Terrestrial Animal Health Code

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 12th edition incorporates the modifications to the Terrestrial Code agreed by the OIE International Committee during the 71st General Session in May 2003. These include revised chapters on the following subjects: general definitions, evaluation of Veterinary Services, animal disease notification, foot and mouth disease, classical swine fever, Rift Valley fever, scrapie, bovine spongiform encephalopathy, leptospirosis, bovine anaplasmosis, bovine babesiosis, theileriosis, and embryos. As well, a new chapter on ‘judgement of equivalence’ (Chapter 1.3.7.) and new appendices on ‘antimicrobial resistance’ (Section 3.9.) and surveillance for scrapie (Appendix 3.8.5.) and for foot and mouth disease (Appendix 3.8.6.) were adopted and have been added to this edition of the Terrestrial Code.

The development of these standards, guidelines and recommendations is the result of the continuous work of one of the OIE’s Specialist Commissions, the International Animal Health Code Commission (now called the OIE Terrestrial Animal Health Standards Commission [in brief ‘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 of the Terrestrial Code or revise existing chapters in 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 Code Commission collaborates closely with the OIE Aquatic Animal Health Standards Commission on issues needing a harmonised approach, and with the Biological Standards and Scientific Commissions to ensure the 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 Users' 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 International Animal Health Code Commission for their hard work over the past three years, Delegates and the members of Ad hoc Groups and other Commissions for their expert advice, and also the staff of OIE Headquarters for their dedication in producing this 12th edition of the Terrestrial Code.

Dr B. Vallat  
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June 2003

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**A. General remarks**

1. The purpose of this guide is to assist the Veterinary Administrations of OIE Member Countries to use the Terrestrial Animal Health Code (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 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 authorize 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 following articles deal with each of the 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 Administration 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. The complete text of the Terrestrial Code is available on the OIE Web site (http://www.oie.int).

**B. Disease Information, the Bulletin and World Animal Health**

These three OIE publications inform Veterinary Administrations 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 should 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 or zone, 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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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:

**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 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.

**Apiary**

means a collection of hives situated in the same bee–keeping establishment.

**Approved**

means approved, accredited or registered by the Veterinary Administration for export purposes.

**Approved abattoir**

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

**Area of direct transit**

means a special area established in a transit country, approved by the relevant Veterinary Administration 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 for the production of semen approved by the Veterinary Administration and used exclusively for donor animals which meet the conditions set out 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 within, and along the border of, an infected zone using measures based on the epidemiology of the disease under consideration to prevent spread of the causative pathogenic agent into a free country or a free zone. These measures may include, but are not limited to, vaccination.

Vaccinated animals must be recognisable by a specific permanent mark. The vaccines used must meet standards defined in the Terrestrial Manual.

The buffer zone should have an intensified degree of disease surveillance and control.

**Case**
means an individual animal infected by a pathogenic agent listed by the OIE.

**Central Bureau**
means the Permanent Secretariat of the Office International des Epizooties 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 premises or place in which animals for breeding, rearing or slaughter coming from different establishments or markets are collected together and which is:

a) under the control of an Official Veterinarian;

b) not located in an infected zone;

c) used only for animals for breeding, rearing or slaughter which meet the conditions of the Terrestrial Code;

d) disinfected before and after use.

**Collection centre**
means a facility approved by the Veterinary Administration 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 an autonomous epidemiological entity defined on the basis of either geography (zone) or management (enterprise) for the purpose of international trade.

**Day-old birds**
means birds aged not more than 72 hours after hatching.

**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.

Enterprise
means one or more establishments with an integrated system of animal management forming an autonomous epidemiological entity.

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.
Chapter 1.1.1. – General definitions

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.

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 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.

International trade
means importation, exportation and transit of commodities.

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 Administration approves and monitors such laboratories with regard to the diagnostic tests required for international trade.

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

List A
means the List of transmissible diseases which have the potential for very serious and rapid spread, irrespective of national borders, which are of serious socio-economic or public health consequence and which are of major importance in the international trade of animals and animal products. Reports are submitted to the OIE as often as necessary to comply with Articles 1.1.3.2. and 1.1.3.3. Diseases in List A are set out in Article 1.1.2.1. of the Terrestrial Code.

List B
means the List of transmissible diseases which are considered to be of socio-economic and/or public health importance within countries and which are significant in the international trade of animals and animal products. Reports are normally submitted once a year, although more frequent reporting may in some cases be necessary to comply with Articles 1.1.3.2. and 1.1.3.3. Diseases in List B are set out in Articles 1.1.2.2. to 1.1.2.10. of the Terrestrial Code.
Chapter 1.1.1. – General definitions

**Market**
means a market which is:

a) placed under the control of an *Official Veterinarian*;
b) not located in an *infected zone*;
c) used only for *animals for breeding, rearing or slaughter* which conform with the conditions provided in the *Terrestrial Code*;
d) disinfected before and after use.

**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*.

**Notifiable disease**
means a disease listed by the *Veterinary Administration*, and that, as soon as detected or suspected, must be brought to the attention of the *Veterinary Authority*.

**Notification**
means the procedure by which:

a) the *Veterinary Administration* informs the *Central Bureau*,
b) the *Central Bureau* informs *Veterinary Administrations*,

of the suspicion or confirmation of an *outbreak* of disease, according to the provisions of Chapter 1.1.3. of the *Terrestrial Code*.

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

**Official Veterinarian**
means a veterinarian authorised by the *Veterinary Administration* of the country to perform animal health and/or public health inspections of *commodities* and, when appropriate, perform certification in conformity with the provisions of Section 1.2. of the *Terrestrial Code*. 

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Official veterinary control
means that the Veterinary Authority 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
means an occurrence of one of the diseases in OIE List A or List B in an agricultural establishment, breeding establishment or premises, including all buildings and all adjoining premises, where animals are present.

Where it cannot be defined in this way, the outbreak shall be considered as occurring in the part of the territory in which, taking local conditions into account, it cannot be guaranteed that both susceptible and non-susceptible animals have had no direct contact with affected or suspected cases in that area.

For example, in the case of certain parts of Africa, an outbreak means the occurrence of the disease within a sixteenth square degree; the occurrence is still referred to as an outbreak even though the disease may occur in several places within the same sixteenth square degree.

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.

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.

Products of animal origin intended for human consumption
means fresh meat, meat products, gelatin, eggs, egg products, milk, milk products and honey when intended for human consumption.

Products of animal origin intended for agricultural or industrial use
means products of animal origin, except those intended for food for human consumption, pharmaceutical or surgical purposes and animal feeding.

Products of animal origin intended for pharmaceutical or surgical use
means animal organs, tissues and organic fluids to be used in the preparation of pharmaceutical products or of surgical devices.

Products of animal origin intended for use in animal feeding

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'.

Quarantine station
means a facility under the control of the Veterinary Authority where a group of animals is maintained in isolation, with no direct or indirect contact with other animals, in order to undergo observation for a specified length of time and, if appropriate, testing and treatment.

Specific surveillance
means the surveillance targeted to a specific disease or infection.
Stamping–out policy
means carrying out under the authority of the Veterinary Administration, 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.

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.

Vehicle
means any method of transport by land, air or water.

Veterinary Administration
means the governmental Veterinary Service having authority in the whole country for implementing the animal health measures and international veterinary certification process which the OIE recommends, and supervising or auditing their application.

Veterinary Authority
means a Veterinary Service, under the authority of the Veterinary Administration, which is directly responsible for the application of animal health measures in a specified area of the country. It may also have responsibility for the issuing or the supervision of the issuing of international veterinary certificates in that area.

Veterinary Services
the Veterinary Services comprise the Veterinary Administration and all the Veterinary Authorities.

Zone
is a clearly defined part of the territory of a country with a distinct animal health status. The following types of zones are recognised: free zone, infected zone, surveillance zone and buffer zone.
CHAPTER 1.1.2.

OIE LIST A AND LIST B DISEASES

Article 1.1.2.1.

The following diseases are included in *List A*:

- Foot and mouth disease
- Vesicular stomatitis
- Swine vesicular disease
- Rinderpest
- Peste des petits ruminants
- Contagious bovine pleuropneumonia
- Lumpy skin disease
- Rift Valley fever
- Bluetongue
- Sheep pox and goat pox
- African horse sickness
- African swine fever
- Classical swine fever
- Highly pathogenic avian influenza
- Newcastle disease.

Article 1.1.2.2.

The following diseases are included in *List B*, within the category of multiple species diseases:

- Anthrax
- Aujeszky's disease
- Echinococcosis/hydatidosis
- Heartwater
- Leptospirosis
- Q fever
- Rabies
- Paratuberculosis
- New world screwworm (*Cochliomyia hominivorax*)
- Old world screwworm (*Chrysomya bezziana*)
- Trichinellosis.

Article 1.1.2.3.

The following diseases are included in *List B*, within the category of cattle diseases:

- Bovine anaplasmosis
- Bovine babesiosis
- Bovine brucellosis
- Bovine genital campylobacteriosis
- Bovine tuberculosis
- Bovine cysticercosis
- Dermatophilosis
- Enzootic bovine leukosis
Chapter 1.1.2. – OIE List A and List B diseases

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Article 1.1.2.4.

The following diseases are included in List B, within the category of sheep and goat diseases:

- Ovine epididymitis (*Brucella ovis*)
- Caprine and ovine brucellosis (excluding *B. ovis*)
- Caprine arthritis/encephalitis
- Contagious agalactia
- Contagious caprine pleuropneumonia
- Enzootic abortion of ewes (ovine chlamydiosis)
- Ovine pulmonary adenomatosis
- Nairobi sheep disease
- Salmonellosis (*S. abortusovis*)
- Scrapie
- Maedi–visna.

Article 1.1.2.5.

The following diseases are included in List B, within the category of equine diseases:

- Contagious equine metritis
- Dourine
- Epizootic lymphangitis
- Equine encephalomyelitis (Eastern and Western)
- Equine infectious anaemia
- Equine influenza
- Equine piroplasmosis
- Equine rhinopneumonitis
- Glanders
- Horse pox
- Equine viral arteritis
- Japanese encephalitis
- Horse mange
- Surra (*Trypanosoma evansi*)
- Venezuelan equine encephalomyelitis.

Article 1.1.2.6.

The following diseases are included in List B, within the category of swine diseases:

- Atrophic rhinitis of swine
- Porcine cysticercosis
- Porcine brucellosis
- Transmissible gastroenteritis
- Enterovirus encephalomyelitis
- Porcine reproductive and respiratory syndrome.
Article 1.1.2.7.

The following diseases are included in List B, within the category of avian diseases:

- Avian infectious bronchitis
- Avian infectious laryngotracheitis
- Avian tuberculosis
- Duck virus hepatitis
- Duck virus enteritis
- Fowl cholera
- Fowl pox
- Fowl typhoid
- Infectious bursal disease (Gumboro disease)
- Marek's disease
- Avian mycoplasmosis (M. gallisepticum)
- Avian chlamydiosis
- Pullorum disease.

Article 1.1.2.8.

The following diseases are included in List B, within the category of lagomorph diseases:

- Myxomatosis
- Tularemia
- Rabbit haemorrhagic disease.

Article 1.1.2.9.

The following diseases are included in List B, within the category of bee diseases:

- Acariosis of bees
- American foulbrood
- European foulbrood
- Nosemosis of bees
- Varroosis.

Article 1.1.2.10.

The following disease is included in List B, within the category of other diseases:

- Leishmaniosis.
CHAPTER 1.1.3.

NOTIFICATION AND EPIDEMIOLOGICAL INFORMATION

Article 1.1.3.1.

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

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

Article 1.1.3.2.

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 1.1.3.3.

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 1.1.3.3., 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 1.1.3.3.

Veterinary Administrations shall send to the Central Bureau:

1. notification by telegram, fax or e-mail, within 24 hours, of any of the following events:
   a) for diseases listed by the OIE, the suspected or (under study) confirmed first occurrence or re-occurrence of a disease, if the country or zone of the country was previously considered to be free from that particular disease;
   b) for diseases listed by the OIE, evidence of changes in the epidemiology of a disease (including host range, pathogenicity, strain) if this represents important new information of epidemiological significance to other countries, in particular if a disease may have a zoonotic impact;
   c) for diseases not listed by the OIE, if there is information of exceptional epidemiological significance to other countries, for example if a disease may be a zoonosis;

in deciding whether findings justify immediate notification, countries must ensure that they comply with the obligations of Section 1.2. (especially Article 1.2.1.3.) of the Terrestrial Code, to report developments which may have implications for international trade;
Chapter 1.1.3. – Notification and epidemiological information

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 disease has been eradicated or the situation has become sufficiently stable that monthly reporting under point 3 will satisfy the obligation of the country to the OIE;

3. monthly reports on the absence or presence, and evolution of diseases listed by the OIE and information of epidemiological significance to other countries;

4. annual reports on all diseases listed by the OIE and any other information of epidemiological significance to other countries.

Article 1.1.3.4.

1. The Veterinary Administration 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 2.1. 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 Administration of a country which sets up one or several free zones shall inform the OIE giving the 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 1.1.3.5.

1. The Central Bureau shall send by telegram, fax, e–mail or Disease Information to the Veterinary Administrations concerned, all notifications received as provided in Articles 1.1.3.2. to 1.1.3.4.

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 1.1.3.6.

All telegrams or faxes sent by Veterinary Administrations in pursuance of Articles 1.1.3.3. and 1.1.3.5. 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 Administrations* 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 Administrations* 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 Administrations* involved.

When Members of a *Veterinary Administration* wish to visit another country for matters of professional interest to the *Veterinary Administration* 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 transmission by the Veterinary Administration of certificates or the communication of import requirements to persons other than the Veterinary Administration of another country, necessitates that copies of these documents are also sent to the Veterinary Administration.

This important procedure avoids delays and difficulties which may arise between traders and Veterinary Administrations when the authenticity of the certificates or permits is not established.

This information is usually the responsibility of Veterinary Administrations. However, it can be the responsibility of Veterinary Authorities at the place of origin of the animals when it is agreed that the issue of certificates does not require the approval of the Veterinary Administration.

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 Administrations 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 Administration 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 the Administration 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 Administration 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 Administration 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 Administration 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 Administration 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 Administration of the exporting country to the Veterinary Administration 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 Administration 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.

IMPORT 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

HAZARD IDENTIFICATION → RISK ASSESSMENT → RISK MANAGEMENT

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 the 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.
Chapter 1.3.1. – General considerations on risk analysis

The process of import risk analysis usually needs to take into consideration the results of an evaluation of Veterinary Services, zoning and regionalisation 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.

List of terms specific to Section 1.3.

Acceptable risk: Risk level judged by Member Countries to be compatible with the protection of animal and public health within their country.

Consequence assessment: See point 3 of Article 1.3.2.4.

Exposure assessment: See point 2 of Article 1.3.2.4.

Hazard: Any pathogenic agent that could produce adverse consequences on the importation of a commodity.

Hazard identification: The process of identifying the pathogenic agents which could potentially be introduced in the commodity considered for importation.

Implementation: See point 3 of Article 1.3.2.6.

Monitoring: See point 4 of Article 1.3.2.6.

Option evaluation: See point 2 of Article 1.3.2.6.

Qualitative risk assessment: 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’.

Quantitative risk assessment: An assessment where the outputs of the risk assessment are expressed numerically.

Release assessment: See point 1 of Article 1.3.2.4.

Review: See point 4 of Article 1.3.2.6.

Risk: 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.
Risk analysis: The process composed of hazard identification, risk assessment, risk management and risk communication.

Risk assessment: 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 (see Articles 1.3.2.3. and 1.3.2.4.).

Risk communication: Risk communication is the interactive exchange of information on risk among risk assessors, risk managers and other interested parties (see Article 1.3.2.7.).

Risk estimation: See point 4 of Article 1.3.2.4.

Risk evaluation: See point 1 of Article 1.3.2.6.

Risk management: The process of identifying, selecting and implementing measures that can be applied to reduce the level of risk (see Articles 1.3.2.5. and 1.3.2.6.).

Sanitary measure: Measures such as those described in each Chapter of the Terrestrial Code which are used for risk reduction and are appropriate for particular diseases.

Sensitivity analysis: The process of examining the impact of the variation in individual model inputs on the model outputs in a quantitative risk assessment.

Transparency: 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.

Uncertainty: 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.

Variability: 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.

Article 1.3.1.4.

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.
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 regionalisation 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 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 management is the process of deciding upon and implementing measures to achieve the Member Country's appropriate level of protection, whilst at the same time ensuring that negative effects on trade are 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 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. The remaining factors of quality are described in Part 1 (notification, principles of certification, etc.) and the document entitled “Guidelines for the evaluation of Veterinary Services” included in Chapter 1.3.4.

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

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 officials 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 shall be taken to ensure that Veterinary Services staff are free from any commercial, financial, hierarchical, political or other pressures which might affect their judgement or decisions.

3. Impartiality
   
   The Veterinary Services shall 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 shall guarantee that the work of each of their officials is of a consistently high level of integrity. Any fraud, corruption or falsification shall be identified and corrected.

5. Objectivity
   
   The Veterinary Services shall 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 an appropriate legislation and 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. In particular, they shall 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* shall have at their disposal effective systems for animal disease surveillance and 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 shall at all times endeavour to improve their performance in terms of animal health information systems and animal disease control.

The *Veterinary Services* shall 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 shall be described. These job descriptions shall include the requirements for education, training, technical knowledge and experience.

7. **Quality policy**

The *Veterinary Services* shall define and document their policy and objectives for, and commitment to, quality, and shall 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* shall develop and document appropriate procedures and standards for the implementation and management of animal health measures and international veterinary certification activities. These procedures and standards may for example relate to:

- a) programming and management of activities, including international veterinary certification activities;
- b) prevention and control 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* shall comply with these standards when applying animal health measures and when issuing *international veterinary certificates*. 
9. **Information, complaints and appeals**

The *Veterinary Administration* shall undertake to reply to legitimate requests from *Veterinary Administrations* 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 shall be maintained of all complaints and appeals and of the relevant action taken by the *Veterinary Services*.

10. **Documentation**

The *Veterinary Services* shall 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 Member Country can request the Director General of the OIE to arrange for an expert or experts to assist in the process.

12. **Communication**

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

**Article 1.3.3.3.**

For the purposes of the *Terrestrial Code*, every Member Country shall 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. of the *Terrestrial Code*.

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* shall 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 Articles 1.3.3.1. and 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.
Chapter 1.3.3. – Evaluation of Veterinary Services

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 1.3.1.4.
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. of the Terrestrial Code.

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 or self–assessment– and for periodic re–evaluation. 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.

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. Article 1.3.4.13. outlines appropriate information requirements for:
   - self-evaluation by national Veterinary Services which perceive 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.

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 Administration alone speaks for the country as far as official international dialogue is concerned. This is also particularly important to cases where zoning and regionalisation are being applied. The responsibilities of the national Veterinary Administration and all Veterinary Authorities in that country should be made clear in the process of evaluation of Veterinary Services.

6. A Veterinary Authority is defined in Chapter 1.1.1. of the Terrestrial Code. As some countries have some official veterinary authority roles 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 national Veterinary Services 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 national Veterinary Services have 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 quality of organisational and functional standards which apply to Veterinary Services should also apply to the services of these other 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 graduate veterinarians. It should also include other qualified professional officers, administrative officials and technical support staff. This does not exclude the possibility of employing, in addition, part–time veterinary and para–veterinary staff and private sector veterinarians. It is essential that all the above categories of staff 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 staff 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 veterinary and animal health technical assistants 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 technical assistant staff 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 practitioners 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 animal health technical assistants) 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 1.3.4.13. 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 national Veterinary Services, to permit reporting of changes in national disease status consistent with OIE recommendations and to allow bilateral contact on urgent matters with counterpart Veterinary Services 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 animal 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.
Functional capabilities and legislative support

1. Animal health and veterinary public health

The Veterinary Services should be able to demonstrate that they have 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 including registration of holdings and animal identification, 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 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. Information on the veterinary public health legislation covering the production of products of animal origin for national consumption may also be considered in the evaluation.

2. Export/import inspection

National Veterinary Services 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 Services 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 Authorities 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 national Veterinary Services 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 animal or 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 national Veterinary Services should be able to demonstrate effective responsibility for the veterinary public health programmes relating to the production and processing of animal products, especially for export. If the national Veterinary Services do 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 national Veterinary Services can provide guarantees of responsibility for and effective control of the sanitary status of animal products prior to export, especially meat and meat products throughout the slaughter, processing, transport and storage periods.
2. **Zoonoses**

Within the structure of Veterinary Services, there should be appropriately qualified staff 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.

4. **Veterinary medicines**

It should be acknowledged that primary control over veterinary medicinal products may not rest with the veterinary authorities in some countries, owing to differences between governments in the division of legislative responsibilities. However, for the purpose of evaluation, the Veterinary Services should be able to demonstrate the existence of effective controls (including nationwide consistency of application) over the registration, supply and use of veterinary medicines, biologicals and diagnostic reagents. 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 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 fresh meat or dairy product establishments and applies this in animal health control should be favourably noted. Such programmes should be integrated within a national epizootiological 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.
Chapter 1.3.4. – Guidelines for the evaluation of Veterinary Services

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 1.3.4.13. 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 document 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.

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 Services

      Organisational chart including numbers, positions and numbers of vacancies.

   b) Sub-national Veterinary Services

      Organisational charts including numbers, positions and numbers 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 in the country who are graduates from internationally
           recognised veterinary schools which are registered accordingly in the WHO/FAO
           World Directory of Veterinary Schools;

         – graduate veterinarians not included above.

      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.)

      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;
         – privately-employed 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;
         – privately-employed 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.

b) Graduate staff (non–veterinarian)
   Details to be provided by category (including biologists, biometricians, economists, engineers, lawyers, other science graduates and others) on numbers within national Veterinary Services and available to national Veterinary Services.

c) Technical assistants employed by the Veterinary Services
   i) Animal health:
      – 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:
      – Numbers 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 staff
   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) Additional information and/or comments.

