources cannot be used for the routine collection of this information and when more accurate and locally specific information is required.

   Periodic collection of this type of information may be sufficient.

   It may be important when writing recommendations on antimicrobial resistance to take into account factors such as seasonality and disease conditions, species affected, agricultural systems (e.g. extensive range conditions and feedlots), dose rate, duration and length of treatment with antimicrobials.

   Collection, storage and processing of data from end-use sources are likely to be inefficient and expensive processes unless carefully designed and well managed, but should have the advantage of producing accurate and targeted information.

2. Categories of data

   a) Requirements for data on antimicrobial use

   The minimal data collected should be the annual weight in kilograms of the active ingredient of the antimicrobial(s) used in food animal production. This should be related to the scale of production (see point 3 below).

   For active ingredients present in the form of compounds or derivatives, the mass of active entity of the molecule should be recorded. For antibiotics expressed in International Units, the calculation required to convert these units to mass of active entity should be stated.

   If a Member Country has the infrastructure for capturing basic animal antimicrobial use data for a specific antimicrobial, then additional information can be considered to cascade from this in a series of subdivisions or levels of detail. Such a cascade of levels should include the following:

   i) The absolute amount in kilograms of active antimicrobial used per antimicrobial family per year, or for a specific antimicrobial chemical entity when this information is required.

   ii) Therapeutic and growth promotion use in kilograms of the specific active antimicrobial.

   iii) Subdivision of antimicrobial use into therapeutic and growth promotion use by animal species.

   iv) Subdivision of the data into the route of administration, specifically in-feed, in-water, injectable, oral, intramammary, intra-uterine and topical.

   v) Further subdivision of these figures by season and region by a Member Country may be useful *(Note: This may be especially management conditions, or where animals are moved from one locality to another during production)*.

   vi) Further breakdown of data for analysis of antimicrobial use at the regional, local, herd and individual veterinarian level may be possible using veterinary practice computer management software as part of specific targeted surveys or audits. Analysis of this information with the local or regional context

could be useful for individual practitioners and practices where specific antimicrobial resistance has been identified and feedback is required.

b) Classes of antimicrobials

Nomenclature of antimicrobials should comply with international standards where available.

Decisions need to be made on what classes of antimicrobials should be considered and what members of various antimicrobial classes should be included in the data collection programme. These decisions should be based on currently known mechanisms of antimicrobial activity and resistance of the particular antimicrobial and its relative potency.

c) Species and production systems

Countries should keep a register of all animal use of antimicrobials for individual food animal species (cattle, sheep, goats, pigs, poultry, horses and fish) and for specific diseases. This will help to identify possible nonauthorised usage.

3. Other important information

Breakdown of farm livestock into species and production categories, including total live weights, would be most useful in any risk analysis or for comparison of animal antimicrobial use with human medical use within and between countries. For example, the total number of food animals by category and their weight in kilograms for food production per year (meat, dairy and draught cattle, and meat, fibre, poultry and dairy sheep) in the country would be essential basic information.

APPENDIX 3.9.3.

GUIDELINES FOR THE RESPONSIBLE AND PRUDENT USE OF ANTIMICROBIAL AGENTS IN VETERINARY MEDICINE

Article 3.9.3.1.

Purpose

These guidelines provide guidance for the responsible and prudent use of antimicrobial agents in veterinary medicine, with the aim of protecting both animal and human health. The *Competent Authorities* responsible for the registration and control of all groups involved in the production, distribution and use of veterinary antimicrobials have specific obligations.

Prudent use is principally determined by the outcome of the marketing authorisation procedure and by the implementation of specifications when antimicrobials are administered to animals.

Article 3.9.3.2.

Objectives of prudent use

Prudent use includes a set of practical measures and recommendations intended to prevent and/or reduce the selection of antimicrobial-resistant bacteria in animals to:

1. 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 micro-organisms (with their resistance determinants) within animal populations;
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;
6. maintain the efficacy of *antimicrobial agents* used in 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. protect consumer health by ensuring the safety of food of animal origin with respect to residues of antimicrobial drugs, and the ability to transfer antimicrobial drug resistant micro-organisms to humans.

Article 3.9.3.3.

Responsibilities of the regulatory authorities

1. Marketing authorisation

   The national 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.

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 only if the criteria of safety, quality and efficacy are met. An 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 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 dose ranges or different durations of treatment that are proposed.

3. Market approval

Regulatory authorities should attempt to expedite the market approval process of a new antimicrobial in order to address a specific need for the treatment of disease.

4. Registration procedures

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 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.

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 range of activity of *antimicrobial agents* on both pathogens and non-pathogens (commensals);
- assess the ability of the *antimicrobial agent* to select for resistance *in vitro* and *in vivo*, taking into consideration pre-existing resistant strains;
- establish an appropriate dosage regimen 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;
- concentration of the antimicrobial at the site of infection and 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 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;

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 to select for resistance

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

For this the following may be considered:

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

b) the route and level of human exposure to food-borne or other resistant organisms;

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

d) the 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 compounds

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

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

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

i) the MRL established for the *antimicrobial agent* under consideration;

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

iii) the target animal species;

iv) the dosage regimen and the duration of treatment;

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. 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 antimicrobial product (VAP)

The summary of product characteristics contains the information necessary for the appropriate use of VAPs and constitutes the official reference for their labelling and package insert. This summary should contain the following items:

a) active ingredient and class;

b) pharmacological properties;

c) any potential adverse effects;

d) target animal species and age or production category;

e) therapeutic indications;

f) target micro-organisms;

g) dosage and administration route;

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 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. Such surveillance will also contribute to general epidemiological surveillance of antimicrobial resistance.

12. Supply and administration of the antimicrobial agents 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 VAPs.

13. Control of advertising

All advertising of antimicrobials should be controlled by a code of advertising standards, and the relevant authorities must ensure that the advertising of antimicrobial 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 antimicrobials 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:

a) information on disease prevention and management strategies;

b) the ability of antimicrobials to select for resistance 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 3.9.3.4.

Responsibilities of the veterinary pharmaceutical industry

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.

2. Marketing and export of VAPs

For the marketing and export of VAPs:

a) only licensed and officially approved 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:

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

b) ensure that the advertising of 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 3.9.3.3.

5. Research

   The veterinary pharmaceutical industry should contribute to research as defined in point 15 of Article 3.9.3.3.

Article 3.9.3.5.

Responsibilities of wholesale and retail distributors

1. Retailers distributing VAPs should only do so on the prescription of a veterinarian or other suitably trained person authorised in accordance with national legislation, and all products should be appropriately labelled.
2. The guidelines on the responsible use of antimicrobials 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) quantity supplied.
3. Distributors should also be involved in training programmes on the responsible use of antimicrobials, as defined in point 14 of Article 3.9.3.3.

Article 3.9.3.6.

Responsibilities of veterinarians

The concern of the veterinarian is to promote public health and animal health and welfare. The veterinarian's responsibilities include preventing, identifying and treating 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;
   b) make an appropriate choice of the antimicrobial based on experience 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) the activity towards the pathogens involved;
      iii) the appropriate 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.

To minimise the likelihood of antimicrobial resistance developing, it is recommended that antimicrobials 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.

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

3. Appropriate use of the antimicrobial chosen

A prescription for *antimicrobial agents* should indicate precisely the treatment regime, the dose, the treatment intervals, the duration of the treatment, the withdrawal period and the amount of drug to be delivered, depending on the dosage and the number of animals to be treated.