3. Financial management information
   a) Total budgetary allocations to the Veterinary Services for the current and past two fiscal years:
      i) for the national Veterinary Services;
      ii) for each of any sub–national veterinary authorities;
      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. Functional capabilities and legislative support

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 and other).

– Estimate of total annual slaughterings which occur but are not recorded under official
statistics.
Chapter 1.3.4. – Guidelines for the evaluation of Veterinary Services

- 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 national Veterinary Services:
  - 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 national Veterinary Services do 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 Services 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 national Veterinary Services do 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 national Veterinary Services 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 national Veterinary Services 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 national Veterinary Services
   
   Copies of official annual reports of the national (sub-national) Veterinary Services.

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 REGIONALISATION

Article 1.3.5.1.

‘Zoning’ is a procedure implemented by a country under the provisions of this Chapter with a view to defining geographical areas of different animal health status within its territory for the purpose of international trade, and in accordance with the recommendations stipulated in the relevant Chapters in the Terrestrial Code.

Article 1.3.5.2.

The requirements necessary to preserve the special health status of a zone must be appropriate to the particular disease. The requirements will differ and size, location and delineation of a zone will depend on the epidemiology of the disease, environmental factors, and surveillance and control measures applicable. The extent of zones and their limits should be established by the Veterinary Administration on the basis of natural, artificial or legal boundaries and made public through official channels.

Thus defined, the zones constitute the relevant geographical units for the application of the recommendations in Part 2 of the Terrestrial Code.

Article 1.3.5.3.

When an exporting country has defined a zone within its territory in respect of one or more of the diseases covered by the Terrestrial Code, it needs to implement the measures stipulated in the Terrestrial Code for setting up and maintaining such a zone.

An importing country should recognise the existence of this zone and accept the application of the appropriate measures recommended in the Terrestrial Code corresponding to the animal health status of the zone with regard to the importation, or transit through its territory, of commodities from the zone.
CHAPTER 1.3.6.  
SURVEILLANCE AND MONITORING OF ANIMAL HEALTH

Article 1.3.6.1. 

Introduction 

The ability of the Veterinary Services to substantiate elements of the reports on the animal health situation of their country by surveillance data, results of monitoring programmes and details of disease history is highly relevant to the procedures of risk analysis. However, if the risk assessment conducted on a commodity demonstrates an insignificant risk, this may not be necessary.

The science of epidemiology provides the foundation for surveillance and monitoring. A national epidemiological system should incorporate agent surveillance and/or monitoring, description of host population characteristics, and environmental assessment. An effective veterinary infrastructure is necessary to support this epidemiological system.

Surveillance means the continuous investigation of a given population to detect the occurrence of disease for control purposes, which may involve testing of a part of the population.

Monitoring constitutes on-going programmes directed at the detection of changes in the prevalence of disease in a given population and in its environment.

The following Articles represent a standardised approach to meet the demand for scientifically based import trade requirements.

Article 1.3.6.2. 

Agent surveillance and monitoring

Agent surveillance and monitoring may involve the clinical or pathological examination of animals, the identification of pathogens, and the detection of immunological or other evidence of previous exposure of animals to pathogens.

1. Early investigation of clinical disease

Investigation of the suspicion of cases of animal disease is one of the most important means of agent surveillance. Investigations may focus on exotic or new and emerging diseases within the country.

2. Agent detection and disease prevalence

A complete epidemiological system may also require the screening of animals for List A and List B diseases having a major economic impact on trade in animals and animal products, as appropriate to the animal health situation of the country.

Depending on the diseases present and the priorities with regard to export, components of agent screening may include the following active and passive surveillance methods:

a) scientifically based surveys;

b) routine sampling and testing of animals on the farm, at market or at slaughter;
c) an organised sentinel programme, sampling animals, herds, flocks, or vectors, and/or collecting diagnostic results from veterinary practices;

d) the banking of biological specimens for retrospective studies;

e) analysis of veterinary diagnostic laboratory records.

Article 1.3.6.3.

Description of host population characteristics

Description of host population characteristics concentrates on the factors in the national animal population which may influence or be associated with disease occurrence. These host factors may include:

1. intrinsic factors such as genetics, animal demographics (age, sex, breed distribution) and physiological state (immature, sexually mature but un–bred, gestating, geriatric);

2. extrinsic factors such as marketing and movement patterns, domestic/wild animal interactions, animal use (draft, meat production, milk or egg production, pets) and management factors (husbandry system, preventive medical practices).

The linkage of demographic data to agent surveillance data is critical for predicting the potential spread of diseases or identifying optimal control measures.

Article 1.3.6.4.

Assessment of environmental factors

Data on environmental assessment include physical factors, biological factors, and economic and structural characteristics of ancillary industries.

Some examples of these data are as follows:

1. Physical factors

   Air and water quality monitoring, topographical and soil distribution maps, and meteorological data are routinely collected in many countries by a variety of government agencies. Additional data may be available from university researchers or private industry.

2. Biological factors

   Vector population distributions may be available from specialists on invertebrates. Vector competence data describes the ability of specific vectors to serve as biological vectors for specific diseases.

3. Ancillary industry characteristics

   Data on feed and slaughter industries, on the biologics and pharmaceutical industries, and on marketing and distribution patterns help define the intervention options available in each country.

This information allows estimation of trends for the future, geographic shifts in animal production and processing, and more accurate assessment of disease risk and characterisation and delineation of zones. Much of the required data may be obtained through governmental or non–governmental sources.
CHAPTER 1.3.7.

GUIDELINES FOR REACHING A JUDGEMENT OF EQUIVALENCE OF SANITARY MEASURES

Article 1.3.7.1.

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 and 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 1.3.7.2.

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 so-called 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. 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 are encouraged to base their sanitary measures on OIE standards, guidelines and recommendations to the extent possible.

It is essential to apply the discipline of risk assessment (the primary scientific component of risk analysis) to the extent practicable in establishing the basis for a judgement of equivalence.

Article 1.3.7.3.

Definitions

For the purposes of these guidelines, the following definitions apply:

**Appropriate level of protection (ALOP) (acceptable risk):** The level of protection deemed appropriate by the country establishing a sanitary measure to protect human or animal life or health within its territory.

**Equivalence of sanitary measures:** 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.

**Hazard:** 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.

**Risk:** 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:** The process composed of hazard identification, risk assessment, risk management and risk communication.

**Risk assessment:** 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.

**Sanitary measure:** 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 WTO SPS Agreement.]

Article 1.3.7.4.

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 a 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.

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**Article 1.3.7.5.**

**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) there are benefits in applying the concept of equivalence to animal health and production systems;

5) countries should, upon request, enter into consultations with the aim of facilitating a judgement of equivalence;

6) any sanitary measure or combination of sanitary measures can be proposed for judgement of equivalence;

7) 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;
8) 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;

9) the exporting country should present a submission for equivalence in a form that facilitates judgement by the importing country;

10) the importing country should evaluate submissions for equivalence in a timely, consistent, transparent and objective manner, and according to appropriate risk assessment principles;

11) the importing country should take into account any knowledge of and prior experience with the Veterinary Administration or other competent authority of the exporting country;

12) 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;

13) the importing country should be the sole determinant of equivalence, but should provide to the exporting country a full explanation for its judgement;

14) to facilitate a judgement of equivalence, Member Countries should base their sanitary measures on relevant OIE standards;

15) to allow the judgement of equivalence to be reassessed if necessary, the importing and exporting countries should keep each other informed of significant changes to infrastructure, health status or programmes which may bear on the judgement of equivalence; and

16) 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 1.3.7.6.

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 and exporting countries 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.
RECOMMENDATIONS FOR TRANSPORT

Article 1.4.1.1.

General arrangements

1. Vehicles (or containers) used for the transport of animals shall be designed, constructed and fitted in such a way as to withstand the weight of the animals and to ensure their safety and welfare during transportation. Vehicles shall be thoroughly cleansed and disinfected before use. There shall be adequate ventilation which can be adjusted to meet possible variations in climate.

2. Animals in transit shall be provided with adequate space and, unless special provisions require to the contrary, room to lie down. They shall be segregated where appropriate, according to species, and uncastrated mature male animals shall be segregated from females and from each other. Horned cattle shall be segregated from animals without horns.

3. Vehicles (or containers) in which animals are confined during carriage by sea or by air shall be secured to the structure of the ship or aircraft. They shall be stowed in such a way as to ensure that there is no interference with ventilation and to allow easy access to the animals by the attendant.

4. Animals that are being transported shall be offered food and water at suitable intervals.

5. These arrangements should be compulsory in all countries, either by legislative or regulatory texts, and should be compiled with their methods of application in a manual available to all concerned.

Article 1.4.1.2.

Particular arrangements for containers

1. The construction of containers intended for transportation of animals shall be such that the release of excreta, bedding, etc. is prevented when they are opened.

2. In the case of transportation of animal products, provision shall be made to enable preliminary observation of the contents (for example, a window or hatch).

3. Containers in transit in which there are animal products shall not be opened unless the Veterinary Authorities of the transit country consider it necessary that they should be opened and then only if subject to precautions being taken to avoid any risk of contamination.

4. Containers shall be loaded only with one kind of product or, at least, with products not likely to be contaminated by one another.

5. It rests with each country to decide on the facilities it intends to give to the transit and importation of animals and animal products in containers.
Chapter 1.4.1. – Recommendations for transport

Article 1.4.1.3.

Particular arrangements for the transport of animals by air

1. The space allowed for the transport of animals in aircraft or containers should be determined by taking the following into consideration:
   a) the available floor and air space for each animal;
   b) the height and other dimensions of the container and aircraft;
   c) the ventilation capacity of the aircraft and containers whilst on the ground and during all stages of the flight.

   With regard to cattle, pigs and sheep, the space reserved for each animal in aircraft or containers which have been fitted for the separate transportation of several animals or for the transportation of groups of animals, should comply with the conditions specified in Appendix 3.7.3.

2. The Regulations for live animals of the International Air Transport Association (IATA) (which are approved by the OIE) may be adopted if they do not conflict with national legislative arrangements. (Copies of these Regulations are obtainable from the IATA in Montreal, Canada.)

Article 1.4.1.4.

Disinfection and other measures

1. Disinfection, disinfestation and other necessary work should be carried out in order to:
   a) avoid all unjustified inconvenience and to prevent damage or injury to the health of people and animals;
   b) avoid the risk of fire;
   c) avoid damage to the structure of the vehicle or its appliances;
   d) prevent, as far as possible, any damage to animal products, semen, embryos/ova, hatching eggs, brood–combs of bees and also to feedstuffs for the embarked livestock and baggage of the attendant.

2. On request, the Veterinary Authority shall provide those responsible for transportation with a certificate indicating the measures which have been applied to all vehicles, the parts of the vehicle which have been treated, the methods used and the reasons which led to the application of the measures.

   In the case of aircraft, the certificate may be replaced, on request, by an entry in the General Declaration of the aircraft.

3. Similarly, the Veterinary Authority shall issue on request:
   a) a certificate showing the date of arrival and departure of the animals;
   b) a certificate to the shipper or exporter, the consignee and the transporter or their representatives, indicating the measures applied.

Article 1.4.1.5.

The Veterinary Authority shall take all practical measures to prevent the discharge of any infective material into internal or territorial waters.
CHAPTER 1.4.2.

ANIMAL HEALTH MEASURES APPLICABLE BEFORE AND AT DEPARTURE

Article 1.4.2.1.

1. Countries should only authorise the exportation from their territory of animals for breeding, rearing or slaughter which are correctly identified and which come from an establishment free from List A diseases and not situated in an infected zone.

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 List A diseases or any other infectious disease 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, rearing or 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 and exporting countries.

Article 1.4.2.2.

Countries should only undertake the exportation from its territory of:

a) semen,

b) embryos/ova,

c) hatching eggs,

from artificial insemination centres, collection centres or farms which are officially controlled by the Veterinary Authority of the district of origin, free from List A diseases and not situated in an infected zone (infected with one of the diseases to which the animals of the corresponding species are susceptible).

Article 1.4.2.3.

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 List A disease 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 1.4.2.4.

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.
Chapter 1.4.2. – Animal health measures applicable before and at departure

Article 1.4.2.5.

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 List A disease or with any other infectious disease;
   b) avoid entry into the vehicle of possible vectors or causal agents of infection.

Article 1.4.2.6.

1. Countries should only authorise the exportation 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 1.4.3.

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 1.4.3.1.

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 Administration and 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 Administration 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 1.4.3.2.

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.
Chapter 1.4.3. – Animal health measures applicable during transit

Article 1.4.3.3.

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 both the Veterinary Administration and 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 Authorities of the transit country may order their return to the exporting country.

If they cannot be returned, the Veterinary Administration 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 1.4.3.4.

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 Administrations, especially to prevent the risk of introduction of diseases transmitted by insects.

Article 1.4.3.5.

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 1.4.4.

BORDER POSTS AND QUARANTINE STATIONS IN THE IMPORTING COUNTRY

Article 1.4.4.1.

1. Countries and their Veterinary Administrations 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 1.4.4.2.

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 1.4.4.3.

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 Administrations, especially to prevent the risk of introducing diseases transmitted by insects.

Article 1.4.4.4.

Each Veterinary Administration, 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 1.4.5.1. to 1.4.5.4.;

c) a list of airports in its territory which are provided with an area of direct transit.
CHAPTER 1.4.5.

ANIMAL HEALTH MEASURES APPLICABLE ON ARRIVAL

Article 1.4.5.1.

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 Administration 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 1.4.5.2.

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 Administration 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 1.4.5.3.

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 1.4.2.6.

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 Administration of the exporting country shall be informed immediately, thereby providing an opportunity for confirming the findings.

Article 1.4.5.4.

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 Administration 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 Authorities 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 Administration of the exporting country shall be informed immediately, thereby providing an opportunity for confirming the findings or correcting the certificate.

Article 1.4.5.5.

On the arrival at a border post of a vehicle transporting an animal or animals infected with any List A disease, 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 Administration 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 1.4.5.6.

On the arrival at a border post of a vehicle transporting an animal or animals suspected of being affected with any List A disease, the vehicle shall be considered as being contaminated, and the Veterinary Authority may apply the measures provided in Article 1.4.5.5.
Chapter 1.4.5. – Animal health measures applicable on arrival

Article 1.4.5.7.
The vehicle shall no longer be considered as contaminated when the measures prescribed by the Veterinary Authority in accordance with Article 1.4.5.5. have been carried out.
The vehicle may then be allowed to enter.

Article 1.4.5.8.
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 1.4.5.9.
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 disinfection immediately after landing, except when such disinfection was carried out immediately before departure or during the flight.
CHAPTER 1.4.6.
INTERNATIONAL TRANSFER AND LABORATORY CONTAINMENT OF ANIMAL PATHOGENS

Article 1.4.6.1.

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

Article 1.4.6.2.

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 1.4.6.7.) 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 1.4.6.3.

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 1.4.6.4.

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.
Chapter 1.4.6. – International transfer and laboratory containment of animal pathogens

Article 1.4.6.5.

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 1.4.6.6.

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

<table>
<thead>
<tr>
<th>REQUIREMENTS OF THE LABORATORY</th>
<th>CONTAINMENT GROUP</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2</td>
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<tr>
<td></td>
<td>3</td>
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<td></td>
<td>4</td>
</tr>
<tr>
<td><strong>A) Laboratory siting and structure</strong></td>
<td></td>
</tr>
<tr>
<td>1. Not next to known fire hazard</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
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<td></td>
<td>Yes</td>
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<tr>
<td>2. Workplace separated from other activities</td>
<td>Yes</td>
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<tr>
<td></td>
<td>Yes</td>
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<td></td>
<td>Yes</td>
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<tr>
<td>3. Personnel access limited</td>
<td>Yes</td>
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<td></td>
<td>Yes</td>
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<td></td>
<td>Yes</td>
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<tr>
<td>4. Protected against entry/exit of rodents and insects</td>
<td>Yes</td>
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<tr>
<td></td>
<td>Yes</td>
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<tr>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>5. Liquid effluent must be sterilised</td>
<td>Yes and monitored</td>
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<tr>
<td></td>
<td>Yes and monitored</td>
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<tr>
<td></td>
<td></td>
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<tr>
<td>6. Isolated by airlock. Continuous internal airflow</td>
<td>Yes</td>
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<td></td>
<td>Yes</td>
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<td></td>
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<tr>
<td>7. Input and extract air to be filtered using HEPA or equivalent</td>
<td>Single on extract</td>
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<td></td>
<td>Single for input, double for extract</td>
</tr>
<tr>
<td></td>
<td></td>
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<tr>
<td>8. Mechanical air supply system with fail-safe system</td>
<td>Yes</td>
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<td></td>
<td>Yes</td>
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<td></td>
<td></td>
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<tr>
<td>9. Laboratory sealable to permit fumigation</td>
<td>Yes</td>
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<tr>
<td></td>
<td>Yes</td>
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<td></td>
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<tr>
<td>10. Incinerator for disposal of carcasses and waste</td>
<td>Available</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
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<tr>
<td></td>
<td>Yes on site</td>
</tr>
<tr>
<td><strong>B) Laboratory facilities</strong></td>
<td></td>
</tr>
<tr>
<td>11. Class 1/2/3 exhaust protective cabinet available</td>
<td>Yes</td>
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<tr>
<td></td>
<td>Yes</td>
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<td></td>
<td>Yes</td>
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<tr>
<td>12. Direct access to autoclave</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Yes with double doors</td>
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<tr>
<td></td>
<td>Yes with double doors</td>
</tr>
<tr>
<td>13. Specified pathogens stored in laboratory</td>
<td>Yes</td>
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<tr>
<td></td>
<td>Yes</td>
</tr>
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<td></td>
<td>Yes</td>
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<tr>
<td>14. Double ended dunk tank required</td>
<td>Preferable</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>15. Protective clothing not worn outside laboratory</td>
<td>Yes</td>
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<tr>
<td></td>
<td>Yes</td>
</tr>
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<td></td>
<td>Yes</td>
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<tr>
<td>16. Showering required before exiting laboratory</td>
<td>Yes</td>
</tr>
<tr>
<td>17. Safety Officer responsible for containment</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
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<td></td>
<td>Yes</td>
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<tr>
<td>18. Staff receive special training in the requirements needed</td>
<td>Yes</td>
</tr>
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<td></td>
<td>Yes</td>
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<td></td>
<td>Yes</td>
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</tbody>
</table>
Table 1. *Guidance on the laboratory requirements for the different containment groups (cont.)*

<table>
<thead>
<tr>
<th>REQUIREMENTS OF THE LABORATORY</th>
<th>CONTAINMENT GROUP</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>C) Laboratory discipline</strong></td>
<td>2</td>
</tr>
<tr>
<td>19. Warning notices for containment area</td>
<td>Yes</td>
</tr>
<tr>
<td>20. Laboratory must be lockable</td>
<td>Yes</td>
</tr>
<tr>
<td>21. Authorised entry of personnel</td>
<td>Yes</td>
</tr>
<tr>
<td>22. On entering all clothing removed and clean clothes put on</td>
<td>Yes</td>
</tr>
<tr>
<td>23. On exiting all laboratory clothes removed, individual must wash and transfer to clean side</td>
<td>Yes</td>
</tr>
<tr>
<td>24. Individual must shower prior to transfer to clean side</td>
<td>Yes</td>
</tr>
<tr>
<td>25. All accidents reported</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>D) Handling of specimens</strong></td>
<td>3</td>
</tr>
<tr>
<td>26. Packaging requirements to be advised prior to submission</td>
<td>Yes</td>
</tr>
<tr>
<td>27. Incoming packages opened by trained staff</td>
<td>Yes</td>
</tr>
<tr>
<td>28. Movement of pathogens from an approved laboratory to another requires a licence</td>
<td>Yes</td>
</tr>
<tr>
<td>29. Standard Operating Procedures covering all areas must be available</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Article 1.4.6.7.

**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 1.4.6.6.

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.
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 microorganisms, 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 Administrations 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 Administration 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 Administration of the exporting country. Relevant data on risk analysis, changes in animal health situations and vaccinovigilance should be shared by Veterinary Administrations 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 'biologica ls' 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 Administrations should follow the Terrestrial Manual. The manufacturer or the Veterinary Administration 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 Administrations 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 1.4.6.
PART 2

RECOMMENDATIONS APPLICABLE TO SPECIFIC DISEASES
SECTION 2.1.
LIST A DISEASES

CHAPTER 2.1.1.
FOOT AND MOUTH DISEASE

Article 2.1.1.1.
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 RNA specific to one or more of the serotypes of FMDV has been identified in samples from 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, 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 with either epidemiological links to a confirmed or suspected outbreak of FMD, or showing clinical signs consistent with recent infection with FMDV.

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

Article 2.1.1.2.
FMD free country where vaccination is not practised

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,
and supply documented evidence that surveillance for both FMD and FMDV infection in accordance with Appendix 3.8.6. is in operation and that regulatory measures for the prevention and control of FMD have been implemented;

3) not have imported since the cessation of vaccination any animals vaccinated against FMD.
The country will be included in the list only after the submitted evidence has been accepted by the OIE.

Article 2.1.1.3.

FMD free country where vaccination is practised

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 infection for the past 12 months, with documented evidence that:
   a) surveillance for FMD and FMDV infection in accordance with Appendix 3.8.6. 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.

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 and provide evidence showing that FMDV infection has not occurred during that period.

Article 2.1.1.4.

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 still infected. The FMD free zone must be separated from the rest of the country and, if relevant, from neighbouring infected countries by a surveillance zone, or physical or geographical barriers, and animal health measures that effectively prevent the entry of the virus must 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:
   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 2.1.1.8.;
Chapter 2.1.1. - Foot and mouth disease

3) supply documented evidence that surveillance for both FMD and FMDV infection in accordance with Appendix 3.8.6. is in operation in the FMD free zone where vaccination is not practised;

4) describe in detail:
   a) regulatory measures for the prevention and control of both FMD and FMDV infection,
   b) the boundaries of the FMD free zone, and the surveillance zone,
   c) the system for preventing the entry of the virus into the FMDV free zone (in particular if the procedure described in Article 2.1.1.8. is implemented),

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

The 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.

Article 2.1.1.5.

FMD free zone where vaccination is practised

An FMD free zone where vaccination is practised can be established in an FMD free country where vaccination is not practised or in a country of which parts are still infected. Vaccination of zoo animals, animals belonging to rare species or breeds, or animals in research centres as a precaution for conservation purposes is an example of implementation of such a zone. The free zone where vaccination is practised is separated from the rest of the country and, if relevant, 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 must 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, where there has been no outbreak of FMD for the past 2 years and no evidence of FMDV infection for the past 12 months, with documented evidence that surveillance for FMD and FMDV in accordance with Appendix 3.8.6. is in operation;

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 infection,
   b) the boundaries of the FMD free zone where vaccination is practised and the buffer zone if applicable,
   c) the system for preventing the entry of the virus into the FMD free zone (in particular if the procedure described in Article 2.1.1.8. is implemented),

and supply evidence that these are properly implemented and supervised;

5) supply documented evidence that it has a system of intensive and frequent surveillance for FMD in the FMD free zone where vaccination is practised.

The 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.
Chapter 2.1.1. - Foot and mouth disease

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 or 12 months after the last outbreak, whichever is later, is required and evidence must be provided showing that FMDV infection has not occurred in the said zone during that period.

Article 2.1.1.6.

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 2.1.1.7.

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 3.8.6., 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 3.8.6., 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 3.8.6., 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.

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 3.8.6. are applied, provided that the serological surveillance based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of infection, or
   b) 12 months after the last case where a stamping-out policy is applied provided that surveillance demonstrates the absence of clinical cases, or
   c) 18 months after the last case where a stamping-out policy is not applied, but emergency vaccination and serological surveillance in accordance with Appendix 3.8.6. are applied, provided that the serological surveillance based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of infection.

Article 2.1.1.8.

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

Live animals from FMD susceptible species can only leave the infected zone if moved by mechanical transport to the nearest designated abattoir located in the buffer zone or the surveillance zone for immediate slaughter. In the absence of an abattoir in the buffer zone or the surveillance zone, live FMD susceptible animals can be transported to the nearest abattoir in a free zone for immediate 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;

6) all products obtained from the animals must be considered infected and treated in such a way as to destroy any residual virus in accordance with Appendix 3.6.2.;

7) vehicles and the abattoir must be subjected to thorough cleansing and disinfection immediately after use.

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 2.1.1.11.

**Article 2.1.1.9.**

When importing from FMD free countries or zones where vaccination is not practised, Veterinary Administrations 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.

**Article 2.1.1.10.**

When importing from FMD free countries or zones where vaccination is practised, Veterinary Administrations 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 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 2.1.1.11.**

When importing from FMD infected countries or zones, Veterinary Administrations 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 10-kilometre radius of the establishment of origin for the relevant period as defined in points a) and b) above; and

3) were isolated for the 30 days prior to quarantine in an establishment, 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 10-kilometre radius of the establishment during that period; or

4) were kept in a quarantine station for the 30 days prior to shipment, 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 10-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 2.1.1.12.

When importing from FMD free countries or zones where vaccination is not practised, Veterinary Administrations 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., Appendix 3.2.2. or Appendix 3.2.3., as relevant.

Article 2.1.1.13.

When importing from FMD free countries or zones where vaccination is not practised, Veterinary Administrations 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;
Chapter 2.1.1. - Foot and mouth disease

2) the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.1., Appendix 3.2.2. or Appendix 3.2.3., as relevant.

**Article 2.1.1.14.**

When importing from FMD free countries or zones where vaccination is practised, Veterinary Administrations 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., Appendix 3.2.2. or Appendix 3.2.3., as relevant;
   b) was stored in a country free from FMD for a period of at least one month before export, and during this period no animal on the *establishment* where the donor animals were kept showed any sign of FMD.

**Article 2.1.1.15.**

When importing from FMD infected countries or zones, Veterinary Administrations 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., Appendix 3.2.2. or Appendix 3.2.3., 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 for a period of at least one month between collection and export, and during this period no animal on the establishment where the donor animals were kept showed any sign of FMD.

Article 2.1.1.16.

Irrespective of the FMD status of the exporting country or zone, Veterinary Administrations should require:

for in vivo derived embryos of cattle

the presentation of an international veterinary certificate attesting that:

1) the donor females showed no clinical sign of FMD 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. or Appendix 3.3.3., as relevant.

Article 2.1.1.17.

When importing from FMD free countries or zones where vaccination is not practised, Veterinary Administrations 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 embryos;
   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 2.1.1.12., 2.1.1.13., 2.1.1.14. or 2.1.1.15., as relevant;

3) the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.2. or Appendix 3.3.3., as relevant.

Article 2.1.1.18.

When importing from FMD free countries or zones where vaccination is practised, Veterinary Administrations 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 embryos;
   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 2.1.1.12., 2.1.1.13., 2.1.1.14. or 2.1.1.15., as relevant;

4) the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.2. or Appendix 3.3.3., as relevant.

Article 2.1.1.19.
When importing from FMD free countries or zones where vaccination is not practised, Veterinary Administrations 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 2.1.1.9., Article 2.1.1.10. or Article 2.1.1.11.;

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 2.1.1.20.
When importing from FMD free countries or zones where vaccination is practised, Veterinary Administrations should require:

for fresh meat of bovines (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 2.1.1.9., Article 2.1.1.10. or Article 2.1.1.11.;

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 2.1.1.21.
When importing from FMD free countries or zones where vaccination is practised, Veterinary Administrations should require:
for fresh meat or meat products of pigs and ruminants other than bovines

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

1) have been kept in the country or zone since birth, or have been imported in accordance with Article 2.1.1.9., Article 2.1.1.10. or Article 2.1.1.11.;

2) have not been vaccinated;

3) have been slaughtered in an approved abattoir and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results.

Article 2.1.1.22.

When importing from FMD infected countries or zones, where an official control programme exists, involving compulsory systematic vaccination of cattle, Veterinary Administrations should require:

for fresh meat of bovines (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 10 kilometres 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 glands 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 2.1.1.23.  
When importing from FMD infected countries or zones, *Veterinary Administrations* 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 2.1.1.24.  
When importing from FMD free countries or zones (where vaccination either is or is not practised), *Veterinary Administrations* 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 2.1.1.9., Article 2.1.1.10. or Article 2.1.1.11.  

Article 2.1.1.25.  
When importing from FMD infected countries or zones where an official control programme exists, *Veterinary Administrations* 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 subjected to any restrictions due to 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 2.1.1.26.  
When importing from FMD infected countries, *Veterinary Administrations* 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 internal temperature of 70°C for at least 30 minutes.
Chapter 2.1.1. - Foot and mouth disease

Article 2.1.1.27.

When importing from FMD infected countries, Veterinary Administrations 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 Articles 3.6.2.2., 3.6.2.3. and 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 Administrations 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 2.1.1.28.

When importing from FMD infected countries or zones, Veterinary Administrations 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 2.1.1.29.

When importing from FMD free countries or zones (where vaccination either is or is not practised), Veterinary Administrations should require:

for skins and trophies derived from wild animals susceptible to FMD

the presentation of an international veterinary certificate attesting that these products are derived from animals that have been kept in such a country or zone since birth, or which have been imported from a country or zone free of FMD (where vaccination either is or is not practised).
Article 2.1.1.30.

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

for skins and trophies derived from wild animals susceptible to FMD

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.

[Note: International veterinary certificates for animal products coming from infected countries or zones may not be required if the products are transported in an approved manner to premises controlled and approved by the Veterinary Administration of the importing country for processing to ensure the destruction of the FMD virus in conformity with the procedures referred to in Articles 3.6.2.2., 3.6.2.3. and 3.6.2.4.]
CHAPTER 2.1.2.

VESICULAR STOMATITIS

Article 2.1.2.1.

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 2.1.2.2.

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 2.1.2.3.

*Veterinary Administrations* 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 2.1.2.4.

When importing from VS free countries, *Veterinary Administrations* 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 in a VS free country since birth or for at least the past 21 days.

Article 2.1.2.5.

When importing from VS free countries, *Veterinary Administrations* 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) 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 2.1.2.6.

When importing from countries considered infected with VS, Veterinary Administrations 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 2.1.2.7.

When importing from countries considered infected with VS, Veterinary Administrations 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 2.1.2.8.

When importing from VS free countries or zones, Veterinary Administrations 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 2.1.2.9.

When importing from countries or zones considered infected with VS, Veterinary Administrations 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 2.1.3.

SWINE VESICULAR DISEASE

Article 2.1.3.1.

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 2.1.3.2.

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 2.1.3.3.

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 2.1.3.4.

Veterinary Administrations 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 2.1.3.5.
When importing from SVD free countries, Veterinary Administrations 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 2.1.3.6.

When importing from SVD free countries, Veterinary Administrations 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 2.1.3.7.

When importing from countries considered infected with SVD, Veterinary Administrations 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 2.1.3.8.

When importing from countries considered infected with SVD, Veterinary Administrations 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 2.1.3.9.
When importing from SVD free countries, *Veterinary Administrations* 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 3.2.3.

**Article 2.1.3.10.**

When importing from countries considered infected with SVD, *Veterinary Administrations* 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 3.2.3.

**Article 2.1.3.11.**

When importing from SVD free countries, *Veterinary Administrations* 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 2.1.3.12.**

When importing from countries considered infected with SVD, *Veterinary Administrations* 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 2.1.3.13.

When importing from countries considered infected with SVD, Veterinary Administrations 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 2.1.3.14.

When importing from SVD free countries, Veterinary Administrations 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 2.1.3.15.

When importing from SVD free countries, Veterinary Administrations 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 2.1.3.16.

When importing from countries considered infected with SVD, Veterinary Administrations 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 2.1.3.17.

When importing from countries considered infected with SVD, Veterinary Administrations 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 Administration of the exporting country.
Chapter 2.1.3. - Swine vesicular disease

Article 2.1.3.18.

When importing from countries considered infected with SVD, Veterinary Administrations 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 2.1.3.19.

When importing from countries considered infected with SVD, Veterinary Administrations 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 2.1.4.

RINDERPEST

Article 2.1.4.1.
For the purposes of the Terrestrial Code, the incubation period for rinderpest shall be 21 days.

Ban on vaccination against rinderpest means a ban on administering a rinderpest vaccine to any susceptible species and a heterologous vaccine against rinderpest to any large ruminants or pigs.

Animal not vaccinated against rinderpest means:

1) for large ruminants and pigs: an animal that has received neither a rinderpest vaccine nor a heterologous vaccine against rinderpest;

2) for small ruminants: an animal that has not received a rinderpest vaccine.

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

Article 2.1.4.2.

Infection free country
To be considered free from infection, a country should meet the requirements contained in Appendix 3.8.2.

Should a localised rinderpest outbreak occur in an infection free country, the waiting period before infection free status can be regained shall be as follows:

1) 6 months after the last case where stamping-out without vaccination and serological surveillance are applied; or

2) 6 months after the slaughtering of the last vaccinated animal where stamping-out complemented by emergency vaccination (vaccinated animals should be clearly identified with a permanent mark) and serological surveillance are applied; or

3) 12 months after the last case or last vaccination (whichever occurs later) where emergency vaccination without slaughter (vaccinated animals should be clearly identified with a permanent mark) and serological surveillance are applied.

Article 2.1.4.3.

Disease free country or zone
To be considered free from the disease, a country or a zone should meet the requirements contained in Appendix 3.8.2.

Article 2.1.4.4.

Provisionally free country or zone
To be considered provisionally free from the disease, a country or a zone should meet the requirements contained in Appendix 3.8.2.
Article 2.1.4.5.

Infected country or zone

When the requirements for acceptance as an infection free country, a disease free country or zone, or a provisionally free country or zone are not fulfilled, a country or zone shall be considered as infected.

Article 2.1.4.6.

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

1) ruminants and swine;
2) semen of ruminants and swine;
3) embryos/ova of ruminants and swine;
4) products of animal origin (from ruminants and swine);
5) pathological material and biological products (see Chapter 1.4.6. and Section 1.5.).

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

Article 2.1.4.7.

When importing from infection free countries, Veterinary Administrations should require:

for ruminants and swine

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

1) showed no clinical sign of rinderpest on the day of shipment;
2) remained in an infection free country since birth or for at least 30 days prior to shipment.

Article 2.1.4.8.

When importing from disease free countries or zones, Veterinary Administrations should require:

for domestic ruminants and swine, and wild ruminants and swine reared under confined conditions

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

1) showed no clinical sign of rinderpest on the day of shipment;
2) were kept in a disease free country or zone since birth or for at least the past 3 months;
3) have not been vaccinated against rinderpest;
4) were kept isolated in their establishment of origin for the 30 days prior to shipment and were subjected to a diagnostic test for rinderpest on two occasions with negative results, at an interval of not less than 21 days;
5) were not exposed to any source of infection during their transportation from the establishment of origin to the place of shipment.
Article 2.1.4.9.

When importing from disease free countries or zones, Veterinary Administrations should require:

for wild ruminants and swine not reared under confined conditions

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

1) showed no clinical sign of rinderpest on the day of shipment;
2) come from a disease free country or zone;
3) have not been vaccinated against rinderpest;
4) were kept in a quarantine station for the 30 days prior to shipment and were subjected to a diagnostic test for rinderpest on two occasions with negative results, at an interval of not less than 21 days;
5) were not exposed to any source of infection during their transportation from the quarantine station to the place of shipment.

Article 2.1.4.10.

When importing from provisionally free countries or zones, Veterinary Administrations should require:

for domestic ruminants and swine, and wild ruminants and swine reared under confined conditions

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

1) showed no clinical sign of rinderpest on the day of shipment;
2) 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 3) below;
3) have not been vaccinated against rinderpest, were isolated in a quarantine station for the 30 days prior to shipment, and were subjected to a diagnostic test for rinderpest on two occasions with negative results, at an interval of not less than 21 days.

Article 2.1.4.11.

When importing from infected countries or zones, Veterinary Administrations should require:

for domestic ruminants and swine, and wild ruminants and swine reared under confined conditions

the presentation of an international veterinary certificate attesting that:

1) in the country or zone, routine vaccination is carried out for the purpose of the prevention of rinderpest;
2) rinderpest 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 3)b) below;
3) the animals:
   a) showed no clinical sign of rinderpest 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;
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Article 2.1.4.12.

When importing from disease or infection free countries, or from disease free zones, Veterinary Administrations should require:

for semen of domestic ruminants and swine

the presentation of an international veterinary certificate attesting that:

1) the donor animals:
   a) showed no clinical sign of rinderpest on the day of collection of the semen;
   b) were kept in a disease or infection free country, or disease free zone, 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. or Appendix 3.2.3., as relevant.

Article 2.1.4.13.

When importing from provisionally free countries or zones, Veterinary Administrations should require:

for semen of domestic ruminants and swine

the presentation of an international veterinary certificate attesting that:

1) the donor animals:
   a) showed no clinical sign of rinderpest on the day of collection of the semen;
   b) were vaccinated against rinderpest before the ban referred to in point 3)a) of Appendix 3.8.2.; or
   c) have not been vaccinated against rinderpest, and were subjected to a diagnostic test for rinderpest on two occasions with negative results, at an interval of not less than 21 days within the 30 days 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. or Appendix 3.2.3., as relevant.

Article 2.1.4.14.

When importing from infected countries or zones, Veterinary Administrations should require:

for semen of domestic ruminants and swine

the presentation of an international veterinary certificate attesting that:

1) in the country or zone, routine vaccination is carried out for the purpose of the prevention of rinderpest;
Chapter 2.1.4. - Rinderpest

2) the donor animals:
   a) showed no clinical sign of rinderpest on the day of collection of the semen;
   b) were kept in an establishment where no rinderpest susceptible animals had been added in the 21 days before collection, and that rinderpest has not occurred within 10 kilometres of the establishment for the 21 days before and after collection;
   c) were vaccinated against rinderpest for at least 3 months prior to collection; or
   d) have not been vaccinated against rinderpest, and were subjected to a diagnostic test for rinderpest 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. or Appendix 3.2.3., as relevant.

Article 2.1.4.15.

When importing from disease or infection free countries, or from disease free zones, Veterinary Administrations should require:

for in vivo derived embryos of domestic ruminants and swine

the presentation of an international veterinary certificate attesting that:

1) the donor females were kept in an establishment located in a disease or infection free country, or in a disease free 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 2.1.4.16.

When importing from provisionally free countries or zones, Veterinary Administrations should require:

for in vivo derived embryos of domestic ruminants and swine

the presentation of an international veterinary certificate attesting that:

1) the donor females:
   a) showed no clinical sign of rinderpest at the time of collection and for the following 21 days;
   b) were kept in an establishment where no rinderpest susceptible animals had been added in the 21 days before collection of the embryos;
   c) were vaccinated against rinderpest before the ban referred to in point 3a) of Appendix 3.8.2.; or
   d) have not been vaccinated against rinderpest, and were subjected to a diagnostic test for rinderpest on two occasions with negative results, at an interval of not less than 21 days within the 30 days prior to 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 2.1.4.17.

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

*for in vivo* derived embryos of domestic ruminants and swine

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

1) in the country or zone, routine vaccination is carried out for the purpose of the prevention of rinderpest;

2) the donor females:
   a) and all other animals in the *establishment* showed no clinical sign of rinderpest at the time of collection and for the following 21 days;
   b) were kept in an *establishment* where no rinderpest susceptible animals had been added in the 21 days before collection of the embryos;
   c) were vaccinated against rinderpest for at least 3 months prior to collection; or
   d) have not been vaccinated against rinderpest, and were subjected to a diagnostic test for rinderpest 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 2.1.4.18.

When importing from infection free countries, *Veterinary Administrations* should require:

*for fresh meat or meat products* of ruminants and swine

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 2.1.4.19.

When importing from disease free countries or zones, *Veterinary Administrations* should require:

*for fresh meat or meat products* of domestic ruminants and swine

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

1) the entire consignment comes from animals which have been kept in the country or zone since birth or for at least 3 months prior to slaughter;

2) the animals were slaughtered in an *approved abattoir* located in a disease free zone.

Article 2.1.4.20.

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

*for fresh meat* (excluding offal) of domestic ruminants and swine

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from:
Chapter 2.1.4. - Rinderpest

1) animals which:
   a) showed no clinical sign of rinderpest within 24 hours before slaughter;
   b) have remained in the country or zone 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;
   d) were vaccinated against rinderpest before the ban referred to in point 3a) of Appendix 3.8.2.; or
   e) were not vaccinated against rinderpest, and were subjected to a diagnostic test for rinderpest with negative results during the 21 days prior to slaughter;

2) deboned carcasses from which the major lymphatic glands have been removed.

Article 2.1.4.21.

When importing from infected countries or zones, Veterinary Administrations should require:

for fresh meat (excluding offal) of domestic ruminants and swine

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

1) comes from a country or zone where routine vaccination is carried out for the purpose of the prevention of rinderpest;

2) comes from animals which:
   a) showed no clinical sign of rinderpest within 24 hours before slaughter;
   b) have remained in the country or zone 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 rinderpest has not occurred within a 10-kilometre radius of the establishment during that period;
   d) were vaccinated against rinderpest 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 rinderpest has been detected during the period between the last disinfection carried out before slaughter and the date on which the shipment has been dispatched;

3) comes from deboned carcasses from which the major lymphatic glands have been removed.

Article 2.1.4.22.

When importing from provisionally free countries or zones, or from infected countries or zones, Veterinary Administrations should require:

for meat products of domestic ruminants and swine

the presentation of an international veterinary certificate attesting that:

1) only fresh meat complying with the provisions of Article 2.1.4.20. or Article 2.1.4.21., as relevant, has been used in the preparation of the meat products; or

2) the meat products have been processed to ensure the destruction of the rinderpest virus in conformity with one of the procedures referred to in Article 3.6.2.1.;

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3) the necessary precautions were taken after processing to avoid contact of the meat products with any possible source of rinderpest virus.

Article 2.1.4.23.

When importing from infection free countries, or from disease free countries or zones, Veterinary Administrations should require:

for milk and milk products intended for human consumption and for products of animal origin (from rinderpest 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 for at least 3 months.

Article 2.1.4.24.

When importing from provisionally free countries or zones, or from infected countries or zones, Veterinary Administrations 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 rinderpest at the time of milk collection;
   b) have been processed to ensure the destruction of the rinderpest 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 rinderpest virus.

Article 2.1.4.25.

When importing from provisionally free countries or zones, or from infected countries or zones, Veterinary Administrations 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 rinderpest virus.

Article 2.1.4.26.

When importing from provisionally free countries or zones, or from infected countries or zones, Veterinary Administrations should require:

for blood and meat-meals (from domestic or wild ruminants and swine)

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 2.1.4.27.

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

- for wool, hair, bristles, raw hides and skins (from domestic or wild ruminants and swine) the presentation of an *international veterinary certificate* attesting that:
  1) these products have been processed to ensure the destruction of the rinderpest virus in conformity with one of the procedures referred to in Articles 3.6.2.2., 3.6.2.3. and 3.6.2.4.;
  2) the necessary precautions were taken after processing to avoid contact of the products with any potential source of rinderpest virus.

*Veterinary Administrations* 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 2.1.4.28.

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

- for hooves, claws, bones and horns, hunting trophies and preparations destined for museums (from domestic or wild ruminants and swine) 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.