The off-label use of a veterinary antimicrobial 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 therapeutic regimen, the route of administration, and the duration of the treatment.

4. Recording

Records on veterinary antimicrobial drugs should be kept in conformity with national legislation. Information records should include the following:

a) quantities of medication used;

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

c) a list of medicine withdrawal period;

d) a record of antimicrobial susceptibilities;

e) comments concerning the response of animals to 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 VAPs to ensure compliance with their directions and use these records to evaluate the efficacy of treatment regimens.

5. Labelling

All medicines supplied by a veterinarian should be labelled according to national legislation.

6. Training

Veterinary professional organisations should participate in the training programmes as defined in point 14 of Article 3.9.3.3. It is recommended that veterinary professional organisations develop for their members species-specific clinical practice guidelines on the responsible use of VAPs.

Article 3.9.3.7.

Responsibilities of food-animal producers

1. Food-animal producers with the assistance of a veterinarian are responsible for implementing 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 (feedlot health plans, mastitis control plans, endo- and ectoparasite control and vaccination programmes, etc.);

b) use *antimicrobial agents* only on prescription, and according to the provisions of the prescription;

c) use *antimicrobial agents* in the species, for the uses and at the dosages on the approved/registered labels and in accordance with product label instructions 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;

f) address hygienic conditions regarding contacts between people (veterinarians, breeders, owners, children) and the animals treated;

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

h) dispose of surplus antimicrobials under safe conditions for the environment; medicines 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;

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;

j) keep adequate records of all medicines used, including the following:

   i) name of the product/active substance and batch number;

   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;

   v) clinical conditions treated;

   vi) dosage;

   vii) withdrawal periods;

   viii) result of laboratory tests;

   ix) effectiveness of therapy;

k) inform the responsible veterinarian of recurrent disease problems.

APPENDIX 3.9.4.

RISK ASSESSMENT FOR ANTIMICROBIAL RESISTANCE ARISING FROM THE USE OF ANTIMICROBIALS IN ANIMALS

Article 3.9.4.1.

Guidelines for analysing the risks to animal and public health from antimicrobial resistant micro-organisms of animal origin

1. Introduction

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

2. Objective

The principal aim of risk analysis for antimicrobial resistance in micro-organisms from animals is to provide Member Countries with a transparent, objective and scientifically defensible method of assessing and managing the human and animal health risks associated with the development of resistance arising from the use of antimicrobials in animals.

3. The risk analysis process

The principles of risk analysis are described in Section 1.3. of this *Terrestrial Code.*

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

4. Hazard identification

For the purposes of this Appendix, the hazard is the resistance determinant that emerges as a result of the use of a specific antimicrobial in animals. This definition reflects the development of resistance in a species of pathogenic micro-organisms, as well as the development of a resistance determinant that may be passed from one species of micro-organisms to another. The conditions under which the hazard might produce adverse consequences include any scenarios through which humans or animals could become exposed to a pathogen which contains that resistance determinant, fall ill and then be treated with an antimicrobial that is no longer effective because of the resistance.

5. Risk assessment

The assessment of the risk to human and animal health from antimicrobial-resistant micro-organisms resulting from the use of antimicrobials in animals should examine:

a) the likelihood of emergence of resistant micro-organisms arising from the use of antimicrobial(s), or more particularly, production of the resistance determinants if transmission is possible between micro-organisms;

b) consideration of all pathways and their importance, by which humans could be exposed to these resistant micro-organisms or resistance determinants, together with the possible degree of exposure;

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

Article 3.9.4.2.

Analysis of risks to human health

1. Definition of the risk

The infection of humans with micro-organisms that have acquired resistance to a specific antimicrobial used in animals, and resulting in the loss of benefit of antimicrobial therapy used to manage the human infection.

2. Hazard identification

- Micro-organisms that have acquired resistance, (including multiple resistance) arising from the use of an antimicrobial(s) in animals.
- Micro-organisms having obtained a resistance determinant(s) from other micro-organisms which have acquired resistance arising from the use of an antimicrobial(s) in animals.

The identification of the hazard must include consideration of the class or subclass of the antimicrobial(s). This definition should be read in conjunction with point 4) of Article 3.9.4.1.

3. Release assessment

A release assessment describes the biological pathways necessary for the use of a specific antimicrobial in animals to lead to the release of resistant micro-organisms or resistance determinants into a particular environment, and estimating either qualitatively or quantitatively the probability of that complete process occurring. The release assessment describes the probability of the release of each of the potential hazards under each specified set of conditions with respect to amounts and timing, and how these might change as a result of various actions, events or measures.

The following factors should be considered in the release assessment:

- species of animal treated with the antimicrobial(s) in question
- number of animals treated, geographical distribution of those animals
- variation in methods and routes of administration of the antimicrobial(s)
- the pharmacodynamics/pharmacokinetics of the antimicrobial(s)
- micro-organisms developing resistance as a result of the antimicrobial(s) use
- mechanism of direct or indirect transfer of resistance
- cross-resistance and/or co-resistance with other antimicrobials
- surveillance of animals, products of animal origin and animal waste products for the existence of resistant micro-organisms.

4. Exposure assessment

An exposure assessment describes the biological pathways necessary for exposure of humans to the resistant micro-organisms or resistance determinants released from a given antimicrobial use in animals, and estimating the probability of the exposures occurring. The probability of exposure to the identified hazards is estimated for specified exposure conditions with respect to amounts, timing, frequency, duration of exposure, routes of exposure and the number, species and other characteristics of the human populations exposed.

The following factors should be considered in the exposure assessment:

- human demographics and food consumption patterns, including traditions and cultural practices
- prevalence of resistant micro-organisms in food
- environmental contamination with resistant micro-organisms
- prevalence of animal feed contaminated with resistant micro-organisms
- cycling of resistant micro-organisms between humans, animals and the environment
- steps of microbial decontamination of food

- microbial load in contaminated food at the point of consumption
- survival capacity and redistribution of resistant micro-organisms during the food production process (including slaughtering, processing, storage, transportation and retailing)
- disposal practices for waste products and the opportunity for human exposure to resistant micro-organisms or resistance determinants in those waste products
- point of consumption of food (professional catering, home cooking)
- variation in consumption and food-handling methods of exposed populations and subgroups of the population
- capacity of resistant micro-organisms to become established in humans
- human-to-human transmission of the micro-organisms under consideration
- capacity of resistant micro-organisms to transfer resistance to human commensal micro-organisms and zoonotic agents
- amount and type of antimicrobials used in response to human illness
- pharmacokinetics (metabolism, bioavailability, access to intestinal flora).

5. Consequence assessment

A consequence assessment describes the relationship between specified exposures to resistant micro-organisms or resistance determinants and the consequences of those exposures. A causal process must exist by which exposures produce adverse health or environmental consequences, which may in turn lead to socio-economic consequences. The consequence assessment describes the potential consequences of a given exposure and estimates the probability of them occurring.

The following factors should be considered in the consequence assessment:

- dose-response relationships
- variation in susceptibility of exposed populations or subgroups of the population
- variation and frequency of human health effects resulting from loss of efficacy of antimicrobials
- changes in human medicinal practices resulting from reduced confidence in antimicrobials
- changes in food consumption patterns due to loss of confidence in the safety of food products and any associated secondary risks
- associated costs
- interference with first line/choice antimicrobial therapy in humans
- perceived future usefulness of the antimicrobial (time reference)
- prevalence of resistance in human bacterial pathogens under consideration.