*[Note: International veterinary certificates for animal products coming from provisionally free countries or zones, or infected countries or zones, may not be required if the products are transported in an approved manner to premises controlled and approved by the Veterinary Administration of the importing country for processing to ensure the destruction of the rinderpest virus as described in Articles 3.6.2.2., 3.6.2.3. and 3.6.2.4.]*
CHAPTER 2.1.5.

PESTE DES PETITS RUMINANTS

Article 2.1.5.1.

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 2.1.5.2.

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 2.1.5.3.

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 2.1.5.4.

Veterinary Administrations 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.
Chapter 2.1.5. - Peste des petits ruminants

Article 2.1.5.5.

When importing from PPR free countries, Veterinary Administrations 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 2.1.5.6.

When importing from PPR free countries, Veterinary Administrations 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 2.1.5.7.

When importing from countries considered infected with PPR, Veterinary Administrations 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 2.1.5.8.

When importing from countries considered infected with PPR, Veterinary Administrations 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 2.1.5.9.

When importing from PPR free countries, Veterinary Administrations 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 2.1.5.10.

When importing from countries considered infected with PPR, Veterinary Administrations 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 2.1.5.11.

When importing from PPR free countries, Veterinary Administrations 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 2.1.5.12.

When importing from countries considered infected with PPR, Veterinary Administrations 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 2.1.5.13.

When importing from PPR free countries, Veterinary Administrations 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 2.1.5.14.

When importing from countries considered infected with PPR, Veterinary Administrations 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 2.1.5.15.

When importing from PPR free countries, Veterinary Administrations 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 2.1.5.16.

When importing from PPR free countries, Veterinary Administrations 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 2.1.5.17.

When importing from countries considered infected with PPR, Veterinary Administrations 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 2.1.5.18.

When importing from countries considered infected with PPR, Veterinary Administrations 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 2.1.5.19.

When importing from countries considered infected with PPR, Veterinary Administrations 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 Administration of the exporting country.
Article 2.1.5.20.
When importing from countries considered infected with PPR, Veterinary Administrations 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 2.1.5.21.
When importing from countries considered infected with PPR, Veterinary Administrations 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 2.1.6.
CONTAGIOUS BOVINE PLEUROPNEUMONIA

Article 2.1.6.1.
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 2.1.6.2.

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 2.1.6.3.

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 2.1.6.4.

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 2.1.6.5.

Veterinary Administrations of CBPP free countries may prohibit importation or transit through their territory, from countries considered infected with CBPP, of domestic and wild bovidae.

Article 2.1.6.6.

When importing from CBPP free countries, Veterinary Administrations should require:

for domestic 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 in a CBPP free country since birth or for at least the past 6 months.
Chapter 2.1.6. - Contagious bovine pleuropneumonia

Article 2.1.6.7.
When importing from CBPP free countries, Veterinary Administrations 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 2.1.6.8.
When importing from CBPP infected countries, Veterinary Administrations 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 2.1.6.9.
When importing from CBPP infected countries, Veterinary Administrations 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 2.1.6.10.

When importing from CBPP infected countries, *Veterinary Administrations* 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 2.1.6.11.

When importing from CBPP infected countries, *Veterinary Administrations* 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 2.1.6.12.

When importing from CBPP free countries, *Veterinary Administrations* 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 Appendices 3.3.1., 3.3.2. or 3.3.3., as relevant.
Article 2.1.6.13.

When importing from CBPP infected countries, Veterinary Administrations 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 Appendices 3.3.1., 3.3.2. or 3.3.3., as relevant.
CHAPTER 2.1.7.

LUMPY SKIN DISEASE
(caused by group III virus, type Neethling)

Article 2.1.7.1.
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 2.1.7.2.

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 2.1.7.3.
Veterinary Administrations 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 2.1.7.4.
When importing from LSD free countries, Veterinary Administrations 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) come from an LSD free country.

Article 2.1.7.5.
When importing from LSD free countries, Veterinary Administrations 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) 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 2.1.7.6.  
When importing from countries considered infected with LSD, Veterinary Administrations 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 2.1.7.7.  
When importing from countries considered infected with LSD, Veterinary Administrations 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 2.1.7.8.  
When importing from LSD free countries, Veterinary Administrations 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 2.1.7.9.  
When importing from countries considered infected with LSD, Veterinary Administrations 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 2.1.7.10.

When importing from LSD free countries, *Veterinary Administrations* 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 2.1.7.11.

When importing from countries considered infected with LSD, *Veterinary Administrations* 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 2.1.7.12.

When importing from countries considered infected with LSD, *Veterinary Administrations* 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 2.1.8.

RIFT VALLEY FEVER

Article 2.1.8.1.

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-Saharan 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 and monitoring programme (carried out in conformity with the provisions of Chapter 1.3.6.) 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 2.1.8.2.

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 infected regions, or

2) a surveillance and monitoring programme as described in Article 2.1.8.1. 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 2.1.8.1. 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 2.1.8.3.

RVF infected country/zone without disease

A RVF disease free country or zone is a country/zone that is not infection free (see Article 2.1.8.2.) but in which disease has not occurred in humans or animals in the past 6 months provided that climatic changes predisposing to outbreaks of RFV have not occurred during this time.

Article 2.1.8.4.

RVF infected country/zone with disease

A RVF infected country/zone with disease is one in which clinical disease in humans or animals has occurred within the past 6 months.

Article 2.1.8.5.

Veterinary Administrations 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 2.1.8.6.

When importing from RVF free countries or zones, Veterinary Administrations 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 2.1.8.7.

When importing from RVF free countries or zones, Veterinary Administrations 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/zone since birth or for the last 30 days.

Article 2.1.8.8.

When importing from RVF infected country/zone without disease, Veterinary Administrations should require:
Chapter 2.1.8. - Rift Valley fever

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 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 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 place of shipment;

AND

5) did not transit through an infected zone with disease during transportation to the place of shipment.

Article 2.1.8.9.

When importing from RVF infected countries or zones without disease, Veterinary Administrations 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 2.1.8.10.

When importing from a RVF infected country/zone with disease, Veterinary Administrations 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 modified live virus vaccine;

OR

3) 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 place of shipment and at the place of shipment.
Article 2.1.8.11.

When importing from a RVF infected country/zone with disease, *Veterinary Administrations* 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.
CHAPTER 2.1.9.

BLUETONGUE

Article 2.1.9.1.

For the purposes of the Terrestrial Code, the infective period for bluetongue virus (BTV) shall be 100 days.

The global BTV distribution historically has been shown to be between latitudes of approximately 40°N and 35°S.

Standards for diagnostic tests are described in the Terrestrial Manual.

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 and monitoring programme (carried out in conformity with the provisions of Chapter 1.3.6.) designed in accordance with the epidemiology of the disease, i.e. focusing on climatic and geographical factors, the biology of Culicoides and/or serology of susceptible animals. 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 and Culicoides population data, or proximity to enzootic or incursional zones. Random and targeted serological surveillance should provide at least a 95% level of confidence of detecting an annual seroconversion incidence of 2% in cattle (or other ruminant species if sufficient cattle are not available).

Countries or zones located outside this part of the world but adjacent to a country or zone not having free status should be subjected to similar surveillance. The surveillance programme should be carried out over a distance of at least 100 kilometres from the border with that country or zone.

Article 2.1.9.2.

BTV free country or zone

A country or a zone may be considered free from BTV when bluetongue is notifiable in the whole country and either:

1) the country or zone lies wholly north of 40°N or south of 35°S, and is not adjacent to a country or zone not having a free status, or

2) a surveillance and monitoring programme as described in Article 2.1.9.1. has demonstrated no evidence of BTV in the country or zone during the past 2 years, nor have any ruminants been vaccinated against bluetongue in the country or zone during the past 12 months, or

3) a surveillance and monitoring programme has demonstrated no evidence of Culicoides in the country or zone.

For maintenance of the free status, the provisions of the last paragraph of Article 2.1.9.1. may need to be complied with on a continuous basis according to the geographical location of the country or zone.

A BTV free country or zone in which surveillance and monitoring has found no evidence that BTV vectors are present will not lose its free status through the importation of seropositive or infective animals, or semen or embryos/ova from infected countries or zones.
A BTV free country or zone adjacent to an infected country or zone should include a surveillance zone as described in Article 2.1.9.1. Animals within the surveillance zone must be subjected to continuing surveillance.

The boundaries of the surveillance zone must be clearly defined, and must take account of geographical and epidemiological factors that are relevant to BTV infection.

Article 2.1.9.3.

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 and monitoring demonstrate no evidence either of BTV transmission or of adult Culicoides.

For the application of Articles 2.1.9.7., 2.1.9.10. and 2.1.9.14., the seasonally free period is taken to commence the day following the last evidence of BTV transmission (as demonstrated by the surveillance and monitoring programme), or of the cessation of adult Culicoides activity.

For the application of Articles 2.1.9.7., 2.1.9.10. and 2.1.9.14., 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 and monitoring programme indicate an earlier resurgence of Culicoides activity.

A BTV seasonally free zone in which surveillance and monitoring has found no evidence that BTV vectors are present will not lose its free status through the importation of seropositive or infective animals, or semen or embryos/ova from infected countries or zones.

Article 2.1.9.4.

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 2.1.9.5.

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

1) ruminants and other BTV susceptible herbivores;

2) semen of these species;

3) embryos/ova of these species;

4) pathological material and biological products (from these species) (see Chapter 1.4.6. and Section 1.5.).

Other commodities should be considered as not having the potential to spread BTV when they are the subject of international trade.
Article 2.1.9.6.

When importing from BTV free countries or zones, *Veterinary Administrations* should require:

for ruminants and other BTV susceptible herbivores

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

1) were kept in a BTV free country or zone since birth or for at least 100 days prior to shipment, or
2) 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, such as the BT competition ELISA or the BT AGID test, and remained in the BTV free country or zone until shipment, or
3) were kept in a BTV free country or zone for at least 7 days, then were subjected, with negative results, to a BTV isolation test or polymerase chain reaction test on a blood sample, and remained in the BTV free country or zone until shipment;

AND

4) 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 *Culicoides* attack at all times when transiting through an infected zone.

Article 2.1.9.7.

When importing from BTV seasonally free zones, *Veterinary Administrations* 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 for at least 100 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, such as the BT competition ELISA or the BT AGID test, with negative results on two occasions, with an interval of not less than 7 days between each test, the first test being carried out at least 21 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 a BTV isolation test or polymerase chain reaction test, with negative results, on blood samples taken on two occasions, with an interval of not less than 7 days between each test, the first test being carried out at least 7 days after the commencement of the residence period;

AND

4) 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 *Culicoides* attack at all times when transiting through an infected zone.
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Article 2.1.9.8.

When importing from BTV infected countries or zones, Veterinary Administrations should require:

for ruminants and other BTV susceptible herbivores

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

1) were protected from Culicoides attack for at least 100 days prior to shipment, or

2) were protected from Culicoides attack for at least 28 days prior to shipment, and were subjected during that period to a serological test to detect antibody to the BTV group, such as the BT competition ELISA or the BT AGID test, with negative results on two occasions, with an interval of not less than 7 days between each test, the first test being carried out at least 21 days after introduction into the quarantine station, or

3) were protected from Culicoides attack for at least 14 days prior to shipment, and were subjected during that period to a BTV isolation test or polymerase chain reaction test, with negative results, on blood samples taken on two occasions, with an interval of not less than 7 days between each test, the first test being carried out at least 7 days after introduction into the quarantine station; AND

4) were protected from Culicoides attack during transportation to the place of shipment.

Article 2.1.9.9.

When importing from BTV free countries or zones, Veterinary Administrations 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 kept in a BTV free country or zone for at least 100 days before commencement of, and during, collection of the semen, or
   b) were subjected to a serological test to detect antibody to the BTV group, such as the BT competition ELISA or the BT AGID test, between 28 and 60 days after the last collection for this consignment, with negative results, or
   c) were subjected to a virus isolation test or polymerase chain reaction (PCR) test on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;

2) the semen was collected, processed and stored in conformity with the provisions of either Appendix 3.2.1. or Appendix 3.2.2.

Article 2.1.9.10.

When importing from BTV seasonally free zones, Veterinary Administrations 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 kept during the BTV seasonally free period in a seasonally free zone for at least 100 days before commencement of, and during, collection of the semen, or
b) were subjected to a serological test to detect antibody to the BTV group such as the BT competition ELISA or the BT AGID test, with negative results, at least every 60 days throughout the collection period and between 28 and 60 days after the final collection for this consignment, or

c) were subjected to a virus isolation test or polymerase chain reaction (PCR) test on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;

2) the semen was collected, processed and stored in conformity with the provisions of either Appendix 3.2.1. or Appendix 3.2.2.

Article 2.1.9.11.

When importing from BTV infected countries or zones, Veterinary Administrations 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 Culicoides attack for at least 100 days before commencement of, and during, collection of the semen, or

   b) were subjected to a serological test to detect antibody to the BTV group such as the BT competition ELISA or the BT AGID test, with negative results, at least every 60 days throughout the collection period and between 28 and 60 days after the final collection for this consignment, or

   c) were subjected to a virus isolation test or polymerase chain reaction (PCR) test on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;

2) the semen was collected, processed and stored in conformity with the provisions of either Appendix 3.2.1. or Appendix 3.2.2.

Article 2.1.9.12.

Regardless of the bluetongue status of the exporting country, Veterinary Administrations 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 2.1.9.13.

When importing from BTV free countries or zones, Veterinary Administrations 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 100 days prior to, and at the time of, collection of the embryos, or
b) were subjected to a serological test to detect antibody to the BTV group, such as the BT competition ELISA or the BT AGID test, between 28 and 60 days after collection, with negative results, or

c) were subjected to a BTV isolation test or polymerase chain reaction test 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 2.1.9.14.**

When importing from BTV seasonally free zones, *Veterinary Administrations* 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 100 days before commencement of, and during, collection of the embryos/oocytes, or

b) were subjected to a serological test to detect antibody to the BTV group such as the BT competition ELISA or the BT AGID test, between 28 and 60 days after collection, with negative results, or

c) were subjected to a BTV isolation test or polymerase chain reaction test 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 2.1.9.15.**

When importing from BTV infected countries or zones, *Veterinary Administrations* 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 *Culicoides* attack for at least 100 days before commencement of, and during, collection of the embryos/oocytes, or

b) were subjected to a serological test to detect antibody to the BTV group such as the BT competition ELISA or the BT AGID test, between 28 and 60 days after collection with negative results, or

c) were subjected to a BTV isolation test or polymerase chain reaction test 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.
CHAPTER 2.1.10.

SHEEP POX AND GOAT POX

Article 2.1.10.1.

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 2.1.10.2.

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 2.1.10.3.

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 2.1.10.4.

Veterinary Administrations 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 2.1.10.5.

When importing from sheep pox and goat pox free countries, Veterinary Administrations 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 in a sheep pox and goat pox free country since birth or for at least the past 21 days.
Article 2.1.10.6.

When importing from countries considered infected with sheep pox and goat pox, Veterinary Administrations 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 2.1.10.7.

When importing from sheep pox and goat pox free countries, Veterinary Administrations 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 2.1.10.8.

When importing from countries considered infected with sheep pox and goat pox, Veterinary Administrations 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 2.1.10.9.

When importing from countries considered infected with sheep pox and goat pox, Veterinary Administrations 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 Administration of the exporting country.
CHAPTER 2.1.11.

AFRICAN HORSE SICKNESS

Article 2.1.11.1.

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 2.1.11.2.

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 2.1.11.3.

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 1.1.3.4. 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 2.1.11.8.

Article 2.1.11.4.

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:
Chapter 2.1.11. - African horse sickness

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 2.1.11.8.

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 2.1.11.8.;

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 2.1.11.5.

_Veterinary Administrations_ 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 2.1.11.6.

When importing from AHS free countries or zones, _Veterinary Administrations_ 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 2.1.11.7.

When importing from AHS free countries or zones, _Veterinary Administrations_ 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 2.1.11.8.

When importing from countries considered infected with AHS or from AHS infected zones, _Veterinary Administrations_ 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 2.1.11.9.
When importing from AHS free countries or zones, Veterinary Administrations 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 2.1.11.10.
When importing from countries considered infected with AHS or from AHS infected zones, Veterinary Administrations 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 2.1.11.11.
When importing from AHS free countries or zones, Veterinary Administrations 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 2.11.12.

When importing from countries considered infected with AHS or from AHS infected zones, Veterinary Administrations 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.
CHAPTER 2.1.12.

AFRICAN SWINE FEVER

Article 2.1.12.1.
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 2.1.12.2.

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 2.1.12.3.

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 1.1.3.4. 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 2.1.12.4.

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 2.1.12.5.

Veterinary Administrations 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;
Chapter 2.1.12. - African swine fever

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 2.1.12.6.
When importing from ASF free countries or zones, Veterinary Administrations should require:

for domestic 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 in an ASF free country or zone since birth.

Article 2.1.12.7.
When importing from ASF free countries or zones, Veterinary Administrations 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) 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 2.1.12.8.
When importing from countries considered infected with ASF, Veterinary Administrations should require:

for domestic 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 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 2.1.12.9.
When importing from countries considered infected with ASF, Veterinary Administrations 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 2.1.12.10.
When importing from ASF free zones, Veterinary Administrations 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 3.2.3. and Appendix 3.3.1., respectively.

Article 2.1.12.11.
When importing from countries considered infected with ASF, Veterinary Administrations 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 3.2.3.

Article 2.1.12.12.
When importing from ASF free zones, Veterinary Administrations 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 2.1.12.13.
When importing from ASF free zones, Veterinary Administrations 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 2.1.12.12.;
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.

When importing from countries considered infected with ASF, Veterinary Administrations 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 2.1.12.15.
When importing from ASF free zones, Veterinary Administrations 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 2.1.12.16.
When importing from ASF free zones, Veterinary Administrations 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 2.1.12.17.
When importing from countries considered infected with ASF, Veterinary Administrations 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 2.1.12.18.
When importing from countries considered infected with ASF, Veterinary Administrations 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 Administration 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 2.1.12.19.
When importing from countries considered infected with ASF, Veterinary Administrations 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 2.1.13.
CLASSICAL SWINE FEVER

Article 2.1.13.1.

The pig is the only natural host for classical swine fever (CSF) virus. The definition of pigs includes all varieties of Sus scrofa, both domestic breeds and wild boar. A distinction is made between farmed and permanently captive pigs, and free-living pigs. Farmed and permanently captive pigs of any breed will hereafter be referred to as domestic pigs. Free-living pigs of any breed will hereafter be referred to as wild pigs. Extensively kept pigs may fall into either of these categories or may alternate between the two.

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 2.1.13.2.

The CSF status of a country or zone can only be determined after considering the following criteria both in domestic and wild pigs:

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 Administration should have current knowledge of, and authority over, all establishments containing pigs in the whole country;
5) the Veterinary Administration should have current knowledge about the population and habitat of wild pigs in the whole country.

Article 2.1.13.3.

For the purposes of the Terrestrial Code.

'CSF infected establishment' means a domestic pig holding in which the presence of the infection has been confirmed by field and/or laboratory investigations.

'Country or zone with CSF infection in domestic pigs' means a country or zone containing a CSF infected establishment.

The size and limits of a CSF domestic pig control area must be based on the control measures used and the presence of natural and administrative boundaries, as well as an assessment of the risks for disease spread.
Article 2.1.13.4.

Country or zone free of CSF in domestic and wild pigs

1) Historically free status

A country or zone may be considered free from the disease in domestic and wild pigs after conducting a risk assessment as referred to in Article 2.1.13.2. but without formally applying a specific surveillance programme (historical freedom) if the country or zone complies with the provisions of Article 3.8.1.2.

2) Free status as a result of an eradication programme

A country or zone which does not meet the conditions of point 1) above may be considered free from CSF in domestic and wild pigs after conducting a risk assessment as referred to in Article 2.1.13.2. and when:

a) it is a notifiable disease;

b) 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;

c) the feeding of swill 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.;

d) animal health regulations to control the movement of commodities covered in this Chapter in order to minimise the risk of introduction of the infection into the establishments of the country or zone have been in place for at least 2 years;

AND EITHER

e) where a stamping-out policy without vaccination has been practised for CSF control, no outbreak has been observed in domestic pigs for at least 6 months; or

f) where a stamping-out policy combined with vaccination has been practised, vaccination against CSF should have been banned for all domestic pigs in the country or zone for at least one year, unless there are validated means of distinguishing between vaccinated and infected pigs; if vaccination has occurred in the last 5 years, a serological monitoring system should have been in place for at least 6 months to demonstrate absence of infection within the population of domestic pigs 6 months to one year old, and no outbreak has been observed in domestic pigs for at least 12 months; or

g) where a vaccination strategy has been adopted without a stamping-out policy, vaccination against CSF should have been banned for all domestic pigs in the country or zone for at least one year, unless there are validated means of distinguishing between vaccinated and infected pigs; if vaccination has occurred in the last 5 years, a serological monitoring system should have been in place for at least 6 months to demonstrate absence of infection within the population of domestic pigs 6 months to one year old, and no outbreak has been observed in domestic pigs for at least 12 months;

AND

h) CSF infection is not known to occur in the wild pig population and monitoring of wild pigs indicates that there is no residual infection.
Article 2.1.13.5.

**Country or zone free of CSF in domestic pigs but with infection in the wild pig population**

Requirements in point 2) of Article 2.1.13.4., as relevant, are complied with, but CSF infection is known to occur in wild pigs. Additional conditions for the free status are that in the country or zone:

1) a programme for the management of CSF in wild pigs is in place, and CSF wild pig control areas are delineated around every CSF case reported in wild pigs, 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) biosecurity measures are applied to prevent transmission from wild pigs to domestic pigs;

3) clinical and laboratory monitoring (under study) is carried out in the domestic pig population, with negative results.

Article 2.1.13.6.

**Recovery of free status**

Should a CSF outbreak occur in an establishment of a free country or zone (free in domestic and wild pigs, or free in domestic pigs only), the status of the country or zone may be restored at least 30 days after completion of a stamping-out policy which should include the following measures:

1) a CSF domestic pig control area (including an inner protection area of at least 3 kilometres radius and an outer surveillance area of at least 10 kilometres radius) should be delineated around the outbreak, taking into account the control measures applied, the presence of natural and administrative boundaries, and an assessment of the risk of disease spread;

2) all the pigs have been killed and their carcasses destroyed, and disinfection has been applied within the establishment;

3) in the protection area around a CSF outbreak:
   a) a risk assessment should be carried out to determine the likelihood of CSF infection in neighbouring establishments; when a significant risk is indicated, a stamping-out policy of all domestic pigs within a radius of at least 0.5 kilometre may be applied;
   b) an immediate clinical examination of all pigs in all pig establishments situated within the protection area has been carried out;

4) in the surveillance area around a CSF outbreak, all sick pigs should be subjected to laboratory tests for CSF;

5) an epidemiological examination including clinical examination, and/or serological and/or virological testing has been carried out in all pig establishments that have been directly or indirectly in contact with the infected establishment and in all pig establishments located within the CSF domestic pig control area, demonstrating that these establishments are not infected;

6) measures aimed at preventing any virus spread by live pigs, pig semen and pig embryos, contaminated material, vehicles, etc. have been implemented.

If emergency vaccination has been practised within the CSF domestic pig control area, recovery of the free status can not occur before all the vaccinated pigs have been slaughtered, unless there are validated means of distinguishing between vaccinated and infected pigs.
Article 2.1.13.7.

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) a monitoring system (under study) 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 or 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 at least 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.

A zoning approach can only be adopted if there is a wild pig population that is isolated from other wild pigs.

Article 2.1.13.8.

When importing from countries or zones free of CSF in domestic and wild pigs, Veterinary Administrations should require:

for domestic pigs

the presentation of an international veterinarian certificate attesting that the animals:

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

2) were kept in a country or zone free of CSF in domestic and wild pigs 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 2.1.13.9.

When importing from countries or zones free of CSF in domestic pigs but with infection in wild pigs, Veterinary Administrations should require:

for domestic pigs

the presentation of an international veterinarian 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 an establishment which is not located in a CSF wild pig control area as defined in Article 2.1.13.5., and has been regularly monitored to verify absence of CSF;

4) have had no contact with pigs introduced into the establishment during the past 40 days;

5) showed no clinical sign of CSF on the day of shipment.

Article 2.1.13.10.

When importing from countries or zones with CSF infection in domestic pigs, Veterinary Administrations 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 an establishment not situated in a CSF domestic or wild pig control area as defined in Articles 2.1.13.5. and 2.1.13.6.;

3) were isolated in a quarantine station for at least 40 days;

4) were subjected during that period of quarantine to a virological test, and a serological test performed at least 21 days after entry into the quarantine station, with negative results;

5) showed no clinical sign of CSF on the day of shipment.

Article 2.1.13.11.

When importing from countries or zones free of CSF in domestic and wild pigs, Veterinary Administrations 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 in domestic and wild pigs;

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 2.1.13.12.

When importing from countries or zones free of CSF in domestic and wild pigs, Veterinary Administrations should require:

for semen of domestic pigs
Chapter 2.1.13. - Classical swine fever

the presentation of an international veterinary certificate attesting that:

1) the donor animals:
   a) were kept in a country or zone free of CSF in domestic and wild pigs since birth or for at least the past 3 months;
   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 3.2.3.

Article 2.1.13.13.

When importing from countries or zones free of CSF in domestic pigs but with infection in wild pigs, Veterinary Administrations should require:

for semen of domestic pigs

the presentation of an international veterinary certificate attesting that:

1) the donor animals:
   a) have been kept in an artificial insemination centre which is not located in a CSF wild pig control area and is regularly monitored to verify absence of CSF;
   b) were isolated in the artificial insemination centre for at least 40 days prior to collection;
   c) 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 3.2.3.


When importing from countries or zones considered infected with CSF in domestic pigs, Veterinary Administrations should require:

for semen of domestic pigs

the presentation of an international veterinary certificate attesting that:

1) the donor animals:
   a) showed no clinical sign of CSF on the day of collection of the semen and for the following 3 months;
   b) 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 3.2.3.

Article 2.1.13.15.

When importing from countries or zones free of CSF in domestic and wild pigs, Veterinary Administrations 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 2.1.13.16.**

When importing from countries or zones free of CSF in domestic pigs but with infection in wild pigs, *Veterinary Administrations* 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 for at least 40 days prior to collection in an *establishment* which is not located in a CSF domestic or wild pig control area and is regularly monitored to verify absence of CSF;
   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 2.1.13.17.**

When importing from countries considered infected with CSF in domestic pigs, *Veterinary Administrations* 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 for at least 40 days prior to collection in an *establishment* which is not located in a CSF domestic or wild pig control area and is regularly monitored to verify absence of CSF;
   b) showed no clinical sign of CSF on the day of collection of the embryos and for the following 21 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 2.1.13.18.**

When importing from countries or zones free of CSF in domestic and wild pigs, *Veterinary Administrations* 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 or zone free of CSF in domestic and wild 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 2.1.13.19.

When importing from countries or zones free of CSF in domestic pigs but with infection in wild pigs, Veterinary Administrations 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 or zone free of CSF in domestic pigs since birth or for at least the past 3 months;

2) were kept in an establishment which was not located in a CSF wild pig control area and had been regularly monitored to verify absence of CSF;

3) have been slaughtered in an approved abattoir not located in a CSF control area, have been subjected to ante-mortem and post-mortem inspections and have been found free of any sign suggestive of CSF.

Article 2.1.13.20.

When importing from countries or zones free of CSF in domestic and wild pigs, Veterinary Administrations 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 in domestic and wild pigs;
   b) have been subjected to 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 2.1.13.21.

Veterinary Administrations 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 2.1.13.18., 2.1.13.19. or 2.1.13.20., as relevant;
   b) in a processing establishment:
      i) approved by the Veterinary Administration for export purposes;
      ii) regularly inspected by the Veterinary Authority;
      iii) not situated in a CSF control area;
      iv) processing only meat meeting the conditions laid down in Articles 2.1.13.18., 2.1.13.19. or 2.1.13.20., as relevant;

OR

2) have been processed in an establishment approved by the Veterinary Administration for export purposes and regularly inspected by the Veterinary Authority 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 2.1.13.22.

Veterinary Administrations 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 2.1.13.18., 2.1.13.19. or 2.1.13.20., as relevant;
   b) in a processing establishment:
      i) approved by the Veterinary Administration for export purposes;
      ii) regularly inspected by the Veterinary Authority;
      iii) not situated in a CSF control area;
      iv) processing only products meeting the conditions laid down in point a) above;

OR

2) have been processed in an establishment approved by the Veterinary Administration for export purposes and regularly inspected by the Veterinary Authority 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 2.1.13.23.

Veterinary Administrations 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 or zone free of CSF in domestic and wild pigs; or

2) have been processed in an establishment approved by the *Veterinary Administration* for export purposes and regularly inspected by the *Veterinary Authority* so as to ensure the destruction of the CSF virus.

**Article 2.1.13.24.**

*Veterinary Administrations* 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 or zone free of CSF in domestic and wild pigs; or

2) come from *establishments* situated in a country or zone free of CSF in domestic pigs but with infection in wild pigs, but not located in a CSF control area; or

3) have been processed in an establishment approved by the *Veterinary Administration* for export purposes and regularly inspected by the *Veterinary Authority* so as to ensure the destruction of the CSF virus.
CHAPTER 2.1.14.

HIGHLY PATHOGENIC AVIAN INFLUENZA


For the purposes of the Terrestrial Code, the incubation period for highly pathogenic avian influenza (HPAI) shall be 21 days.

Standards for diagnostic tests are described in the Terrestrial Manual.

Article 2.1.14.2.

HPAI free country

A country may be considered free from HPAI when it has been shown that HPAI 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 HPAI.

Article 2.1.14.3.

HPAI infected zone

A zone shall be considered as infected with HPAI 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 2.1.14.4.

Veterinary Administrations of importing countries should require similar arrangements to those provided in Chapter 2.1.15. (Newcastle disease) of the Terrestrial Code for 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) products of animal origin (from birds) intended for use in animal feeding or for agricultural or industrial use;
7) pathological material and biological products (from birds) which have not been processed to ensure the destruction of the HPAI virus.
CHAPTER 2.1.15.

NEWCASTLE DISEASE

Article 2.1.15.1.

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 2.1.15.2.

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 2.1.15.3.

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 2.1.15.4.

Veterinary Administrations 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 2.1.15.5.

When importing from ND free countries, *Veterinary Administrations* 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 2.1.15.6.

When importing from ND free countries, *Veterinary Administrations* 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 2.1.15.7.

When importing from countries considered infected with ND, *Veterinary Administrations* 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).
Chapter 2.1.15. - Newcastle disease

Article 2.1.15.8.

When importing from countries considered infected with ND, *Veterinary Administrations* 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 2.1.15.9.

When importing from ND free countries, *Veterinary Administrations* 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 2.1.15.10.

When importing from countries considered infected with ND, *Veterinary Administrations* 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 2.1.15.11.

When importing from ND free countries, *Veterinary Administrations* 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 2.1.15.12.

When importing from countries considered infected with ND, Veterinary Administrations 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 2.1.15.13.

When importing from ND free countries, Veterinary Administrations 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 2.1.15.14.

When importing from countries considered infected with ND, Veterinary Administrations 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 2.1.15.15.

When importing from ND free countries, Veterinary Administrations 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 approved abattoir and have been subjected to ante-mortem and post-mortem inspections for ND with favourable results.
Article 2.1.15.16.

When importing from countries considered infected with ND, *Veterinary Administrations* 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 *approved abattoir* not situated in an ND infected zone and have been subjected to ante-mortem and post-mortem inspections for ND with favourable results.

Article 2.1.15.17.

When importing from countries considered infected with ND, *Veterinary Administrations* 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 *approved abattoir* 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 2.1.15.18.

When importing from ND free countries, *Veterinary Administrations* 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 2.1.15.19.

When importing from countries considered infected with ND, *Veterinary Administrations* 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 2.1.15.20.

When importing from countries considered infected with ND, *Veterinary Administrations* 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 2.2.
MULTIPLE SPECIES DISEASES IN LIST B

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 Administrations 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 Administrations 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
Chapter 2.2.1. - Anthrax

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 XXX (under study).

Article 2.2.1.4.

Veterinary Administrations 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 Administrations 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 Administrations 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 Administrations 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 analysis 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 Administration 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 1)e) 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 1)b) and 1)d) 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 ≤ 1% for at least 6 months, and this result is confirmed by a serological survey conducted in conformity with point 1)c) 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 1)e) above should be carried out every 4 months.

For establishments located in a provisionally free country or zone, the testing procedure described in point 1)e) 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 Administrations 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 1.4.6. 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 Administrations 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 Administrations 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 Administrations 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 from AD infected countries or zones, Veterinary Administrations 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 Administrations 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.
Chapter 2.2.2. - Aujeszky’s disease

Article 2.2.2.12.

When importing from AD free countries or zones, Veterinary Administrations 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 3.2.3.

Article 2.2.2.13.

When importing from AD provisionally free countries or zones, Veterinary Administrations 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 3.2.3.

Article 2.2.2.14.

When importing from AD infected countries or zones, Veterinary Administrations 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 3.2.3.
Chapter 2.2.2. - Aujeszky's disease

Article 2.2.2.15.
When importing from AD free countries or zones, *Veterinary Administrations* 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 Administrations* 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 Administrations* 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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.

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

Article 2.2.4.2.

_Veterinary Administrations of importing countries_ should require:

_for domestic ruminants, equines and pigs for breeding_

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

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

2) were kept in an *establishment* in which no clinical sign of leptospirosis was officially reported during the 90 days prior to shipment;

3) were treated with an agreed effective antimicrobial in accordance with the manufacturer's instructions.

Article 2.2.4.3.

_Veterinary Administrations of importing countries_ should require:

_for semen of ruminants and pigs_

the presentation of an *international veterinary certificate* attesting that the semen was collected, processed and stored in conformity with the provisions of either Appendix 3.2.1., or Appendix 3.2.2., or Appendix 3.2.3., as relevant.

Article 2.2.4.4.

_Veterinary Administrations of importing countries_ should require:

_for in vivo derived embryos/oocytes of ruminants and pigs_

the presentation of an *international veterinary certificate* attesting that the embryos/oocytes were collected, processed and stored in conformity with the provisions of Appendices 3.3.1., 3.3.2. or 3.3.3., as relevant.
Article 2.2.4.5.

Veterinary Administrations of importing countries should require:

for in vitro produced embryos/oocytes of ruminants and pigs

the presentation of an international veterinary certificate attesting that:

1) the donor females:
   a) showed no clinical sign of leptospirosis on the day of collection of the embryos/oocytes;
   b) were kept in an establishment in which no clinical sign of leptospirosis was reported during the 90 days prior to shipment;

2) all fluids used during the collection, processing and storage of the embryos/oocytes contained efficacious levels of antibiotics;

3) the oocytes were fertilised with semen meeting the conditions referred to in Article 2.2.4.3.;

4) the embryos/oocytes were collected, processed and stored in conformity with the provisions of Appendices 3.3.1., 3.3.2. or 3.3.3., as relevant.
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 Administrations should require:

for domestic mammals, and wild mammals 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 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 Administrations should require:

for wild mammals 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) 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 Administrations* 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;

3) were identified by a permanent mark (including a microchip) before the vaccination (their identification number shall be stated in the certificate);

4) were subjected not less than 3 months and not more than 24 months prior to shipment to a neutralising antibody titration test, and that their serum contained at least 0.5 IU/ml;

OR

5) have not been vaccinated against rabies or do not meet all the conditions set out in points 1), 2), 3) and 4) 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 Administrations* 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 no case of rabies was reported for at least 12 months prior to shipment.
Chapter 2.2.5. - Rabies

Article 2.2.5.7.
When importing from countries considered infected with rabies, *Veterinary Administrations* 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 Administrations* 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 Administrations* 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.

[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*.

Article 2.2.6.2.

*Veterinary Administrations of importing countries* should require:

for domestic ruminants for breeding or rearing

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

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

2) were kept in a herd in which no clinical sign of paratuberculosis was officially reported during the 5 years prior to shipment;

3) were subjected to diagnostic tests for paratuberculosis with negative results during the 30 days prior to shipment.
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 Administrations* 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 Administrations* 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 Administrations 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.
Chapter 2.2.8. - New world screwworm and old world screwworm

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 Administrations 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 5-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 5-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 veterinary control 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 Administrations 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.
SECTION 2.3.

BOVINE DISEASES IN LIST B

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 Administration 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 paragraph 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 Administrations of importing countries should require:

for cattle for breeding or rearing (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) 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 \textit{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.

\textbf{Article 2.3.1.6.}

\textit{Veterinary Administrations} of \textit{importing countries} should require:

for cattle for slaughter (except castrated males)

the presentation of an \textit{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.

\textbf{Article 2.3.1.7.}

\textit{Veterinary Administrations} of \textit{importing countries} should require:

for bovine semen

the presentation of an \textit{international veterinary certificate} attesting that:

1) when the semen is from an \textit{artificial insemination centre}, the testing programme includes the buffered \textit{Brucella} antigen and complement fixation tests;

2) when the semen is not from an \textit{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 \textit{Brucella} antigen test with negative results during the 30 days prior to collection; or
Chapter 2.3.1. - Bovine brucellosis

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
d) showed no clinical sign of bovine brucellosis on the day of collection, were subjected to the buffered Brucella antigen and complement fixation tests with negative results during the 30 days prior to collection and no Brucella agglutinin was detected in the semen;

3) the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.1.

Article 2.3.1.8.

Veterinary Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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.

Standards for diagnostic tests are described in the Terrestrial Manual.

Article 2.3.3.2.

Country or zone officially free from bovine tuberculosis

To qualify as officially free from bovine tuberculosis, a country or zone shall satisfy the following requirements:

1) bovine tuberculosis is notifiable in the country;

2) 99.8% of the herds in the considered geographical area have been officially free from bovine tuberculosis for at least the past 3 years as disclosed by periodic testing of all cattle in the area to determine the absence of bovine tuberculosis (periodic testing of all cattle is not required in an area where a surveillance programme as described in point 4) below reveals that at least 99.9% of the cattle have been in herds officially free from tuberculosis for at least 6 years);

3) cattle introduced into a country or zone officially free from bovine tuberculosis must be accompanied by a certificate from an Official Veterinarian attesting that they come from a herd of cattle officially free from bovine tuberculosis or from a country or zone officially free from bovine tuberculosis;

4) a country or zone officially free from bovine tuberculosis must have a Veterinary Administration which should be able to trace and test the herd of origin of any reactor to a tuberculin test disclosed after removal from the considered territory. Also animals which disclosed gross pathological lesions of tuberculosis in an abattoir or elsewhere. In addition, such a country or zone must have in place a surveillance programme to ensure the discovery of bovine tuberculosis should the disease be present in the country or zone, through slaughter monitoring and/or tuberculin testing.

Article 2.3.3.3.

Herd officially free from bovine tuberculosis

To qualify as officially free from bovine tuberculosis, a herd of cattle shall satisfy the following requirements:

1) the herd is in a country or zone officially free from bovine tuberculosis; or

2) all cattle in the herd:
   a) show 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;
3) **cattle introduced into the herd:**

   a) must be accompanied by a certificate from an **Official Veterinarian** attesting that they were subjected to a tuberculin test during the 30 days prior to entry into the herd, with negative result; or

   b) were kept in a herd officially free from bovine tuberculosis.

**Article 2.3.3.4.**

**Veterinary Administrations of importing countries** should require:

for cattle for breeding or rearing

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) were isolated for the 3 months prior to shipment and were subjected to the test for bovine tuberculosis with negative results on two occasions, with an interval of not less than 60 days between each test; 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 officially free from bovine tuberculosis; or

4) were subjected to the tuberculin test for bovine tuberculosis with negative results during the 30 days prior to shipment and come from a country or zone officially free from bovine tuberculosis.

**Article 2.3.3.5.**

**Veterinary Administrations of importing countries** should require:

for cattle for slaughter

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

1) were subjected to a tuberculin test for bovine tuberculosis with negative results during the 30 days prior to shipment;

2) were kept in a herd officially free from bovine tuberculosis; or

3) were kept in a country or zone officially free from bovine tuberculosis.

This certificate may be complemented in paragraphs 2) and 3) by:

4) are not being eliminated as part of an eradication programme against bovine tuberculosis.

**Article 2.3.3.6.**

**Veterinary Administrations of importing countries** should require:

for wild bovines destined for zoological gardens

the presentation of an **international veterinary certificate** attesting that the animals were subjected to a tuberculin test for bovine tuberculosis with negative results during the 30 days prior to shipment.
Article 2.3.3.7.

Veterinary Administrations 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 bovine tuberculosis on the day of shipment; and/or

2) were subjected to a tuberculin test for bovine tuberculosis with negative results, the test being performed on the posterior aspect of the base of the ear (the result should be read after 48 hours); and/or

3) were kept in a country, zone or herd officially free from bovine tuberculosis.

Article 2.3.3.8.

Veterinary Administrations 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 country, zone or herd officially free from bovine tuberculosis;

2) are not being eliminated as part of an eradication programme against bovine tuberculosis.

Article 2.3.3.9.

Veterinary Administrations of importing countries should require:

for semen of cattle and pigs

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 isolated in the establishment of origin during the 3 months prior to collection and were subjected to a tuberculin test for bovine tuberculosis with negative results on two occasions, with an interval of not less than 60 days between each test; or
   c) were kept in the exporting country for the 30 days prior to collection, in an establishment or artificial insemination centre where all animals are officially free from bovine tuberculosis;

2) the semen was collected, processed and stored in conformity with the provisions of either Appendix 3.2.1. or Appendix 3.2.3.
Article 2.3.3.10.  
(under study)

Veterinary Administrations of importing countries should require:

for embryos/ova of cattle and pigs

the presentation of an international veterinary certificate attesting that the donor females:

1) and all other susceptible animals in the herd of origin showed no clinical sign of bovine tuberculosis during the 24 hours prior to departure to the collection centre;

2) were kept in a herd officially free from bovine tuberculosis;

3) were isolated in the establishment of origin for the 30 days prior to departure to the collection centre and were subjected to a tuberculin test for bovine tuberculosis with negative results.

Article 2.3.3.11.

Veterinary Administrations of importing countries should require:

for fresh meat of cattle and pigs

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 for bovine tuberculosis with favourable results.
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;
Chapter 2.3.4. - Enzootic bovine leukosis

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 1)a), 1)c) and 1)d) 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 1)b) above with negative results at least 4 months after removal of the positive animals and their progeny.

Article 2.3.4.4.

Veterinary Administrations 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 Administrations 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 Administrations 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 Appendices 3.3.1., 3.3.2. or 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 vullovaginitis (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 vullovaginitis

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 vullovaginitis

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 points a) or 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 Administrations 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 1)c) 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 Administrations 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) came 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Appendices 3.3.1., 3.3.2. or 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 the 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 Administrations 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 Administrations 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 Administrations 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.

Article 2.3.13.2.