6. Risk estimation

A risk estimation integrates the results from the release assessment, exposure assessment and consequence assessment to produce overall estimates of risks associated with the hazards. Thus, risk estimation takes into account the whole of the risk pathway from hazard identification to the unwanted consequences.

The following factors should be considered in the risk estimation:

- number of people falling ill and the proportion of that number affected with resistant strains of micro-organisms
- increased severity or duration of infectious disease
- number of person/days of illness per year
- deaths (total per year; probability per year or lifetime for a random member of the population or a member of a specific more exposed sub-population)
- importance of the pathology caused by the target micro-organisms
- absence of alternate antimicrobial therapy

- incidence of resistance observed in humans
- consequences to allow weighted summation of different risk impacts (e.g. illness and hospitalisation).

7. Risk management options and risk communication

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

Article 3.9.4.3.

Analysis of risks to animal health

1. Definition of the risk

The infection of animals with micro-organisms that have acquired resistance from the use of a specific antimicrobial(s) in animals, and resulting in the loss of benefit of antimicrobial therapy used to manage the animal infection.

2. Hazard identification

- Micro-organisms that have acquired resistance, (including multiple resistance) arising from the use of an antimicrobial(s) in animals.
- Micro-organisms having obtained a resistance determinant(s) from another micro-organisms which have acquired resistance arising from the use of an antimicrobial(s) in animals.

The identification of the hazard must include considerations of the class or subclass of the antimicrobial(s). This definition should be read in conjunction with point 4) of Article 3.9.4.1.

3. Release assessment

The following factors should be considered in the release assessment:

- animal species treated
- number of animals treated, sex, age and their geographical distribution
- amounts used and duration of treatment
- variation in methods and routes of administration of the antimicrobial(s)
- the pharmacodynamics/ pharmacokinetics of the antimicrobial(s)
- site and type of infection
- development of resistant micro-organisms
- mechanisms and pathways of resistance transfer
- cross-resistance and/or co-resistance
- surveillance of animals, products of animal origin and animal waste products for the existence of resistant micro-organisms.

4. Exposure assessment

The following factors should be considered in the exposure assessment:

- prevalence and trends of resistant micro-organisms in clinically ill and clinically unaffected animals
- prevalence of resistant micro-organisms in feed /the animal environment
- animal-to-animal transmission of the resistant micro-organisms
- number/percentage of animals treated
- dissemination of resistant micro-organisms from animals (animal husbandry methods, movement of animals)
- quantity of antimicrobial(s) used in animals
- treatment regimens (dose, route of administration, duration)

- survival capacity of resistant micro-organisms
- exposure of wild life to resistant micro-organisms
- disposal practices for waste products and the opportunity for animal exposure to resistant micro-organisms or resistance determinants in those products
- capacity of resistant micro-organisms to become established in animal intestinal flora
- exposure to resistance determinants from other sources
- dose, route of administration and duration of treatment
- pharmacokinetics (metabolism, bioavailability, access to intestinal flora)
- cycling of resistant micro-organisms between humans, animals and the environment.

5. Consequence assessment

The following factors should be considered in the consequence assessment:

- dose-response relationships
- variation in disease susceptibility of exposed populations and subgroups of the populations
- variation and frequency of animal health effects resulting from loss of efficacy of antimicrobials
- changes in practices resulting from reduced confidence in antimicrobials
- associated cost
- perceived future usefulness of the drug (time reference).

6. Risk estimation

The following factors should be considered in the risk estimation:

- number of therapeutic failures due to resistant micro-organisms
- animal welfare
- economic cost
- deaths (total per year; probability per year or lifetime for a random member of the population or a member of a specific more exposed sub-population)
- incidence of resistance observed in animals.

7. Risk management options and risk communication

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

The relevant recommendations (Articles 1.3.2.5., 1.3.2.6. and 1.3.2.7.) in the *Terrestrial Code* apply.

A range of risk management options is available to minimize the emergence and spread of antimicrobial resistance and these include both regulatory and non-regulatory risk management options, such as the development of codes of practice concerning the use of antimicrobials in animal husbandry. Risk management decisions need to consider fully the implications of these different options for human health and animal health and welfare and also take into account economic considerations and any associated environmental issues. Effective control of certain bacterial diseases of animals will have the dual benefit of reducing the risks linked to antimicrobial resistance, in cases where the bacterial disease under consideration has also developed antimicrobial resistance. Appropriate communication with all stakeholders is essential throughout the risk assessment process.

SECTION 3.10.

ANIMAL PRODUCTION FOOD SAFETY

APPENDIX 3.10.1.

GUIDELINES FOR THE CONTROL OF BIOLOGICAL HAZARDS OF ANIMAL HEALTH AND PUBLIC HEALTH IMPORTANCE THROUGH ANTE- AND POST-MORTEM MEAT INSPECTION

Article 3.10.1.1.

Introduction

Foodborne disease and zoonoses are important public health problems and causes of decreased economic productivity in developed and developing countries. Similarly, transmission of hazards of animal health importance via the meat production chain and associated by-products can result in significant economic loss in livestock. Inspection of animals at slaughter can provide a valuable contribution to surveillance for certain diseases of animal and public health importance. Control and/or reduction of biological hazards of animal and public health importance by ante- and post-mortem meat inspection are a core responsibility of *Veterinary Services*.

Article 3.10.1.2.

Purpose

These guidelines provide a basis for future development of OIE standards for animal production food safety.

Article 3.10.1.3.

Hygienic practice throughout the meat production chain

The Codex Alimentarius Code of Hygienic Practice for Meat (CHPM) constitutes the primary international standard for meat hygiene and incorporates a risk-based approach to application of sanitary measures throughout the meat production chain. Ante-mortem inspection is described as a primary component of meat hygiene before slaughter, and post-mortem inspection is described as a primary component of process control in post-slaughter meat hygiene. The CHPM specifically recognises the dual objectives that slaughterhouse inspection activities deliver in terms of animal and public health.

The CHPM does not provide inspection measures for specific hazards, which remain the responsibility of national competent authorities. The animal and public health risks associated with livestock populations vary across regions and animal husbandry systems, and ante- and post-mortem inspection needs to be tailored to the individual country situation and its animal and public health objectives.

The CHPM provides a platform for development of meat hygiene systems that are based on risk assessment. There are few risk assessment models and little relevant scientific information available on public health hazards derived specifically from animals and their products, making difficult the development of risk-based standards for

food-borne diseases and zoonoses. While this scientific information is being accumulated, ante- and post-mortem inspection systems will remain dependent on traditional approaches.

Article 3.10.1.4.

Veterinary Services and meat inspection programmes

Veterinary Services are primarily responsible for the development of ante- and post-mortem meat inspection programmes. Wherever practicable, inspection procedures should be risk-based and management systems should reflect international norms and cover the significant hazards to both human and animal health in the livestock being slaughtered, as determined by the *Veterinary Services*. In respect of ante- and post-mortem inspection as a component of meat hygiene, responsibilities of *Veterinary Services* include:

1. risk assessment and risk management;
2. establishment of policies and standards;
3. design and management of inspection programmes;
4. assurance and certification of appropriate delivery of inspection and compliance activities;
5. dissemination of information throughout the meat production chain.

Article 3.10.1.5.