The BSE status of the cattle population of a country or zone can only be determined on the basis of the following criteria:

1) the outcome of a risk assessment identifying all potential factors for BSE occurrence and their historic perspective, in particular:
   a) the potential for introduction and recycling of the BSE agent through consumption by cattle of meat-and-bone meal or greaves of ruminant origin;
   b) importation of meat-and-bone meal or greaves potentially contaminated with a transmissible spongiform encephalopathy (TSE) or feedstuffs containing either;
   c) importation of animals or embryos/oocytes (other than cattle embryos described in Article 2.3.13.8.) potentially infected with a TSE;
   d) epidemiological situation concerning all animal TSE in the country or zone;
   e) extent of knowledge of the population structure of cattle, sheep and goats in the country or zone;
   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) on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of cattle to encourage reporting of all cases of neurological disease in adult cattle;

3) compulsory notification and investigation of all cattle showing clinical signs compatible with BSE;

4) a BSE surveillance and monitoring system with emphasis on risks identified in point 1) above, taking into account the guidelines in Appendix 3.8.4.; records of the number and results of investigations should be maintained for at least 7 years;

5) examination in an approved laboratory of brain or other tissues collected within the framework of the aforementioned surveillance system.

Standards for diagnostic tests are described in the Terrestrial Manual.
Article 2.3.13.3.

BSE free country or zone

The cattle population of a country or zone may be considered free of BSE should the following conditions be met:

1) a risk assessment, as described in point 1) of Article 2.3.13.2., 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;

2) either:
   a) there has been no case of BSE; and either:
      i) the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 7 years; or
      ii) the criteria in point 3) of Article 2.3.13.2. have been complied with for at least 7 years and it has been demonstrated that for at least 8 years no meat-and-bone meal or greaves have been fed to ruminants;

OR

b) all cases of BSE have been clearly demonstrated to originate directly from the importation of live cattle, and the affected cattle as well as, if these are females, their last progeny born within 2 years prior to, or after, clinical onset of the disease, if alive in the country or zone, have been slaughtered and completely destroyed; and either:
   i) the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 7 years; or
   ii) the criteria in point 3) of Article 2.3.13.2. have been complied with for at least 7 years and it has been demonstrated that for at least 8 years no meat-and-bone meal or greaves have been fed to ruminants;

OR

c) the last indigenous case of BSE was reported more than 7 years ago, the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 7 years and the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants has been banned and the ban has been effectively enforced for at least 8 years.

Article 2.3.13.4.

BSE provisionally free country or zone

The cattle population of a country or zone may be considered as provisionally free of BSE should the following conditions be met:

1) a risk assessment, as described in point 1) of Article 2.3.13.2., 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;

2) either:
   a) there has been no case of BSE; and either:
      i) the criteria in points 2) to 5) of Article 2.3.13.2. are complied with, but have not been complied with for 7 years; or
      ii) it has been demonstrated that for at least 8 years no meat-and-bone meal or greaves have been fed to ruminants, but the criteria in point 3) of Article 2.3.13.2. have not been complied with for 7 years;
OR

b) all cases of BSE have been clearly demonstrated to originate directly from the importation of live cattle, and the affected cattle as well as, if these are females, all their progeny born within 2 years prior to, and after, clinical onset of the disease, if alive in the country or zone, have been slaughtered and completely destroyed; and either:

i) the criteria in points 2) to 5) of Article 2.3.13.2. are complied with, but have not been complied with for 7 years; or

ii) it has been demonstrated that for at least 8 years no meat-and-bone meal or greaves have been fed to ruminants, but the criteria in point 3) of Article 2.3.13.2. have not been complied with for 7 years.

Article 2.3.13.5.

Country or zone with a minimal BSE risk

The cattle population of a country or zone may be considered as presenting a minimal BSE risk should the country or zone comply with the following requirements:

1) a risk assessment, as described in point 1) of Article 2.3.13.2., 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;

2) EITHER:

a) the last indigenous case of BSE was reported more than 7 years ago, the criteria in points 2) to 5) of Article 2.3.13.2. are complied with and the ban on feeding ruminants with meat-and-bone meal and greaves derived from ruminants is effectively enforced, but:

i) the criteria in points 2) to 5) of Article 2.3.13.2. have not been complied with for 7 years; or

ii) the ban on feeding ruminants with meat-and-bone meal and greaves derived from ruminants has not been effectively enforced for 8 years;

OR

b) the last indigenous case of BSE has been reported less than 7 years ago, and the BSE incidence rate, calculated on the basis of indigenous cases, has been less than one case per million during each of the last four consecutive 12-month periods within the cattle population over 24 months of age in the country or zone (Note: For countries with a population of less than one million adult cattle, the maximum allowed incidence should be expressed in cattle-years.), and:

i) the ban on feeding ruminants with meat-and-bone meal and greaves derived from ruminants has been effectively enforced for at least 8 years;

ii) the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 7 years;

iii) the affected cattle as well as:

- if these are females, all their progeny born within 2 years prior to, and after, clinical onset of the disease, if alive in the country or zone, when slaughtered or at death, are completely destroyed, and

- all cattle which, during their first year of life, were reared with the affected cattle during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, or

- where the results of an investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the affected cattle if alive in the country or zone, when slaughtered or at death, are completely destroyed.
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Article 2.3.13.6.

Country or zone with a moderate BSE risk

The cattle population of a country or zone may be considered as presenting a moderate BSE risk if:

1) a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted, and the other criteria listed in Article 2.3.13.2. are complied with;

2) the BSE incidence rate has been:

   a) if based only on surveillance in accordance with Article 3.8.4.2., greater than or equal to, one indigenous case per million and less than or equal to, one hundred indigenous cases per million within the cattle population over 24 months of age in the country or zone calculated over the past 12 months; or

   b) if based on surveillance in accordance with Article 3.8.4.2., Article 3.8.4.3. and Article 3.8.4.4., greater than, or equal to, one indigenous case per million and less than, or equal to, two hundred indigenous cases per million within the cattle population over 24 months of age in the country or zone calculated over the past 12 months; or

   c) less than one indigenous case per million for less than four consecutive 12-month periods (Note: For countries with a population of less than one million adult cattle, the maximum allowed incidence should be expressed in cattle-years);

3) the affected cattle as well as:

   a) if these are females, all their progeny born within 2 years prior to, and after, clinical onset of the disease, if alive in the country or zone, when slaughtered or at death, are completely destroyed, and

   b) all cattle which, during their first year of life, were reared with the affected cattle during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, or

   c) where the results of an investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the affected cattle, if alive in the country or zone, when slaughtered or at death, are completely destroyed.

Countries and zones where the BSE incidence rate has been less than one indigenous case per million within the cattle population over 24 months of age during each of the last four consecutive 12-month periods, but where at least one of the other requirements to be considered as provisionally free from BSE or as presenting a minimal BSE risk is not complied with, shall be considered as countries or zones with a moderate BSE risk.

Article 2.3.13.7.

Country or zone with a high BSE risk

The cattle population of a country or zone may be considered as presenting a high BSE risk if it cannot demonstrate that it meets the requirements of another category.

Article 2.3.13.8.

Regardless of the BSE status of the exporting country, Veterinary Administrations should authorise without restriction the import or transit through their territory of the following commodities:

1) milk and milk products;
2) semen and in vivo derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;

3) protein-free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;

4) dicalcium phosphate (with no trace of protein or fat);

5) hides and skins;

6) gelatin and collagen prepared exclusively from hides and skins.

**Article 2.3.13.9.**

When importing from a BSE free country or zone, Veterinary Administrations should require:

for all commodities from cattle not listed in Article 2.3.13.8.

the presentation of an international veterinary certificate attesting that the country or zone complies with the conditions in Article 2.3.13.3. to be considered as free of BSE.

**Article 2.3.13.10.**

When importing from a BSE provisionally free country or zone, Veterinary Administrations should require:

for cattle

the presentation of an international veterinary certificate attesting that:

1) the country or zone complies with the conditions in Article 2.3.13.4. to be considered as provisionally free of BSE;

2) cattle selected for export are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE suspect females.

**Article 2.3.13.11.**

When importing from a country or zone with a minimal BSE risk, Veterinary Administrations should require:

for cattle

the presentation of an international veterinary certificate attesting that:

1) the country or zone complies with the conditions in Article 2.3.13.5. to be considered as presenting a minimal BSE risk;

2) the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants has been banned and the ban has been effectively enforced;

3) cattle selected for export:

   a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE suspect or confirmed females;

   b) were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants has been effectively enforced.
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Article 2.3.13.12.

When importing from a country or zone with a moderate BSE risk, Veterinary Administrations should require:

for cattle

the presentation of an international veterinary certificate attesting that:

1) the country or zone complies with the conditions in Article 2.3.13.6. to be considered as presenting a moderate BSE risk;

2) the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants has been banned and the ban has been effectively enforced;

3) cattle selected for export:
   a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE suspect or confirmed females;
   b) were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants has been effectively enforced.

Article 2.3.13.13.

When importing from a country or zone with a high BSE risk, Veterinary Administrations should require:

for cattle

the presentation of an international veterinary certificate attesting that:

1) the country or zone complies with the conditions in Article 2.3.13.7. to be considered as presenting a high BSE risk;

2) the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants has been banned and the ban has been effectively enforced;

3) all affected cattle as well as:
   a) if these are females, all their progeny born within 2 years prior to, and after, clinical onset of the disease, if alive in the country or zone, when slaughtered or at death, are completely destroyed, and
   b) all cattle which, during their first year of life, were reared with the affected cattle during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, or
   c) where the results of an investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the affected cattle, if alive in the country or zone, when slaughtered or at death, are completely destroyed;

4) cattle selected for export:
   a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE suspect or confirmed females;
   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 2.3.13.14.

When importing from a BSE provisionally free country or zone, Veterinary Administrations should require:

*for fresh meat* (bone-in or deboned) and *meat products* from cattle

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

1) the country or zone complies with the conditions in Article 2.3.13.4. to be considered as provisionally free of BSE;

2) ante-mortem inspection is carried out on all cattle from which the meat or *meat products* destined for export originate.

Article 2.3.13.15.

When importing from a country or zone with a minimal BSE risk, Veterinary Administrations should require:

*for fresh meat* (bone-in or deboned) and *meat products* from cattle

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

1) the country or zone complies with the conditions in Article 2.3.13.5. to be considered as presenting a minimal BSE risk;

2) ante-mortem inspection is carried out on all cattle from which the meat or *meat products* destined for export originate;

3) cattle from which the meat or *meat products* destined for export originate 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 (laceration, after stunning, of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity);

4) the *fresh meat* and *meat products* destined for export do not contain brain, eyes, spinal cord or mechanically separated meat from skull and vertebral column from cattle over 30 months of age, all of which have been removed in a hygienic manner.

Article 2.3.13.16.

When importing from a country or zone with a moderate BSE risk, Veterinary Administrations should require:

*for fresh meat* (bone-in or deboned) and *meat products* from cattle

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

1) the country or zone complies with the conditions in Article 2.3.13.6. to be considered as presenting a moderate BSE risk;

2) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;

3) ante-mortem inspection is carried out on all bovines;
4) cattle from which the meat or meat products destined for export originate 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;

5) the fresh meat and meat products destined for export do not contain brain, eyes, spinal cord, distal ileum or mechanically separated meat from skull and vertebral column from cattle over 6 months of age, all of which have been removed in a hygienic manner.

Article 2.3.13.17.

When importing from a country or zone with a high BSE risk, Veterinary Administrations should require:

for fresh meat and meat products from cattle

the presentation of an international veterinary certificate attesting that:

1) the country or zone complies with the conditions in Article 2.3.13.7. to be considered as presenting a high BSE risk;

2) the meat destined for export does not contain the tissues listed in point 1) of Article 2.3.13.19., all of which have been removed in a hygienic manner;

3) the meat destined for export, if obtained from animals over 9 months of age, has been deboned and does not contain nervous and lymphatic tissues exposed during a deboning process, all of which have been removed in a hygienic manner;

4) the meat products destined for export are derived from deboned meat and do not contain the tissues listed in point 1) of Article 2.3.13.19. nor nervous and lymphatic tissues exposed during a deboning process, nor mechanically separated meat from skull and vertebral column of bovine animals, all of which have been removed in a hygienic manner;

5) a system is in operation enabling the fresh meat and meat products destined for export to be traced back to the establishments from which they are derived;

6) ante-mortem inspection is carried out on all bovines;

7) the cattle from which the meat or meat products destined for export originate:

   a) were identified by a permanent identification system enabling them to be traced back to the dam and herd of origin;

   b) are not the progeny of BSE suspect or confirmed females; and either:

      i) were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants has been effectively enforced; or

      ii) were born, raised and had remained in herds in which no case of BSE had been confirmed for at least 7 years;

   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;

8) the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants has been banned and the ban has been effectively enforced;
9) the affected cattle as well as:

a) if these are females, all their progeny born within 2 years prior to, and after, clinical onset of the disease, if alive in the country or zone, when slaughtered or at death, are completely destroyed, and

b) all cattle which, during their first year of life, were reared with the affected cattle during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, or

c) where the results of an investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the affected cattle, if alive in the country or zone, when slaughtered or at death, are completely destroyed.

Article 2.3.13.18.
Ruminant-derived meat-and-bone meal or greaves, or any commodities containing such products, which originate from countries with a minimal, moderate or high BSE risk should not be traded between countries.

Article 2.3.13.19.
1) From cattle originating from a country or zone with a high BSE risk, that were at the time of slaughter over 6 months of age, 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, tonsils, thymus, spleen, intestines, dorsal root ganglia, trigeminal ganglia, skull and vertebral column, and derived protein products. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

2) From cattle, originating from a country or zone with a moderate BSE risk, that were at the time of slaughter over 6 months of age, 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, distal ileum, skull, vertebral column and derived protein products. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

3) From cattle, originating from a country or zone with a minimal BSE risk, that were at the time of slaughter over 30 months of age, 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 and spinal cord, skull, vertebral column and derived protein products. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

Article 2.3.13.20.
Veterinary Administrations of importing countries should require:

for gelatin 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 the bones came from:

1) a BSE free or provisionally free country or zone, or from a country or zone with a minimal BSE risk; or
2) a country or zone with a moderate BSE risk; and
   a) skulls and vertebrae (excluding tail vertebrae) have been excluded;
   b) the bones have been subjected to a process which includes all the following steps:
      i) pressure washing (degreasing),
      ii) acid demineralisation,
      iii) prolonged alkaline treatment,
      iv) filtration,
      v) sterilisation at $\geq 138^\circ C$ for a minimum of 4 seconds,
   or to an equivalent process in terms of infectivity reduction.

Article 2.3.13.21.

Veterinary Administrations of importing countries should require:

for tallow (other than protein-free tallow as defined in Article 2.3.13.8.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an international veterinary certificate attesting that it originates from:

1) a BSE free or provisionally free country or zone, or
2) a country or zone with a minimal BSE risk, and it originates from cattle which have been subjected to an ante-mortem inspection for BSE with favourable results and has not been prepared using the tissues listed in point 3 of Article 2.3.13.19., or
3) a country or zone with a moderate BSE risk, and it originates from cattle which have been subjected to an ante-mortem inspection for BSE with favourable results and has not been prepared using the tissues listed in point 2 of Article 2.3.13.19.

Article 2.3.13.22.

Veterinary Administrations of importing countries should require:

for tallow derivatives (other than those made from protein-free tallow as defined in Article 2.3.13.8.) 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 BSE free or provisionally free country or zone, or from a country or zone with a minimal BSE risk;

OR

2) they have been produced by hydrolysis, saponification or transesterification using high temperature and pressure.

Article 2.3.13.23.

Careful selection of source materials is the best way to ensure maximum safety of ingredients or reagents of bovine origin used in the manufacture of medicinal products.

Countries wishing to import bovine materials for such purposes should therefore consider the following factors:
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1) the BSE status of the country and herd(s) where the animals have been kept, as determined under the provisions of Articles 2.3.13.2. to 2.3.13.7.;

2) the age of the donor animals;

3) the tissues required and whether or not they will be pooled samples or derived from a single animal.

Additional factors may be considered in assessing the risk from BSE, including:

4) precautions to avoid contamination during collection of tissues;

5) the process to which the material will be subjected during manufacture;

6) the amount of material to be administered;

7) the route of administration.
SECTION 2.4.

SHEEP AND GOAT DISEASES IN LIST B

CHAPTER 2.4.1.

OVINE EPIDIDYMITIS

(\textit{Brucella ovis})

Article 2.4.1.1.

Standards for diagnostic tests and vaccines are described in the \textit{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 \textit{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.

\textit{Veterinary Administrations} of \textit{importing countries} should require:

for sheep for breeding or rearing (except castrated males)

the presentation of an \textit{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 \textit{establishment} of origin for the 30 days prior to shipment and were subjected to the diagnostic tests for \textit{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 \textit{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 Administrations 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 *B. 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;
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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 1)(d) 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 1)d) 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 3.2.2.

Article 2.4.2.9.

*Veterinary Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 kept in a CCPP free country since birth or for at least 3 months.
Chapter 2.4.6. - Contagious caprine pleuropneumonia

Article 2.4.6.6.
When importing from CCPP free countries, Veterinary Administrations 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 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 Administrations 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 Administrations 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 Administrations* 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 Administrations* 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 Administrations 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 Administrations 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 Chapter 1.3.6;
b) a Veterinary Administration 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 XXX (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 3.8.5.;

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 Administration, 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 Administrations 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 Administrations should require:
Chapter 2.4.8. - Scrapie

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for sheep and goats for breeding or rearing
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 Administrations should require:
for sheep and goats for slaughter
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 Administrations 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 3.2.2.

Article 2.4.8.9.
When importing from countries or zones not considered free from scrapie, Veterinary Administrations 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 Administrations 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 Administrations 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.
SECTION 2.5.

EQUINE DISEASES IN LIST B

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 Administrations of importing countries should require:

for stallions and mares considered free from CEM (for countries where an official control organisation is present)

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 Administrations of importing countries should require:

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)

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 Administrations should require:

for equines

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 Administrations should require:

for equines

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 Administrations 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 Administrations 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 Administrations 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 Administrations of importing countries should require:

for equines imported on a permanent basis

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;

2) for breeding animals only, no case of EIA has been associated with any premises where the animals were kept during the 3 months prior to shipment;

3) the animals were subjected to a diagnostic test for EIA with negative results during the 30 days prior to shipment.

Article 2.5.4.3.

Veterinary Administrations of importing countries should require:

for equines imported on a temporary basis

the presentation of an international veterinary certificate attesting that:

1) the animals showed no clinical sign of EIA on the day of shipment and during the 48 hours prior to shipment;

2) no case of EIA has been associated with any premises where the animals were kept during the 3 months prior to shipment;

3) the animals were subjected to a diagnostic test for EIA with negative results during the 30 days prior to shipment (the negative response to the serological test remains valid for 120 days).
CHAPTER 2.5.5.

EQUINE INFLUENZA

Article 2.5.5.1.

For the purposes of the Terrestrial Code, the infective period for equine influenza shall be 14 days and the incubation period 5 days.

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

Article 2.5.5.2.

Equine influenza free country

1) Qualification

To qualify as free from equine influenza, a country must satisfy the following requirements:

a) the disease is notifiable;

b) vaccination against equine influenza is not authorised, except for equines intended for export;

c) no clinical case of the disease has been reported for at least one year;

d) a serological survey has been carried out on a representative sample of the equine population of the country (excluding imported vaccinated equines) sufficient to provide at least a 99% level of confidence of detecting the disease if it is present at a prevalence rate exceeding 5%.

2) Maintenance of free status

For a country to maintain its status as free from equine influenza:

a) no clinical case of the disease has been reported since the achievement of the serological survey referred to in point 1)d) above;

b) all imported equines comply with the provisions of Article 2.5.5.3.

Article 2.5.5.3.

Veterinary Administrations of equine influenza free importing countries should require:

for equines

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

1) come from an equine influenza free country; or

2) meet the following conditions:

a) the animals were kept in isolation for 4 weeks prior to shipment and showed no clinical sign of equine influenza during this period;
b) no new animal has been introduced into the isolation facilities during this period;

c) no animal in the isolation facilities showed clinical signs of equine influenza during the isolation period;

d) the animals have been vaccinated against both subtypes of equine influenza virus and have received a booster dose of vaccine not less than 2 weeks and not more than 8 weeks prior to shipment.
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 Administrations 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 (Babesia equi and B. caballi) with negative results during the 30 days prior to shipment;
3) were treated against ticks within the 7 days prior to shipment (the importing country may decide to import only during seasons when ticks are not active on its territory).

Article 2.5.6.3.

Veterinary Administrations 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 Administrations 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

Article 2.5.7.1.

Standards for diagnostic tests are described in the Terrestrial Manual.

Article 2.5.7.2.

Veterinary Administrations 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 rhinopneumonitis 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 rhinopneumonitis was officially 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 confirmed for at least the last 2 years.

When importing equines for immediate slaughter from an infected country (see Article 2.5.8.5.), a glanders free country will not be considered as infected if one of the imported equines is found infected.

The conditions for such imports will require direct transport of the animals from the place of disembarkation to a designated abattoir and completion of cleansing and disinfection of the means of transport, the lairages and the abattoir immediately after use. These conditions should be prescribed and enforced by the Veterinary Administration.

Article 2.5.8.3.

When importing from glanders free countries, Veterinary Administrations should require:

for equines

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

1) showed no clinical evidence of glanders on the day of shipment;

2) were kept since birth, or for the past 6 months prior to shipment, in the exporting country; or

3) were subjected to the mallein test and/or the complement fixation test for glanders with negative results during the 15 days prior to shipment.

Article 2.5.8.4.

When importing from countries considered infected with glanders, Veterinary Administrations should require:

for equines

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 officially reported during that period;

3) were subjected to the mallein test and the complement fixation test for glanders with negative results during the 15 days prior to shipment.

Article 2.5.8.5.

When importing from countries considered infected with glanders, Veterinary Administrations should require:

for equines for immediate slaughter

the presentation of an international veterinary certificate attesting that the animals showed no clinical sign of glanders on the day of shipment. (See also Article 2.5.8.2.)
CHAPTER 2.5.9.

HORSE POX

Article 2.5.9.1.

Veterinary Administrations 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 mares and geldings. The health status of seropositive stallions should be checked to ensure that they do not shed equine arteritis virus in their semen.

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

Article 2.5.10.2.

Veterinary Administrations of importing countries should require:

for uncastrated male equines imported on a temporary basis for breeding or on a permanent basis

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 two diagnostic tests for EVA on blood samples at least 14 days apart with negative results during the 28 days prior to shipment; or

3) were subjected between 6 and 12 months of age to a diagnostic test for EVA on a blood sample with negative results, immediately vaccinated for EVA and regularly revaccinated; or

4) have been subjected to a diagnostic test for EVA with positive results and then:
   a) either were subsequently test mated to two mares which were subjected to two diagnostic tests with negative results on blood samples collected at the time of test mating and again 28 days after the mating;
   b) or were subjected to a virus isolation test with negative results (under study), carried out on semen collected during the 28 days prior to shipment.

Article 2.5.10.3.

Veterinary Administrations of importing countries should require:

for uncastrated male equines imported on a temporary basis other than for breeding, and for equines other than uncastrated males

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 during the 28 days prior to shipment to two diagnostic tests on blood samples collected not less than 14 days apart which demonstrated negative results or stable or declining antibody titres;

3) were subjected between 6 and 12 months of age to a diagnostic test for EVA on a blood sample with negative results, immediately vaccinated for EVA and regularly revaccinated.
Chapter 2.5.10. - Equine viral arteritis

Article 2.5.10.4.

*Veterinary Administrations of importing countries* should require:

**for fresh semen**

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

1) were kept for the 30 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 12 months of age to a diagnostic test for EVA on a blood sample with negative results, immediately vaccinated for EVA and regularly revaccinated; or

4) were subjected to a diagnostic test for EVA on a blood sample with negative results within 14 days prior to semen collection, and had not been used for natural breeding from the time of the taking of the blood sample to the time of semen collection; or

5) have been subjected to a diagnostic test for EVA with positive results and then:

   a) either were test mated within one year prior to semen collection to two mares which showed negative results to two diagnostic tests on blood samples collected at the time of test mating and again 28 days after the test mating,

   b) or were subjected to a virus isolation test with negative results (under study), carried out on semen collected within one year prior to collection of the semen to be exported.

Article 2.5.10.5.

*Veterinary Administrations of importing countries* should require:

**for frozen semen**

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

1) showed no clinical sign of EVA on the day of semen collection;

2) were subjected to a diagnostic test for EVA on a blood sample with negative results not less than 14 days after semen collection; or

3) were subjected between 6 and 12 months of age to a diagnostic test for EVA on a blood sample with negative results, immediately vaccinated for EVA and regularly revaccinated; or

4) have been subjected to a diagnostic test for EVA with positive results and then:

   a) either were test mated within one year prior to, or as soon as possible after, semen collection to two mares which showed negative results to two diagnostic tests on blood samples collected at the time of test mating and again 28 days after the test mating;

   b) or were subjected to a virus isolation test with negative results (under study), carried out on semen collected within one year prior to collection of the semen to be exported, or on 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 Administrations 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 Administrations 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 Administrations of importing countries should require:

for domestic and wild equines

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 Administrations 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 Administrations 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.

JAPANESE ENCEPHALITIS

Article 2.5.14.1.

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 2.5.14.2.

When importing from countries or zones infected with Japanese encephalitis, Veterinary Administrations 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.
SECTION 2.6.

SWINE DISEASES IN LIST B

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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 3.2.3.
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 Administrations 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 Administrations* 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 Administrations* 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 Administrations* 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.**
Chapter 2.6.3. - Enterovirus encephalomyelitis

When importing from countries considered infected with enterovirus encephalomyelitis, Veterinary Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administration 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 Administrations 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 Administrations 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 Administrations 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 3.2.3.
SECTION 2.7.

AVIAN DISEASES IN LIST B

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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations* 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 Administrations* 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations of importing countries should require:
for batching eggs of domestic birds
the presentation of an international veterinary certificate attesting that the batching 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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 Administrations 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.
SECTION 2.8.
LAGOMORPH DISEASES IN LIST B

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 Administrations 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 Administrations 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.

TULAREMIA

Article 2.8.2.1.
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 2.8.2.2.

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 2.8.2.3.

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 2.8.2.4.

Veterinary Administrations of tularemia free countries may prohibit importation or transit through their territory, from countries considered infected with tularemia, of live hares.

Article 2.8.2.5.

When importing from countries considered infected with tularemia, Veterinary Administrations should require:

for live hares

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.
CHAPTER 2.8.3.

RABBIT HAEMORRHAGIC DISEASE

Article 2.8.3.1.

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 2.8.3.2.

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 2.8.3.3.

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 2.8.3.4.

Veterinary Administrations 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.
Chapter 2.8.3. - Rabbit haemorrhagic disease

Article 2.8.3.5.

When importing from RHD free countries, Veterinary Administrations of importing countries should require:

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

Article 2.8.3.6.

When importing from RHD free countries, Veterinary Administrations 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 2.8.3.7.

When importing from countries considered infected with RHD, Veterinary Administrations 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 2.8.3.8.

When importing from countries considered infected with RHD, Veterinary Administrations 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 2.8.3.9.

When importing from countries considered infected with RHD, Veterinary Administrations 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 2.8.3.10.

When importing from countries considered infected with RHD, Veterinary Administrations 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 2.8.3.11.

When importing from countries considered infected with RHD, Veterinary Administrations 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 establishments 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 2.8.3.12.

When importing from RHD free countries, Veterinary Administrations 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 2.8.3.13.

When importing from countries considered infected with RHD, Veterinary Administrations 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 IN LIST B

CHAPTER 2.9.1.

ACARIOSIS OF BEES

Article 2.9.1.1.

For the purposes of the Terrestrial Code, the incubation period for acariosis of bees shall be 60 days (not including the wintering period which may vary according to country).

Standards for diagnostic tests are described in the Terrestrial Manual.

Article 2.9.1.2.

Veterinary Administrations of importing countries should require:

for bees (worker bees, queen bees and drones)

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

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

2) were raised in and come from an apiary controlled and approved for at least the past 2 years by the Veterinary Authority responsible for the application of the sanitary measures and special breeding techniques referred to in Appendix 3.4.2.;

3) come from an apiary which satisfies the requirements for sanitary surveillance referred to in Appendix 3.4.2.
CHAPTER 2.9.2.

AMERICAN FOULBROOD

Article 2.9.2.1.

For the purposes of the Terrestrial Code, the incubation period for American foulbrood shall be 45 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.

Veterinary Administrations of importing countries should require:

for brood-combs and accompanying bees (worker bees, queen bees and drones)

the presentation of an international veterinary certificate attesting that:

1) the brood-combs showed no clinical sign of American foulbrood on the day of shipment;

2) the brood-combs and accompanying bees:

   a) come from an apiary controlled and approved for at least the past 2 years by the Veterinary Authority responsible for the application of the sanitary measures and special breeding techniques referred to in Appendix 3.4.2.;

   b) come from an apiary which satisfies the requirements for sanitary surveillance referred to in Appendix 3.4.2.
CHAPTER 2.9.3.

EUROPEAN FOULBROOD

Article 2.9.3.1.

For the purposes of the Terrestrial Code, the incubation period for European foulbrood shall be 45 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.

Veterinary Administrations of importing countries should require:

for brood-combs and accompanying bees (worker bees, queen bees and drones)

the presentation of an international veterinary certificate attesting that:

1) the brood-combs showed no clinical sign of European foulbrood on the day of shipment;

2) the brood-combs and accompanying bees:

   a) come from an apiary controlled and approved for at least the past 2 years by the Veterinary Authority responsible for the application of the sanitary measures and special breeding techniques referred to in Appendix 3.4.2.;

   b) come from an apiary which satisfies the requirements for sanitary surveillance referred to in Appendix 3.4.2.
CHAPTER 2.9.4.

NOSEMOSIS OF BEES

Article 2.9.4.1.

For the purposes of the Terrestrial Code, the incubation period for nosemosis of bees shall be 60 days (not including the wintering period which may vary according to country).

Standards for diagnostic tests are described in the Terrestrial Manual.

Article 2.9.4.2.

Veterinary Administrations of importing countries should require:

for bees (worker bees, queen bees and drones)

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

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

2) were raised in and come from an apiary controlled and approved for at least the past 2 years by the Veterinary Authority responsible for the application of the sanitary measures and special breeding techniques referred to in Appendix 3.4.2.;

3) come from an apiary which satisfies the requirements for sanitary surveillance referred to in Appendix 3.4.2.
CHAPTER 2.9.5.

VARROOSIS

Article 2.9.5.1.

For the purposes of the Terrestrial Code, the incubation period for varroosis shall be 9 months (not including the wintering period which may vary according to country).

Standards for diagnostic tests are described in the Terrestrial Manual.

Article 2.9.5.2.

Veterinary Administrations of importing countries should require:

for brood-combs and accompanying bees (worker bees, queen bees and drones)

the presentation of an international veterinary certificate attesting that:

1) the brood-combs showed no clinical sign of the presence of Varroa on the day of shipment;

2) the brood-combs and accompanying bees:
   a) come from hives in which all colonies, during the export period, were subjected to special diagnostic tests which did not reveal any sign of the presence of Varroa;
   b) come exclusively from an apiary situated in the centre of a zone of 50 kilometres in radius, in which special diagnostic tests have shown the absence of varroosis for at least the past 2 years;
   c) come from an apiary which satisfies the requirements for sanitary surveillance referred to in Appendix 3.4.2.
SECTION 2.10.

DISEASES NOT COVERED BY LIST A AND LIST B

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 Administration of the exporting country.

Most diseases referred to in this Chapter are not included in List A or List B, 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 Administrations of exporting countries should issue international veterinary certificates only upon presentation of valid CITES documentation.
Veterinary Administrations 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 Administrations 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 Administrations 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 Administration 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 Administrations 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 Administration 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 Appendix 3.5.1.

Article 2.10.1.3.

General certification and transportation requirements

Veterinary Administrations of importing countries should require:

for all non-human primates
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 Administrations 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 Appendix 3.5.1. 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 determined 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:

<table>
<thead>
<tr>
<th>Disease/agent</th>
<th>Animal groups</th>
<th>Schedule</th>
<th>Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hepatitis B</strong></td>
<td>Gibbons and great apes</td>
<td>First test during first week; second test after 3 to 4 weeks</td>
<td>Serological tests for anti-hepatitis B core antigen and for hepatitis B surface antigen, and additional parameters as appropriate.</td>
</tr>
<tr>
<td><strong>Tuberculosis</strong></td>
<td>Marmosets and tamarins, Prosimians, New World monkeys, Old World monkeys, gibbons and great apes</td>
<td>Two tests at an interval of 2 to 4 weeks</td>
<td>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.</td>
</tr>
<tr>
<td><strong>Other bacterial pathogens</strong> (Salmonella, Shigella, Yersinia and others as appropriate)</td>
<td>All species</td>
<td>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</td>
<td>Faecal culture. The fresh faeces or rectal swabs have to be cultured immediately or to be placed immediately in the transportation medium.</td>
</tr>
<tr>
<td><strong>Endo- and ectoparasites</strong></td>
<td>All species</td>
<td>At least two tests, one of which should be at the start, the other towards the end of the quarantine</td>
<td>Testing methods and antiparasitic treatment as appropriate to species of animal and parasitic agent.</td>
</tr>
</tbody>
</table>

In addition, Veterinary Administrations 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 Administrations 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 Administrations 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 Appendix 3.5.1. 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.:

<table>
<thead>
<tr>
<th>Disease/agent</th>
<th>Animal groups</th>
<th>Schedule</th>
<th>Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bacterial pathogens</strong></td>
<td>All species</td>
<td>Daily test for 3 days within the first 5 days after arrival</td>
<td>Faecal culture. (See further comments in the Table of Article 2.10.1.4.)</td>
</tr>
<tr>
<td><em>(Salmonella, Shigella, Yersinia and others as appropriate)</em></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Endo- and ectoparasites</strong></td>
<td>All species</td>
<td>At least two tests, one of which should be at the start, the other towards the end of the quarantine</td>
<td>Testing methods and antiparasitic treatment as appropriate to species of animal and parasitic agent.</td>
</tr>
</tbody>
</table>

*Veterinary Administrations 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 Administrations 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:

<table>
<thead>
<tr>
<th>Disease/agent</th>
<th>Animal groups</th>
<th>Schedule</th>
<th>Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tuberculosis</td>
<td>All species</td>
<td>One test</td>
<td>Skin test or serology. (See further comments in the Table of Article 2.10.1.4.)</td>
</tr>
<tr>
<td>Other bacterial pathogens</td>
<td>All species</td>
<td>Daily test for 3 days within the first 5 days after arrival, and another test at least 1 week later</td>
<td>Faecal culture. (See further comments in the Table of Article 2.10.1.4.)</td>
</tr>
<tr>
<td>Endo- and ectoparasites</td>
<td>All species</td>
<td>At least two tests, one of which should be at the start, the other towards the end of the quarantine</td>
<td>Testing methods and antiparasitic treatment as appropriate to species of animal and parasitic agent.</td>
</tr>
</tbody>
</table>
Veterinary Administrations 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 Administrations 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 Administrations 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 Administrations 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.
SECTION 3.1.

DIAGNOSTIC TESTS FOR INTERNATIONAL TRADE PURPOSES

APPENDIX 3.1.1.

PRESCRIBED AND ALTERNATIVE DIAGNOSTIC TESTS FOR LIST A AND LIST B 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 disease on List A and List B, 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**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agent id.</td>
<td>Agent identification</td>
</tr>
<tr>
<td>Agg.</td>
<td>Agglutination test</td>
</tr>
<tr>
<td>AGID</td>
<td>Agar gel immunodiffusion</td>
</tr>
<tr>
<td>BBAT</td>
<td>Buffered <em>Brucella</em> antigen test</td>
</tr>
<tr>
<td>CF</td>
<td>Complement fixation (test)</td>
</tr>
<tr>
<td>DTH</td>
<td>Delayed-type hypersensitivity</td>
</tr>
<tr>
<td>ELISA</td>
<td>Enzyme-linked immunosorbent assay</td>
</tr>
<tr>
<td>FAVN</td>
<td>Fluorescent antibody virus neutralisation</td>
</tr>
<tr>
<td>FPA</td>
<td>Fluorescence polarisation assay</td>
</tr>
<tr>
<td>HI</td>
<td>Haemagglutination inhibition</td>
</tr>
<tr>
<td>IFA</td>
<td>Indirect fluorescent antibody (test)</td>
</tr>
<tr>
<td>MAT</td>
<td>Microscopic agglutination test</td>
</tr>
<tr>
<td>NPLA</td>
<td>Neutralising peroxidase-linked assay</td>
</tr>
<tr>
<td>PCR</td>
<td>Polymerase chain reaction</td>
</tr>
<tr>
<td>PRN</td>
<td>Plaque reduction neutralisation</td>
</tr>
<tr>
<td>VN</td>
<td>Virus neutralisation</td>
</tr>
<tr>
<td>_</td>
<td>No test designated yet</td>
</tr>
</tbody>
</table>
### Appendix 3.1.1. - Prescribed and alternative diagnostic tests

#### Terrestrial Code chapter No. | Terrestrial Manual chapter No. | Disease name | Prescribed tests | Alternative tests
--- | --- | --- | --- | ---

| List A diseases |
|---|---|---|---|---|
| 2.1.1. | 2.1.1. | Foot and mouth disease* | ELISA, VN | CF |
| 2.1.2. | 2.1.2. | Vesicular stomatitis | CF, ELISA, VN | _ |
| 2.1.3. | 2.1.3. | Swine vesicular disease | VN | ELISA |
| 2.1.4. | 2.1.4. | Rinderpest | ELISA | VN |
| 2.1.5. | 2.1.5. | Peste des petits ruminants | VN | ELISA |
| 2.1.6. | 2.1.6. | Contagious bovine pleuropneumonia | CF | ELISA |
| 2.1.7. | 2.1.7. | Lumpy skin disease | _ | VN |
| 2.1.8. | 2.1.8. | Rift Valley fever | _ | HI, ELISA, PRN |
| 2.1.9. | 2.1.9. | Bluetongue | Agent id., AGID, ELISA, PCR | VN |
| 2.1.10. | 2.1.10. | Sheep pox and goat pox | _ | VN |
| 2.1.11. | 2.1.11. | African horse sickness | CF, ELISA | VN |
| 2.1.12. | 2.1.12. | African swine fever | ELISA | IFA |
| 2.1.13. | 2.1.13. | Classical swine fever | NPLA, FAVN, ELISA | _ |
| 2.1.14. | 2.1.14. | Highly pathogenic avian influenza | _ | AGID, HI |
| 2.1.15. | 2.1.15. | Newcastle disease | _ | HI |

| List B 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 |
### Appendix 3.1.1. - Prescribed and alternative diagnostic tests

#### List B diseases (cont.)

<table>
<thead>
<tr>
<th>Terrestrial Code chapter No.</th>
<th>Terrestrial Manual chapter No.</th>
<th>Disease name</th>
<th>Prescribed tests</th>
<th>Alternative tests</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cattle</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.3.1.</td>
<td>2.3.1.</td>
<td>Bovine brucellosis</td>
<td>BBAT, CF, ELISA</td>
<td>FPA</td>
</tr>
<tr>
<td>2.3.2.</td>
<td>2.3.2.</td>
<td>Bovine genital campylobacteriosis</td>
<td>Agent id.</td>
<td>_</td>
</tr>
<tr>
<td>2.3.3.</td>
<td>2.3.3.</td>
<td>Bovine tuberculosis</td>
<td>Tuberculin test</td>
<td>_</td>
</tr>
<tr>
<td>2.3.4.</td>
<td>2.3.4.</td>
<td>Enzootic bovine leukosis</td>
<td>AGID, ELISA</td>
<td>PCR</td>
</tr>
<tr>
<td>2.3.5.</td>
<td>2.3.5.</td>
<td>Infectious bovine rhinotracheitis/ infectious pustular vulvovaginitis</td>
<td>VN, ELISA, Agent id. (semen only)</td>
<td>_</td>
</tr>
<tr>
<td>2.3.6.</td>
<td>2.3.6.</td>
<td>Trichomonosis</td>
<td>Agent id.</td>
<td>Mucus agg.</td>
</tr>
<tr>
<td>2.3.7.</td>
<td>2.3.7.</td>
<td>Bovine anaplasmosis</td>
<td>_</td>
<td>CF, Agg. card</td>
</tr>
<tr>
<td>2.3.8.</td>
<td>2.3.8.</td>
<td>Bovine babesiosis</td>
<td>_</td>
<td>ELISA, IFA</td>
</tr>
<tr>
<td>2.3.9.</td>
<td>2.3.9.</td>
<td>Bovine cisticercosis</td>
<td>_</td>
<td>Agent id.</td>
</tr>
<tr>
<td>2.3.11.</td>
<td>2.3.11.</td>
<td>Theileriosis</td>
<td>Agent id., IFA</td>
<td>_</td>
</tr>
<tr>
<td>2.3.12.</td>
<td>2.3.12.</td>
<td>Haemorrhagic septicaemia</td>
<td>_</td>
<td>Agent id.</td>
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* Please refer to Terrestrial Manual chapters to verify which method is prescribed.
SECTION 3.2.
COLLECTION AND PROCESSING OF SEMEN

APPENDIX 3.2.1.
BOVINE 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 having negligible risk of infecting other animals or humans with specific pathogenic organisms that can be transmitted by semen;
2. ensure that semen is hygienically collected, processed and stored.

The disease position in one country generally differs from that in another, thus prophylactic programmes vary widely in the range of organisms for which donor bulls and teaser animals are tested before admission to an artificial insemination centre, while in isolation, and periodically after full admission into the stud.

Article 3.2.1.2.

Conditions applicable to artificial insemination centres

1. The artificial insemination centre is comprised of:
   a) bull accommodation areas (including one isolation facility for sick bulls) and a semen collection room, these two premises hereon designated as semen collection facilities;
   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 Administration.

3. The centre should be under the supervision and control of the Veterinary Authority 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 bulls 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 Administration 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 fully health tested resident bulls, semen collection, feed storage, manure storage, and isolation of suspect bulls.

2. Only bovines 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 bulls or security, provided that they are kept physically apart from the bovines when not being used and when bovine semen is being collected. All bovine animals resident at the semen collection facilities must meet the minimum health requirements for donor bulls.

3. Bovines 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.

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. Trucks and vehicles used for transport of animals to and from the semen collection facilities should not be allowed to enter the facilities.

7. The bull 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 can enter an artificial insemination centre only if they fulfil the requirements laid down by the Veterinary Administration.

1. Pre-quarantine testing

Bovines must appear healthy and normal and must comply with the following requirements prior to entry into isolation at the quarantine station prior to entering the semen collection facilities.

a) Bovine brucellosis

The animals should comply with the provisions referred to in point 3 or 4 of Article 2.3.1.5. of the Terrestrial Code.

b) Bovine tuberculosis

The animals should comply with the provisions referred to in point 3 or 4 of Article 2.3.3.4. of the Terrestrial Code.

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.

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, bovines must 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 and Trichomonas foetus, for which testing may commence after at least 7 days in quarantine, and 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 animals test positive, these animals 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.

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 ELISA 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 bovines resident in the semen collection facilities

All bovines resident in the semen collection facilities should be tested at least annually for the following diseases, with negative results:

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) *Trichomonas foetus*
   i) A preputial swab 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.

f) 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.

General considerations for hygienic collection and handling of semen

1. Observation of the recommendations described in the articles below should result in the production of semen almost free from common bacteria which are potentially pathogenic. Micro-organisms found in semen are mostly saprophytic species, but pathogens such as *Actinomyces pyogenes bovis*, *Staphylococcus aureus*, *Streptococi* (Lancefield groups A and D), *Escherichia coli* and *Pseudomonas aeruginosa* may also be present.