Risk assessment and risk management

Veterinary Services should utilise risk assessment to the greatest extent practicable in the development of sanitary measures. *Veterinary Services* should give priority to addressing microbiological contamination, while not neglecting gross abnormalities detected at ante- and post-mortem inspection, as this has been found to be the most important source of hazards.

Microbiological, serological or other testing at single-animal and herd level as part of ante- and post-mortem inspection should be used to support surveillance, as well as risk assessment of prioritised foodborne hazards. The information gathered should be linked to human disease data to allow an assessment of the effectiveness of various management options, as well as a general evaluation of food sources of foodborne disease.

Application of a generic framework should provide a systematic and consistent process for managing all biosecurity risks, while accommodating the different risk assessment methodologies used in animal and public health.

Article 3.10.1.6.

Establishment of policies and standards

The national competent authority(s) should provide an appropriate institutional environment to allow *Veterinary Services* to develop the necessary policies and standards.

As well as meeting public health objectives, policies and standards relating to ante- and post-mortem inspection should aim to detect and remove hazards of animal health significance from the meat production chain. This may be achieved by the removal of live animals at ante-mortem inspection or by the removal of specific tissues at post-mortem inspection.

Veterinary Services should integrate their activities to the maximum extent practicable so as to prevent duplication of effort and unnecessary costs e.g. within the process of international certification.

Article 3.10.1.7.

Design and management of inspection programmes

In meeting animal and public health objectives prescribed in national legislation or required by *importing countries*, *Veterinary Services* contribute through the direct performance of some veterinary tasks or through the auditing of animal and public health activities conducted by other agencies or the private sector. To this end, *Veterinary Services* provide assurances domestically and to trading partners that safety and suitability standards have been met.

Veterinary Services should allow flexibility in meat inspection service delivery through an officially recognised competent body operating under its supervision and control. In recognition of the contribution of industry to food safety, quality assurance systems may be extended in the case of ante- and post-mortem inspection to systems that integrate industry and *Veterinary Services* activities. Nevertheless, *Veterinary Services* should take into account the factors identified in Chapter 1.3.3. on the Evaluation of Veterinary Services. For example, if personnel from the private sector are used to carry out ante- and post-mortem inspection activities under the overall supervision and responsibility of the *Veterinary Services*, the *Veterinary Services* should specify the competency requirements for all such persons and verify their performance.

Article 3.10.1.8.

Assurance and certification

Assurance and certification of appropriate delivery of inspection and compliance activities is a vital function of *Veterinary Services*. International health certificates providing official assurances for trading of meat must engender full confidence to the country of importation.

Article 3.10.1.9.

Dissemination of information

Organisation and dissemination of information throughout the meat production chain involves multidisciplinary inputs. To ensure the effective implementation of ante- and post-mortem inspection procedures, *Veterinary Services* should have in place systems for the monitoring of these procedures and the exchange of information gained. Further, there should be an ongoing programme for monitoring of hazards at appropriate points throughout the meat production chain so as to help evaluate the efficacy of controls. *Animal identification* and *animal traceability* systems should be integrated in order to be able to trace slaughtered animals back to their place of origin, and products derived from them forward through the meat production chain.

PART 4

MODEL INTERNATIONAL VETERINARY CERTIFICATES

SECTION 4.1.

MODEL INTERNATIONAL VETERINARY CERTIFICATES FOR LIVE ANIMALS

APPENDIX 4.1.1.

MODEL INTERNATIONAL VETERINARY CERTIFICATE FOR DOGS AND CATS ORIGINATING FROM RABIES INFECTED COUNTRIES

MODEL INTERNATIONAL VETERINARY CERTIFICATE FOR DOGS AND CATS ORIGINATING FROM 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 (tattoo or other permanent method of identification) (see note 1)

III. ADDITIONAL INFORMATION

Country of origin: .....
.....

Countries visited .....
over the past 2 years .....
as declared by the owner .....
(give dates) .....
.....
.....

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. ..... 3.	

PERIOD OF VALIDITY OF VACCINATION FOR INTERNATIONAL MOVEMENT (see note 3)		Name (in capital letters) and signature of the Official Veterinarian
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 3)		Name (in capital letters) and signature of the Official Veterinarian
from (dd/mm/yy)	to (dd/mm/yy)	

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 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 Official Veterinarian

NOTE

1. The identification number stated in the certificate should 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 inactivated virus vaccines are authorised for international movements of dogs and cats.
3. In the case of a primary vaccination, 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. The animal should have been subjected not less than 3 months and not more than 24 months prior to its introduction into the importing country, to a neutralising antibody titration test. It should be carried out by an official diagnostic laboratory approved by the Competent Authority of the exporting country. 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 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. 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.

APPENDIX 4.1.2.

MODEL INTERNATIONAL VETERINARY CERTIFICATE FOR DOMESTIC OR WILD ANIMALS OF THE BOVINE, BUBALINE, OVINE, CAPRINE OR PORCINE SPECIES

MODEL INTERNATIONAL VETERINARY CERTIFICATE FOR DOMESTIC OR WILD ANIMALS OF THE BOVINE, BUBALINE, OVINE, CAPRINE OR PORCINE SPECIES

Exporting country: .....
Ministry of: .....
Department: .....
Province or District, etc.: .....

I. Identification of the animal/s

Official ear mark	Breed	Sex	Age

II. Origin of the animal/s

Name and address of exporter:.....
.....
Place of origin of the animal/s:.....
.....

III. Destination of the animal/s

Country of destination:.....
Name and address of consignee:.....
.....
.....
Nature and identification of means of transport:.....
.....

IV. Sanitary information

The undersigned Official Veterinarian certifies that the animal/s described above and examined on this day:

a) shows/show no clinical sign of disease;

b) satisfies/satisfy the following requirements[2]:

Official stamp:

Issued at..... on .....
Name and address of Veterinarian .....
.....
.....

Signature: .....

1 It is recommended that individual certificates be drawn up for breeding animals.

2 These conditions are agreed between the Veterinary Services of the importing and exporting countries in accordance with the options provided in this Terrestrial Code.

APPENDIX 4.1.3.

MODEL INTERNATIONAL VETERINARY CERTIFICATE FOR SEMEN OF ANIMALS OF THE BOVINE, BUBALINE, EQUINE, OVINE, CAPRINE OR PORCINE SPECIES

MODEL INTERNATIONAL VETERINARY CERTIFICATE FOR SEMEN OF ANIMALS OF THE BOVINE, BUBALINE, EQUINE, OVINE, CAPRINE OR PORCINE SPECIES

Exporting country: .....
Ministry of: .....
Department: .....
Province or District, etc.: .....

I. Information concerning the donor animal[1]

Species: .....
Breed: .....
Name: .....
Date of birth: .....
Place of birth: .....
Registered entry in the herd/stud book: .....
Date of approval of animal for artificial insemination purposes: .....
.....

II. Information concerning the semen[1]

Date of collection: .....
Quantity and packaging of exported semen: .....
.....

III. Origin of the semen

Name and address of exporter (artificial insemination centre or exporting owner): .....
.....
.....

IV. Destination of the semen

Name and address of consignee: .....
.....
.....
Nature and identification of means of transport: .....
.....

V. Sanitary information

The undersigned Official Veterinarian certifies that the donor animal:

a) shows no sign of disease on the day of collection;

b) satisfies the following requirements[2]:

Official stamp:

Issued at..... on .....
Name and address of Veterinarian .....
.....
.....

Signature: .....

1 Zootechnical information supplied by: .....
.....
.....

2 These conditions are agreed between the Veterinary Services of the importing and exporting countries in accordance with the options provided in this Terrestrial Code.

APPENDIX 4.1.4.

MODEL INTERNATIONAL VETERINARY CERTIFICATE FOR EQUINES

MODEL INTERNATIONAL VETERINARY CERTIFICATE FOR EQUINES

Exporting country: .....
Ministry of: .....
Department: .....
Province or District, etc.: .....

I. Identification of the animal/s

Species	Age	Sex	Breed	Marks and description

II. Origin of the animal/s

Name and address of exporter: .....
.....
Place of origin of the animal/s: .....
.....
.....

III. Destination of the animal/s

Country of destination: .....
Name and address of consignee: .....
.....
.....
Nature and identification of means of transport: .....
.....

IV. Sanitary information

The undersigned Official Veterinarian certifies that the animal/s described above and examined on this day:

a) shows/show no clinical sign of disease;

b) satisfies/satisfy the following requirements[2]:

Official stamp:

Issued at..... on .....
Name and address of Veterinarian .....
.....
.....

Signature: .....

1 It is recommended that individual certificates be drawn up for breeding animals.

2 These conditions are agreed between the Veterinary Services of the importing and exporting countries in accordance with the options provided in this Terrestrial Code.

APPENDIX 4.1.5.

MODEL PASSPORT FOR INTERNATIONAL MOVEMENT OF COMPETITION HORSES

MODEL PASSPORT FOR INTERNATIONAL MOVEMENT OF COMPETITION HORSES

INTRODUCTION

The object is to establish criteria which will assist in the unrestricted movement of competition horses between countries or zones of countries, while still protecting the health status of the respective countries or zones. To achieve this aim, it is intended that the passport of any competition horse shall serve as a unique identification document including harmonised information in the form of records of vaccinations and results of laboratory tests.

In addition to the passport, a separate veterinary certificate may be required by the importing country.

CONTENTS OF THE PASSPORT

The passport should contain:

1. Details of ownership

   Information regarding the name and address of the owner of the horse should be indicated according to Appendix A, and be authenticated by the National Federation issuing the passport.

2. Identification of the horse

   The horse should be identified by the competent authority according to Appendices B and C.

3. Movement records

   The identification of the horse should be checked at each time it is required by rules and regulations and recorded in accordance with Appendix D.

4. Vaccination record

   All vaccinations should be recorded according to Appendix E (equine influenza only) and Appendix F (all other vaccinations).

5. Laboratory health tests

   The result of every test undertaken for a transmissible disease will be recorded according to Appendix G.

BASIC HEALTH REQUIREMENTS

Appendix H is a document which outlines the basic health requirements which apply to the international movement of competition horses.

For the movement of competition horses between countries or zones of countries with a different health status, Veterinary Services may require additional veterinary certification.

The reverse side of Appendix H lists diseases which may be considered for inclusion in the veterinary certificate.

Appendix A

Propriétaires successifs

1. La nationalité du cheval est celle de son propriétaire.
2. Lors de tout changement de propriétaire, le passeport doit être immédiatement retourné, en mentionnant le nom et l'adresse du nouveau propriétaire, à la Fédération équestre nationale, qui le remettra au nouveau propriétaire après enregistrement.
3. S'il y a plus d'un seul propriétaire, ou si le cheval appartient à une société, on indiquera dans le passeport le nom de la personne responsable du cheval et sa nationalité. Si les propriétaires sont de nationalités différentes, ils doivent préciser la nationalité du cheval.
4. Lorsqu'il y a location du cheval, dûment enregistrée par une Fédération équestre nationale avec accord de la Fédération équestre internationale, celle-ci doit être mentionnée sur cette page par cette Fédération nationale.

Details of ownership

1. The nationality of the horse is that of its owner.
2. On change of ownership the passport must immediately be lodged with the National Equestrian Federation, giving the name and address of the new owner, for re-registration and forwarding to the new owner.
3. If there is more than one owner or the horse is owned by a company, then the name of the individual responsible for the horse shall be entered in the passport together with his nationality. If the owners are of different nationalities, they have to determine the nationality of the horse.
4. When the Federation Equestre Internationale approves the leasing of a horse by a National Equestrian Federation, the details of these transactions must be recorded on this page by the National Equestrian Federation concerned.

Detalles del propietario

1. La nacionalidad del caballo es la nacionalidad de su propietario.
2. En caso de cambio de propietario, el pasaporte debe ser entregado inmediatamente, indicando el nombre y la dirección del nuevo propietario, a la Federación Ecuestre Nacional, que lo remitirá al nuevo propietario después de haberlo registrado.
3. Si el caballo tiene más de un propietario, o si pertenece a una sociedad, el nombre y la nacionalidad de la persona responsable del caballo deben inscribirse en el pasaporte. Si los propietarios son de diferente nacionalidad, deben precisar la nacionalidad del caballo.
4. Cuando la Federación Ecuestre Internacional aprueba el alquiler de un caballo por una Federación Ecuestre Nacional, la Federación Ecuestre Nacional debe registrar los detalles de la transacción en esta página.

Date d'enregistrement par la Fédération équestre nationale Date of registration by the National Equestrian Federation Fecha de registro por la Federación Ecuestre Nacional	Nom du propriétaire Name of owner Nombre del propietario	Adresse du propriétaire Address of owner Dirección del propietario	Nationalité du propriétaire Nationality of owner Nacionalidad del propietario	Signature du propriétaire Signature of owner Firma del propietario	Cachet de la Fédération équestre nationale et signature officielle National Equestrian Federation stamp and signature of the secretary Sello de la Federación Ecuestre Nacional y firma oficial

Appendix B

(1) N° d'identification :

Identification No.:

N° de identificación:

(2) Nom :

Name:

Nombre:

(3) Sexe :

Sex:

Sexo:

(4) Robe :

Colour:

Color:

(5) Race :

Breed:

Raza:

(6) par :

by:

por:

(7) et :

out of:

y:

(8) par :

by:

por:

(9) Date de naissance :

Date of foaling:

Fecha de nacimiento:

(10) Lieu d'élevage :

Place where bred:

Lugar de cría:

(11) Naisseur(s) :

Breeder(s):

Criador(es):

(12) Certificat d'origine validé le :

par :

Origin certificate validated on:

by:

Certificado de origen visado el:

por:

- Nom de l'autorité compétente :

  Name of the competent authority:

  Nombre de la autoridad competente:

- Adresse :

  Address:

  Dirección:

- N° de téléphone : - N° de télécopie :

  Telephone No.: - Telecopy No.:

  N° de teléfono: - N° de fax:

- Signature :

  (nom en lettres capitales et qualité du signataire)

- Signature:

  (Name in capital letters and capacity of signatory)

  Firma:

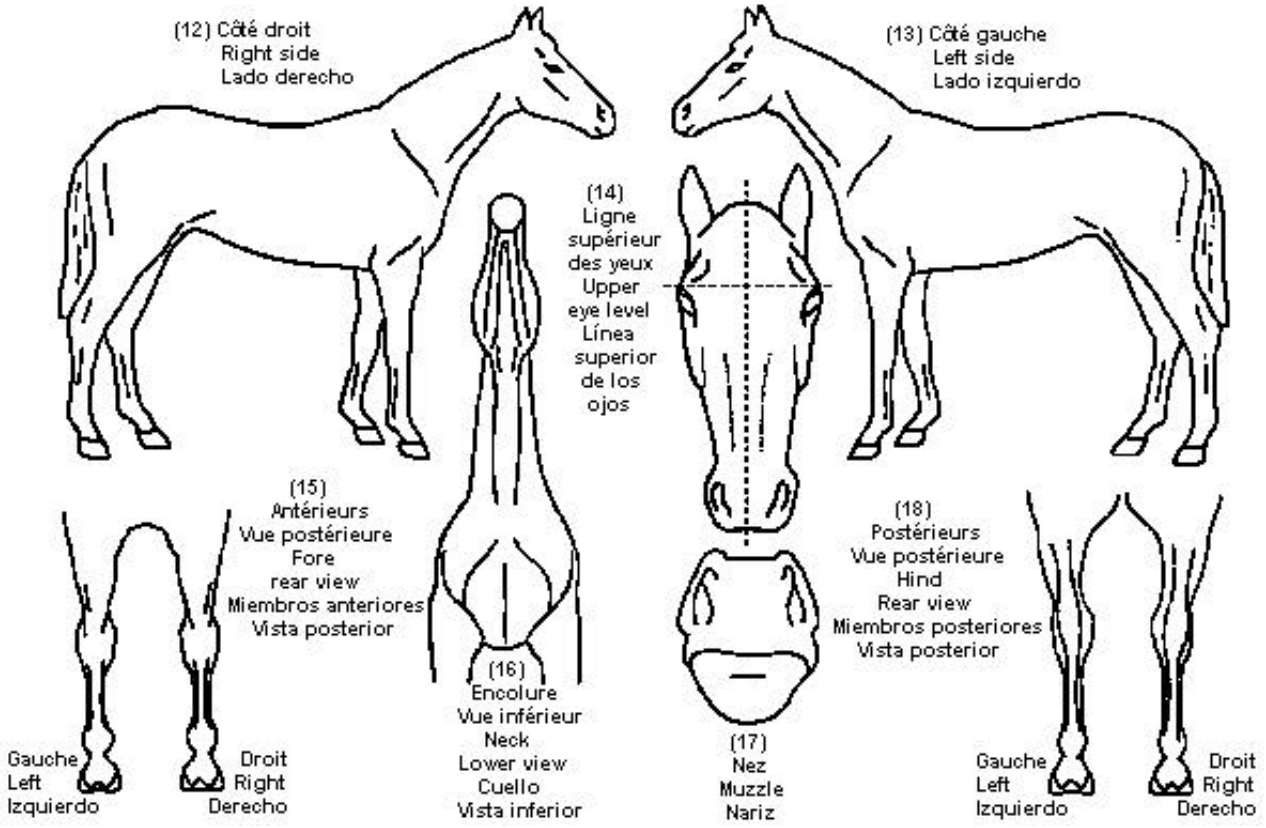
  (Nombre en letras mayúsculas y calidad del firmante)

- Cachet

  Stamp

  Sello

Appendix C


(12) Côté droit
Right side
Lado derecho
(13) Côté gauche
Left side
Lado izquierdo
(14)
Ligne
supérieur
des yeux
Upper
eye level
Línea
superior
de los
ojos
(15)
Antérieurs
Vue postérieure
Fore
rear view
Miembros anteriores
Vista posterior
(16)
Encolure
Vue inférieur
Neck
Lower view
Cuello
Vista inferior
(17)
Nez
Muzzle
Nariz
(18)
Postérieurs
Vue postérieure
Hind
Rear view
Miembros posteriores
Vista posterior
Gauche
Left
Izquierdo
Droit
Right
Derecho
Gauche
Left
Izquierdo
Droit
Right
Derecho

(2) Nom :
Name:
Nombre:

(5) Race :
Breed:
Raza:

(3) Sexe :
Sex:
Sexo:

(4) Robe :
Colour:
Color:

(19) Signalement relevé sous la mère par :
Description taken with dam by:
Descripción registrada con la madre por:

Tête :
Head:
Cabeza:

Ant. G. :
Foreleg L.:
Ant. I.:

Ant. D. :
Foreleg R.:
Ant. D.:

Post. G. :
Hindleg L.:
Post. I.:

Post. D. :
Hindleg R.:
Post. D.:

Corps :
Body:
Cuerpo:

(21) Signature et cachet du vétérinaire agréé
(ou de l'autorité compétente)
Signature and stamp of qualified veterinary surgeon
(or competent authority)

Marques :
Markings:
Marcas:

Firma y sello del veterinario autorizado
(o de la autoridad competente)
(en lettres capitales)
(in capital letters)
(en letras mayúsculas)

Fait le (date) :
Made on (date):
A (fecha):

Date :
Date:
Fecha:

Appendix D

Contrôles d'identité du cheval décrit dans ce passeport

L'identité du cheval doit être contrôlée chaque fois que les lois et règlements l'exigent : signer cette page signifie que le signalement du cheval présenté est conforme à celui de la page du signalement.

Identification of the horse described in this passport

The identity of the horse must be checked each time it is required by the rules and regulations and certified that it conforms with the description given on the diagram page of this passport.

Controles de identidad del caballo descrito en este pasaporte

Se controlará la identidad del caballo cada vez que lo exijan las leyes y reglamentos, y se certificará, firmando esta página, que el caballo presentado corresponde al caballo descrito en este pasaporte.

Date Date Fecha	Ville et pays Town and country Ciudad y país	Motif du contrôle (concours, certificat sanitaire, etc.) Purpose of control (event, veterinary certificate, etc.) Motivo del control (concurso, certificado sanitario, etc)	Signature, nom en lettres capitales et position de la personne ayant vérifié l'identité Signature, name (in capital letters) and status of official verifying the identification Firma, nombre (en letras mayúsculas) y calidad de la persona que controla la identidad

Appendix E

GRIPPE ÉQUINE SEULEMENT
Enregistrement des vaccinations

Toute vaccination subie par le cheval doit être portée dans le cadre ci-dessous de façon lisible et précise avec le nom et la signature du vétérinaire.

EQUINE INFLUENZA ONLY
Vaccination record

Details of every vaccination which the horse undergoes must be entered clearly and in detail, and certified with the name and signature of the veterinarian.

GRIPE EQUINA SOLAMENTE
Registro de vacunas

Todas las vacunas administradas al caballo, así como el nombre y la firma del veterinario, deben figurar de manera clara y detallada en el cuadro siguiente.

Date Date Fecha	Lieu Place Lugar	Pays Country País	Vaccin/Vaccine/Vacuna		Nom en lettres capitales et signature du vétérinaire Name (in capital letters) and signature of the veterinarian Nombre (en letras mayúsculas) y firma del veterinario
			Nom Name Nombre	Numéro de lot Batch number Número de lote	

Appendix F

MALADIES AUTRES QUE LA GRIPPE ÉQUINE
Enregistrement des vaccinations

Toute vaccination subie par le cheval doit être portée dans le cadre ci-dessous de façon lisible et précise avec le nom et la signature du vétérinaire.

DISEASES OTHER THAN EQUINE INFLUENZA
Vaccination record

Details of every vaccination which the horse undergoes must be entered clearly and in detail, and certified with the name and signature of the veterinarian.

ENFERMEDADES DISTINTAS DE LA GRIPE EQUINA
Registro de vacunas

Todas las vacunas administradas al caballo, así como el nombre y la firma del veterinario, deben figurar de manera clara y detallada en el cuadro siguiente.

Date Date Fecha	Lieu Place Lugar	Pays Country País	Vaccin/Vaccine/Vacuna			Nom en lettres capitales et signature du vétérinaire Name (in capital letters) and signature of the veterinarian Nombre (en letras mayúsculas) y firma del veterinario
			Nom Name Nombre	Numéro de lot Batch number Número de lote	Maladie(s) Disease(s) Enfermedad(es)	

Appendix G

Contrôles sanitaires effectués par des laboratoires

Le résultat de tout contrôle effectué par un vétérinaire pour une maladie transmissible ou par un laboratoire agréé par le Service vétérinaire gouvernemental du pays doit être noté clairement et en détail par le vétérinaire qui représente l'autorité demandant le contrôle.

Laboratory health test

The result of every test undertaken for a transmissible disease by a veterinarian or a laboratory authorised by the Government Veterinary Service of the country must be entered clearly and in detail by the veterinarian acting on behalf of the authority requesting the test.

Controles sanitarios efectuados por laboratorios

El veterinario que representa a la autoridad que solicita el control sanitario debe inscribir en el cuadro siguiente, de manera clara y detallada, el resultado de cada control relativo a una enfermedad transmisible efectuado por un veterinario o por un Servicio Veterinario gubernamental.

Date	Maladies transmissibles concernées	Nature de l'examen	Résultat de l'examen	Laboratoire officiel ayant analysé le prélèvement	Nom en lettres capitales et signature du vétérinaire
Date	Transmissible diseases tested for	Type of test	Result of test	Official laboratory to which sample transmitted	Name (in capital letters) and signature of Veterinarian
Fecha	Enfermedades transmisibles examinadas	Tipo de examen	Resultado del examen	Laboratorio oficial que ha analizado la muestra	Nombre (en letras mayúsculas) y firma del veterinario

Appendix H

EXIGENCES SANITAIRES DE BASE - BASIC HEALTH REQUIREMENTS - REQUISITOS SANITARIOS BÁSICOS

Je soussigné certifie[1] que le cheval décrit dans le passeport n° ..... délivré par ..... satisfait aux conditions suivantes :

I, the undersigned, certify[1] that the horse described in the Passport No. ..... issued by ..... meets the following requirements:

El que suscribe certifica[1] que el caballo descrito en el pasaporte n° ..... extendido por ..... cumple con los siguientes requisitos:

(a) il a été examiné ce jour, ne présente aucun signe clinique de maladie et est apte au transport ;

(a) it has been examined today, shows no clinical sign of disease and is fit for transport;

(a) ha sido examinado hoy, no presenta ningún signo clínico de enfermedad y se encuentra en condiciones de ser transportado;

(b) il n'est pas destiné à l'abattage dans le cadre d'un programme national d'éradication d'une maladie transmissible ;

(b) it is not intended for slaughter under a national programme of transmissible disease eradication;

(b) no ha sido destinado al sacrificio sanitario en el marco de un programa nacional de erradicación de una enfermedad transmisible;

(c) il ne provient pas d'une écurie mise en interdit pour des raisons zoosanitaires et n'a pas été en contact avec des équidés d'une écurie de ce type ;

(c) it does not come from a holding which was subject to prohibition for animal health reasons nor had contact with equidae from a holding which was subject to such prohibition;

(c) no procede de una cuadra sujeta a interdicción por razones zoosanitarias ni ha estado en contacto con équidos procedentes de una cuadra sujeta a interdicción;

(d) à ma connaissance, après avoir dûment enquêté, il n'a pas été en contact avec des équidés atteints d'une maladie transmissible au cours des 15 jours précédant l'embarquement.

(d) to the best of my knowledge and after due inquiry, it has not been in contact with equidae suffering from transmissible disease during 15 days prior to embarkation.

(d) según me consta, tras haber efectuado las indagaciones pertinentes, no ha estado en contacto con équidos afectados de enfermedades transmisibles durante los 15 días anteriores a su embarque.

LE PRÉSENT CERTIFICAT EST VALABLE 10 JOURS À COMPTER DE LA DATE DE SA SIGNATURE.

THIS CERTIFICATE IS VALID FOR 10 DAYS FROM THE DATE OF SIGNATURE.

EL PRESENTE CERTIFICADO ES VÁLIDO 10 DÍAS A PARTIR DE LA FECHA DE SU FIRMA.

Date Date Fecha	Lieu Place Lugar	Pour des raisons épidémiologiques particulières, un certificat sanitaire séparé accompagne le présent passeport. For special epizootic reasons a separate veterinary certificate accompanies this passport. Por razones epidemiológicas particulares se adjunta al presente pasaporte un certificado sanitario.	Nom en lettres capitales et signature du vétérinaire officiel Name (in capital letters) and signature of official veterinarian Nombre en letras mayúsculas y firma del veterinario oficial
		Oui / non (barrer la mention inutile) Yes / No (Delete One) Si / no (tachar lo que no procede)	
		Oui / non (barrer la mention inutile) Yes / No (Delete One) Si / no (tachar lo que no procede)	

(1) Ce document doit être signé dans les 48 heures précédant le déplacement international du cheval.

(1) The document should be signed within the 48 hours prior to international movement of the horse.

(1) Este documento debe ser firmado 48 horas antes del desplazamiento internacional del caballo.

LIST OF DISEASES WHICH SHOULD BE CONSIDERED FOR INCLUSION IN THE VETERINARY CERTIFICATE WHICH ACCOMPANIES THE PASSPORT

1. African horse sickness
2. Vesicular stomatitis
3. Dourine
4. Glanders
5. Equine encephalomyelitis (all types)
6. Equine infectious anaemia
7. Rabies
8. Anthrax

---

1 *For the movement of competition horses between countries or zones of countries with a different health status, Veterinary Services may require additional veterinary certification.*

APPENDIX 4.1.6.

MODEL INTERNATIONAL VETERINARY CERTIFICATE FOR BIRDS

MODEL INTERNATIONAL VETERINARY CERTIFICATE FOR BIRDS

Exporting country: .....
Ministry of: .....
Department: .....
Province or District, etc.: .....

I. Identification of the birds

Number	Mark	Species	Sex	Age

II. Origin of the birds

Name and address of exporter: .....
.....
Place of origin of the birds: .....
.....

III. Destination of the birds

Country of destination: .....
Name and address of consignee: .....
.....
.....
Nature and identification of means of transport: .....
.....
Type of containers: .....
.....

IV. Sanitary information

The undersigned Official Veterinarian certifies that the birds described above and examined on this day:

a) show no clinical sign of disease;

b) satisfy the following requirements[1]:

Official stamp:

Issued at..... on .....
Name and address of Veterinarian .....
.....
.....

Signature: .....

1 These conditions are agreed between the Veterinary Services of the importing and exporting countries in accordance with the options provided in this Terrestrial Code.

APPENDIX 4.1.7.

MODEL INTERNATIONAL VETERINARY CERTIFICATE FOR DAY-OLD BIRDS AND HATCHING EGGS

MODEL INTERNATIONAL VETERINARY CERTIFICATE FOR DAY-OLD BIRDS AND HATCHING EGGS

Exporting country: .....
Ministry of: .....
Department: .....
Province or District, etc.: .....

I. Identification of the birds or hatching eggs

Number	Mark	Species	Breed

II. Origin of the birds or hatching eggs

Name and address of the establishment of origin[1]: .....
.....
or of the hatchery[1]: .....
.....
Name and address of exporter: .....
.....

III. Destination of the birds or hatching eggs

Country of destination: .....
Name and address of consignee: .....
.....
.....
Nature and identification of means of transport: .....
.....
Type of containers: .....

IV. Sanitary information

The undersigned Official Veterinarian certifies that the day-old birds[1] or hatching eggs[1]:

a) come from an establishment[1] or a hatchery[1] which is regularly inspected;

b) come from an establishment[1] or a hatchery[1] come from an establishment[1] or a hatchery[1] which satisfies the following requirements[2]:

Official stamp:

Issued at..... on .....
Name and address of Veterinarian .....
.....
.....

Signature: .....

1 Delete where not applicable.

2 These conditions are agreed between the Veterinary Services of the importing and exporting countries in accordance with the options provided in this Terrestrial Code.

APPENDIX 4.1.8.

MODEL INTERNATIONAL VETERINARY CERTIFICATE FOR RABBITS

MODEL INTERNATIONAL VETERINARY CERTIFICATE FOR RABBITS

Exporting country: .....
Ministry of: .....
Department: .....
Province or District, etc.: .....

I. Identification of the animal/s

Number	Breed	Sex	Age

II. Origin of the animal/s

Name and address of exporter: .....
.....
Place of origin of the animal/s: .....
.....
.....

III. Destination of the animal/s

Country of destination: .....
Name and address of consignee: .....
.....
.....
Nature and identification of means of transport: .....
.....

IV. Sanitary information

The undersigned Official Veterinarian certifies that the animal/s described above and examined on this day:

a) shows/show no clinical sign of disease;

b) satisfies/satisfy the following requirements:[1]

Official stamp:

Issued at..... on .....
Name and address of Veterinarian .....
.....
.....

Signature: .....

1 These conditions are agreed between the Veterinary Services of the importing and exporting countries in accordance with the options provided in this Terrestrial Code.

APPENDIX 4.1.9.

MODEL INTERNATIONAL VETERINARY CERTIFICATE FOR BEES AND BROOD-COMBS

MODEL INTERNATIONAL VETERINARY CERTIFICATE FOR BEES AND BROOD-COMBS

Exporting country: .....
Ministry of: .....
Department: .....
Province or District, etc.: .....

I. Identification

Kind[1]	Number	Breed and variety	Peculiarities	Characteristics	
			Marks or age or weight or surface, etc.	Packing material	Accompanying products

II. Origin

Name and address of exporter: .....
.....
Name and address of producing bee-keeper: .....
.....
Place of origin of the bees, products and material: .....
.....

III. Destination

Country of destination: .....
Name and address of consignee: .....
.....
.....
Nature and identification of means of transport: .....
.....

IV. Sanitary information

The undersigned Official Veterinarian certifies that:

a) at the time of shipment, the exported bees and/or brood-combs showed no symptom of any of the contagious bee diseases listed by the OIE;

b) the breeding apiary of origin is officially approved and controlled by the Authority of the zone responsible for the application of the sanitary measures and special breeding techniques recommended by the OIE;

c) the breeding apiary of origin has been recognised as being free from contagious bee diseases for at least the past 2 years with regard to varroosis and for at least the past 2 years with regard to the other bee diseases listed by the OIE;

d) in the zone of origin, the arrangements for sanitary surveillance, as recommended by the OIE, have been continuously applied for at least the past 2 years under the control of the veterinary service or of a sanitary service operating under its authority;

e) the packing material and accompanying products come directly from the exporting breeding apiary and have not been in contact with diseased bees or brood-combs, nor with any products or equipment which are contaminated or extraneous to the exporting apiary.

Official stamp:

Issued at..... on .....
Name and address of Veterinarian .....
.....
.....

Signature: .....

1 Hive with bees, swarm, consignment of bees (worker bees, drones), queen bees, brood-combs, royal cells, etc.

SECTION 4.2.

MODEL INTERNATIONAL VETERINARY CERTIFICATE FOR PRODUCTS OF ANIMAL ORIGIN

APPENDIX 4.2.1.

MODEL INTERNATIONAL VETERINARY CERTIFICATE FOR MEAT OF DOMESTIC ANIMALS OF THE BOVINE, BUBALINE, EQUINE, OVINE, CAPRINE OR PORCINE SPECIES OR OF POULTRY

MODEL INTERNATIONAL VETERINARY CERTIFICATE FOR MEAT OF DOMESTIC ANIMALS OF THE BOVINE, BUBALINE, EQUINE, OVINE, CAPRINE OR PORCINE SPECIES OR OF POULTRY

Exporting country: .....
Ministry of: .....
Department: .....
Province or District, etc.: .....

I. Identification of the meat

Type of portions of meat: .....
Type of package: .....
Number of objects or packages: .....
Net weight: .....

II. Origin of the meat

[1]Address/es and number/s of veterinary approval of the abattoir/s:.....
.....
.....
[1]Address/es and number/s of veterinary approval of the cutting-up establishment/s: .....
.....

III. Destination of the meat

The meat is being sent from (place of dispatch) .....
to (country and place of destination) .....
Nature and identification of means of transport: .....
.....
Name and address of exporter: .....
.....
Name and address of consignee: .....
.....
.....

IV. Attestation of wholesomeness

The undersigned Official Veterinarian certifies that:

a) the meat[1], packages of meat[1] referred to above is/are stamped, thereby attesting that all the meat comes from animals or birds slaughtered in abattoirs;

b) the meat is considered to be fit for human consumption;

c) the meat was cut up in a cutting-up establishment;

d) the meat satisfies the following requirements[2]:

Official stamp:

Issued at..... on .....
Name and address of Veterinarian .....
.....
.....

Signature: .....

1 Delete where not applicable.

2 These conditions are agreed between the Veterinary Services of the importing and exporting countries in accordance with the options provided in this Terrestrial Code.

APPENDIX 4.2.2.

MODEL INTERNATIONAL VETERINARY CERTIFICATE FOR PRODUCTS OF ANIMAL ORIGIN DESTINED FOR USE IN ANIMAL FEEDING, OR FOR AGRICULTURAL OR INDUSTRIAL OR PHARMACEUTICAL OR SURGICAL USE

MODEL INTERNATIONAL VETERINARY CERTIFICATE FOR PRODUCTS OF ANIMAL ORIGIN DESTINED FOR USE IN ANIMAL FEEDING, OR FOR AGRICULTURAL OR INDUSTRIAL OR PHARMACEUTICAL OR SURGICAL USE

Exporting country: .....
Ministry of: .....
Department: .....
Province or District, etc.: .....

I. Identification of the products

Type of products: .....
Number of packages: .....
Identification marks: .....
Net weight: .....

II. Origin of the products

Address of the establishment of origin: .....
.....
.....

III. Destination of the products

The above mentionned products are being sent from (place of dispatch) .....
to (country and place of destination) .....
Nature and identification of means of transport: .....
.....
Name and address of exporter: .....
.....
Name and address of consignee: .....
.....
.....

IV. Sanitary information

The undersigned Official Veterinarian certifies that the products described above satisfy the following requirements[1]:

Official stamp:

Issued at..... on .....
Name and address of Veterinarian .....
.....
.....

Signature: .....

1 These conditions are agreed between the Veterinary Services of the importing and exporting countries in accordance with the options provided in this Terrestrial Code.

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