2. These recommendations apply to bulls kept in artificial insemination centres under official supervision, which implies adoption of the recommendations referred to above.

3. These recommendations take account of the following considerations:

   a) there is no scientific information which demonstrates a significant correlation between the size of the population of common bacteria normally present in semen and fertility; the latter does not seem to be affected by the abundance of this population;
b) investigations of cows, whether during oestrus, or during the luteal phase on the occasion of embryo transfer, have revealed a population of common bacteria in the cervix and uterus, particularly in multiparous cows, qualitatively and quantitatively similar to that found in the male prepuce; however, the introduction of large numbers or particular combinations of such an exogenous microflora may weaken immune defenses, leading to an infectious process.

4. Excessive contamination of semen may be avoided by the application of these recommendations.

Bacterial counts (CFU/ml) carried out on the processed semen give a useful indication of the hygienic standard of the semen laboratory. The count should not exceed $5 \times 10^3$ per ml.

**Article 3.2.1.7.**

**Conditions applicable to the management of bulls**

The objective is to keep bulls in a satisfactory state of cleanliness, particularly of the lower thorax and abdomen.

1. Whether on pasture or housed, the bull 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 bull should be kept clean and generally short.

3. 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 bull is brought into the collection area, the technician must make sure that the bull 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.

**Article 3.2.1.8.**

**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 bull'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 70% ethyl or 98-99% isopropyl 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 bull 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 3.2.1.9.

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) 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.
   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 IU), 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 it arrives in the laboratory, 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 sterilised with alcohol, ethylene oxide, steam or other approved sterilisation 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)*.

Containers should be sealed with an official numbered seal under the responsibility of the Veterinary Administration before export and accompanied by an international veterinary certificate listing the contents.

**Article 3.2.1.10.**

**Method of counting the micro-organisms in semen**

1. To measure the extent of contamination of a sample of semen by the common microflora, by a standardised method, it is important to observe a number of rules for handling samples within the microbiological laboratory.

2. These rules concern:
   a) appropriate media for dilution and counting;
   b) thawing and diluting procedures;
   c) inoculation and incubation of the cultures;
   d) method of calculating the total count;
   e) mode of expressing the results.

3. Recommendations for the technique of counting micro-organisms present in semen are as follows:
   a) Media
      i) **Dilution media**
         This is composed of buffered peptone water made up as follows:
         - peptone 10.0 g
         - NaCl 85.5 mM (5.0 g)
         - Na₂HPO₄·12H₂O 25.1 mM (9.0 g)
         - KH₂PO₄ 11.0 mM (1.5 g)
         - Distilled water to 1,000 ml
         - pH = 7.0 ± 0.2 (25°C)

         This solution is placed in 10 ml screw-capped tubes each containing 3.6 or 9 ml of solution, then it is sterilised in the autoclave for 20 minutes at 121°C.
      
      ii) **Agar for counting**
         Tryptic soy agar is prepared as follows:
         - Bacto Tryptone (pancreatic digest of casein) 15.0 g
         - Bacto Soytone (papaic digest of soyabean meal) 5.0 g
         - NaCl 85.5 mM (5.0 g)
         - Bacto Agar 15.0 g
         - Anhydrous glucose 5.6 mM (1.0 g)
         - Distilled water to 1,000 ml
         - pH = 7.0 ± 0.2 (25°C)
This is placed in 30 ml flasks and then sterilised in the autoclave for 20 minutes at 121°C. It is then cooled to 45°C before use.

For use the following are added under sterile precautions:

- 5-10% inactivated, sterile bovine serum (56/58°C for 30 minutes)
- 5% sterile erythrocyte extract
- 3 ml SPS (sodium polyanethol sulphate) 5% solution.

iii) White or plain agar

Prepared from 9-18 g agar-agar (according to source), made up to 1,000 ml with distilled water.

b) Method of preparing dilutions of semen

i) Thawing

Prepare one tube containing 3.6 ml dilution media and four tubes containing 9 ml.

The samples of semen are kept in liquid nitrogen until required. They are then thawed in a water bath at 37°C for 2 minutes before being transferred to cultures. Two semen samples from the same ejaculate are required for each analysis.

ii) Dilution

After thawing, rapidly dry the semen container then disinfect it with 70° ethyl or 98-99% isopropyl alcohol.

After opening, transfer the two semen samples into a sterile tube. Measure exactly 0.4 ml of semen and place this in the tube containing 3.6 ml of dilution medium (1:10 dilution). Mix the contents by stirring (vortex apparatus), then prepare dilutions of $10^{-2}$ to $10^{-5}$ in four tubes each containing 9 ml of dilution medium (1 ml + 9 ml).

c) Inoculation and incubation

Take 0.5 ml of each dilution and introduce under sterile conditions into each of four Petri dishes, 9-10 cm diameter.

Add to each Petri dash about 15 ml of counting agar cooled to 45°C. Mix by circular agitation. Allow to solidify on a level surface.

In order to prevent invasion of the culture medium by certain saprophytic bacteria, the surface of the inoculated and cooled medium may be covered with 4 ml of white (plain) agar cooled to 45°C, if there is room.

Incubate the dishes for 48-72 hours at 37°C.
d) Counting and method of calculation

After 72 hours of incubation at 37°C, the colonies are counted by the standard procedure, selecting for the purpose the dilution which contains between 30 and 300 colony-forming units (CFU) per dish.

The method of calculation is that specified in the current International Standard (ISO 4833).

e) Expression of the results

Record the number of CFU counted. Multiply by the dilution factor. Express the results as the number of micro-organisms or CFU per sample or per ml of semen.

* 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.

SMALL RUMINANT SEMEN

Article 3.2.2.1.

Conditions applicable to artificial insemination centres

1. The centre should be under the direct supervision of a veterinarian approved by the Veterinary Administration.

2. These centres should be built so as to ensure total isolation, thus preventing any contact with animals on the outside, and so as to facilitate the cleaning and disinfecting of the various installations.

   Each centre should comprise at least the following distinct installations:

   a) housing and isolation of animals;
   b) semen collection room or mounting area;
   c) room for cleaning, disinfection and storage of artificial vaginas;
   d) laboratory where the semen is prepared, which should contain separate facilities for cleaning and sterilisation (glassware, etc.);
   e) storage room;
   f) room for the distribution of semen.

3. Only personnel at the centre and the Veterinary Authority are permitted to enter installations where animals are housed or the laboratory area; no other person may do so unless authorised and supervised by the centre veterinarian.

   The personnel shall not enter either the animal section or the laboratory section without first removing outdoor clothing and putting on clothing which is specific to each section.

   Only animals having attained a health status equivalent to that of the population of the centre (see below) shall be allowed to enter the centre. Any vehicles used for their transport must remain outside.

   Lastly, no vehicle or material from outside the centre shall be allowed within the closed area of the animal section, other than new materials to be used exclusively within the centre.

4. Artificial insemination centres situated in areas where viral vector-borne diseases occur should be constructed and managed in such a way to protect the animals from vectors, or semen collection should only take place during seasons when the vectors are at low level of activity.

5. The artificial insemination centres must be subjected to regular inspections at least twice a year by the official Veterinary Authority.

6. They must be supervised so as to ensure that only sheep and goats with the required health status are housed therein and that only authorised personnel may enter, after passing through a suitable cloakroom area.
7. A register shall be kept of all the animals present, giving for each animal its identification, date of birth, date of entry, date of departure or death, breed and all the diagnostic test results, vaccinations and treatments carried out.

8. The good condition of the animals and the hygiene of the premises including the mounting area should be carefully checked.

Article 3.2.2.2.

Conditions applicable to the introduction of donor animals

1. Only duly identified animals from a quarantine station accredited by the Veterinary Administration are authorised to enter the centres.
   These animals should have spent a minimum of 30 days in the quarantine station where they should not have been in contact with any animal which did not give negative results to the tests referred to below.

2. The animals should originate from flocks which are not subjected to any movement restrictions on health grounds. The flocks must have been free from diseases that are notifiable, free or officially free from caprine and ovine brucellosis and free from clinical signs of the following diseases:
   a) contagious agalactia (Mycoplasma agalactiae), for at least 6 months;
   b) peste des petits ruminants, contagious caprine pleuropneumonia, caseous lymphadenitis and ovine epididymitis, for at least 12 months;
   c) paratuberculosis, for at least 2 years;
   d) scrapie, pulmonary adenomatosis and maedi-visna or caprine arthritis/encephalitis (CAE), for at least 3 years.

3. During quarantine, the animals must be subjected to a clinical examination, in particular to check the integrity of their reproductive organs and their good health status.
   The results of the microscopic examination of their semen must be compatible with artificial insemination usage. Authorisation should not be given for the dissemination of semen collected in the quarantine station.
   The animals must be subjected to the following diagnostic tests with negative results in countries considered infected:
   a) for tuberculosis (for goats only), single or comparative tuberculin test;
   b) for caprine and ovine brucellosis, a buffered antigen test coupled with a complement fixation test;
   c) for ovine epididymitis, a complement fixation test coupled with culture of a semen sample;
   d) for maedi-visna or CAE, a serological test;
   e) for Border disease, a virus isolation test;
   f) for contagious caprine pleuropneumonia (for goats only), a serological test;
   g) for bluetongue, a serological test (under study).
4. Animals leaving a quarantine station for an artificial insemination centre must be free from any clinical signs of disease and must originate from a quarantine station which meets the following conditions on the day of departure:
   a) be situated at the centre of a 10-km zone in which there has been no case of foot and mouth disease and peste des petits ruminants for at least 30 days;
   b) be free from notifiable diseases of the species concerned.

Article 3.2.2.3. Testing programme for donor animals

All animals housed in an artificial insemination centre shall undergo, with favourable results, the following examinations and controls at least twice a year:

1. clinical examination, with particular attention being given to the reproductive organs (testicular and epididymal palpation);
2. microscopic examination of semen and examination of any somatic cells present; in the event of any anomalies, a microbe count with qualitative detection of specific micro-organisms should be carried out;
3. diagnostic tests in countries considered infected:
   a) for caprine and ovine brucellosis;
   b) for ovine epididymitis, serological tests coupled with culture of a semen sample;
   c) for maedi-visna or CAE;
   d) for tuberculosis (for goats only), single or comparative tuberculin test;
   e) for bluetongue.

Should any of the above tests or examinations give unfavourable results, the accreditation for export of the centre should be suspended and the animal concerned must be isolated and eliminated as quickly as possible and its semen collected since the date of the last negative examination eliminated. This semen may be sent to the official veterinary laboratories for further investigations if necessary.

The health status of the remaining animals in the centre should be reviewed by the Veterinary Authority and, if relevant, appropriate procedures for the restoration of its accreditation should be carried out.

Article 3.2.2.4. Conditions applicable to the collection, processing, packing and storage of semen

1. Only semen collected in the centre may be processed therein.
2. The collection, handling, packing and storage of semen should be carried out exclusively in the areas set aside for this purpose.
3. Any equipment coming into contact with semen or the donor animal during collection, processing or packing must be suitably cleansed, disinfected and sterilised immediately after use.
4. Any products of animal origin used in the treatment of semen, including diluents and additives, shall originate from a source free from any health risks, or be treated prior to use to render the products safe.
5. Receptacles used for storage and transport must be suitably disinfected and sterilised before the start of any filling operation.

6. Where a cryogenic agent is used, this should not previously have been used for other products of animal origin.

7. Each individual dose of semen shall be clearly marked to enable the date of collection of the semen, the identity of the donor animal, and the name of the centre to be easily ascertained, if necessary by means of a code.

Article 3.2.2.5.

Conditions applicable to trade in semen

Semen intended for use in trade must:

1. have been collected in an accredited centre duly supervised as described above, and in which there were no case of foot and mouth disease or peste des petits ruminants within a radius of 10 kilometres during the 3 months prior to and the 30 days following collection;

2. come from animals which:
   a) spent an uninterrupted period of at least 30 days prior to and 30 days after collection in the centre;
   b) showed no clinical sign of disease during that period;
   c) were not used for natural service during the 30 days prior to collection;

3. have been securely stored, for at least 30 days before shipment, in receptacles which were cleansed, disinfected and sterilised before use and which left the storage place duly sealed.

An international veterinary certificate attesting compliance with the above conditions must accompany the semen, suitably identified, during transport. The names and concentrations of antibiotics included in the semen diluent should be stated in the certificate.
APPENDIX 3.2.3.

PORCINE SEMEN

Article 3.2.3.1.

Conditions applicable to artificial insemination centres

1. The centre should be officially approved by the Veterinary Administration.

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 Administration, 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 3.2.3.2.

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 Administration.

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 3.2.3.3.

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 3.2.3.3. Boars may only enter the stud on the successful completion of these tests and must be clinically healthy.
Appendix 3.2.3. - Porcine semen

Article 3.2.3.3.

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)* Brucellosis (B. abortus, B. suis)

Boars to give negative results to serological tests in accordance with the Terrestrial Manual.

3. Routine tests

a)* Swine vesicular disease

Boars to give negative results to a serum-neutralisation test in accordance with the Terrestrial Manual (see also Articles 2.1.3.9. and 2.1.3.10. of the Terrestrial Code).

Routine tests to be applied at least every 12 months.

b)* African swine fever

Boars to give negative results to enzyme-linked immunosorbent assay and indirect immunofluorescent tests in accordance with the Terrestrial Manual (see also Articles 2.1.12.10. and 2.1.12.11. of the Terrestrial Code).

Routine tests to be applied at least every 6 months.

c)* Enterovirus encephalomyelitis (ex Teschen disease)

Boars to meet certification standards in Articles 2.6.3.9. or 2.6.3.10. of the Terrestrial Code.

Routine tests to be applied at least every 12 months.

d)* Vesicular stomatitis

Boars to give negative results to a complement fixation test in accordance with the Terrestrial Manual.

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 3.2.3.4.

Optional tests and requirements

Artificial insemination centres may be required by the Veterinary Administration 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 the 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 3.2.3.5.

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 3.2.3.6.

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 Administration. 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.

* 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 the 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 Administration 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*.
   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., Appendix 3.2.2. or Appendix 3.2.3., 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*, 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**. 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 viruses (e.g. bovine herpesvirus-1, and Aujeszky’s disease virus) is required, the standard washing procedure should be modified to include additional washes with the enzyme trypsin, as described in the IETS Manual**.
   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** and handled in such a manner as to ensure that sterility is maintained. Antibiotics should be added to collection, processing, washing and storage media as recommended in the IETS Manual**.

2. Equipment

a) All equipment used to collect, handle, wash, freeze and store embryos should be sterilized prior to use as recommended in the IETS Manual**.

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** 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**).

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**. 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 Administration 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**.

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 health 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 Administrations.

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.

* Based on available research and field information, the Research Subcommittee of the International Embryo Transfer Society (IETS) has categorized 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.

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)**.

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 Administration 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.
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** 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**.

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**.

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. 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 Administration 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**.

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.

* Where transportation of in vitro maturing (IVM) oocytes is intended, the conditions outlined in this Appendix are also applicable.


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 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)* 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* 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. **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*.

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 the 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** 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*.
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.


** 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* 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**.

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** 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**.

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***.

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**. 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.
Appendix 3.3.4. - Laboratory rodent and rabbit embryos/ova

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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APPENDIX 3.3.5.

CATEGORISATION OF DISEASES AND PATHOGENIC AGENTS BY THE INTERNATIONAL EMBRYO TRANSFER SOCIETY

Article 3.3.5.1.

In 2002, the Research Subcommittee of the International Embryo Transfer Society (IETS) Health and Safety Advisory Committee 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.

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*.

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*, 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*, 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:
Appendix 3.3.5. - Categorisation of diseases and pathogenic agents by the IETS

– 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)
– 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 on which preliminary work has been conducted or is in progress.

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 O9:K99 (cattle)
– Leptospira borgpetersenii serovar hardjo (cattle)
– Leptospira sp. (swine)
– Maedi-visna (sheep)
– Mycobacterium bovis (cattle)
– Mycobacterium paratuberculosis (cattle)
– Mycoplasma spp. (swine)
– Parainfluenza-3 virus (cattle)
– Parvovirus (swine)
– Scrapie (goats)
– Ureaplasma/Mycoplasma spp. (cattle, goats)
– Vesicular stomatitis (cattle, swine).

SECTION 3.4.

HEALTH CONTROL AND HYGIENE 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 pelleted 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.
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 Authorities.

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 m³ 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.

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 m³ 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 ft³ of space; or 25 ml formalin to 12.5 g potassium permanganate per m³. 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 I. **Properties and uses of disinfectants**

<table>
<thead>
<tr>
<th>Properties</th>
<th>Chlorine</th>
<th>Iodine</th>
<th>Phenol</th>
<th>Quats</th>
<th>Formaldehyde</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bactericidal</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Bacteriostatic</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Fungicidal</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>±</td>
<td>+</td>
</tr>
<tr>
<td>Virucidal</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>±</td>
<td>+</td>
</tr>
<tr>
<td>Toxicity</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Activity with organic matter*</td>
<td>+++++</td>
<td>++</td>
<td>+</td>
<td>+++</td>
<td>+</td>
</tr>
</tbody>
</table>

**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
Monitorimg 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 II 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>
<thead>
<tr>
<th>Number of birds in the flock</th>
<th>Number of samples to be taken on each occasion</th>
</tr>
</thead>
<tbody>
<tr>
<td>25-29</td>
<td>20</td>
</tr>
<tr>
<td>30-39</td>
<td>25</td>
</tr>
<tr>
<td>40-49</td>
<td>30</td>
</tr>
<tr>
<td>50-59</td>
<td>35</td>
</tr>
<tr>
<td>60-89</td>
<td>40</td>
</tr>
<tr>
<td>90-199</td>
<td>50</td>
</tr>
<tr>
<td>200-499</td>
<td>55</td>
</tr>
<tr>
<td>500 or more</td>
<td>60</td>
</tr>
</tbody>
</table>

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 accommodation.
      Where birds are moved from the rearing premises other than direct to laying accommodation, 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 Authorities.
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 disinestation 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 Administration and should be performed either by representatives of this Administration 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 the 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 Administrations 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.
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.

QUARANTINE RECOMMENDATIONS

APPENDIX 3.5.1.

QUARANTINE MEASURES APPLICABLE TO NON-HUMAN PRIMATES

Article 3.5.1.1.

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. of Chapter 2.10.1., 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 3.5.1.2.

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 3.5.1.3.**

**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.
Appendix 3.5.1. - Quarantine measures applicable to non-human primates

Article 3.5.1.4.

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 3.5.1.5.

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, tranquilisation 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 Administration 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 3.6.
INACTIVATION OF PATHOGENS AND VECTORS

APPENDIX 3.6.1.
GENERAL RECOMMENDATIONS ON DISINFECTION AND DISINFESTATION

Article 3.6.1.1.

Veterinary Administrations 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 hydroxide (soda) or potassium hydroxide (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 1 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$_2$CO$_3$) 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$_2$CO$_3$).
APPENDIX 3.6.3.

TRANSMISSIBLE Spongiform Encephalopathy Agents Inactivation Procedures

Article 3.6.3.1.

Meat-and-bone meal

For the inactivation of transmissible spongiform encephalopathy agents for the production of meat-and-bone meal containing ruminant proteins, the following procedure should be used:

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.
SECTION 3.7.
TRANSPORT OF ANIMALS

APPENDIX 3.7.1.
PRINCIPLES APPLICABLE TO ALL FORMS OF TRANSPORT

Article 3.7.1.1.
The following factors should be taken into account by veterinarians in the supervision and control of the international transport of animals:

a) climate, temperature/humidity and time of day;
b) distance to be travelled and route;
c) mode of transport: air/rail/road/sea/roll-on~roll-off/on foot;
d) suitability of transport vehicle;
e) species of animals;
f) stocking density;
g) physiological status: fat/slaughter animal, store animal, pregnant/near to giving birth, age and sex, suckling, shorn/unshorn, horned/dehorned, lactating animals;
h) facilities and ability to feed/water on board transport, on the journey;
i) staging post facilities on the journey.

Article 3.7.1.2.

Pre-transport

1. Prior to the assembly of the animals, where necessary, provision should be made for the supply of suitable feed, water, bedding, veterinary equipment and medications for use during the pre-transport holding period, during the journeys and after arrival.

   Feed, water, bedding and medications should be of suitable quality and as far as possible free of pests and specified pathogens.

2. All premises used for pre-export quarantine or holding animals before a journey should:
   a) be constructed:
      i) in accordance with the physical and behavioural requirements of particular animal species;
Appendix 3.7.1. - Principles applicable to all forms of transport

ii) of material which allows satisfactory cleansing and disinfection between consignments;

iii) to allow adequate separation of consignments of differing health status;

iv) to enable feeding and watering to be undertaken when required;

v) with facilities for the carrying out of any necessary veterinary tests or treatments;

b) be under the supervision of the competent Veterinary Authorities and staffed with suitably trained attendants;

c) be provided with adequate lighting to enable the inspection and care of all animals.

Article 3.7.1.3.

Holding period before transport

1. Where required, this period will vary in length depending on:

   a) veterinary inspection tests, treatments and vaccination, either on farm or in quarantine, which should be carried out as agreed by the Veterinary Administrations of the exporting, importing and transit countries;

   b) the need to precondition the animals to change of feeding and watering practices; e.g. from grazing to pellet feeding, water trough to nipple drinker;

   c) the need for the detection and removal of animals unsuitable, for behavioural, physiological or health reasons, for the proposed journey;

   d) the time period of the proposed journeys;

   e) the need for a resting period for animals that have been transported to the holding premises.

2. During this period, selection of groups should be made based on compatible species and classes to ensure the well-being of the animals during transport.

3. The holding and/or pre-export quarantine premises should be located as close as possible to the point of departure.

4. Animals should be regularly inspected by a veterinarian or a suitably qualified person under veterinary authority to ensure that they remain fit to travel.

5. A record should be kept of the species, breed, age, sex and number of animals to be transported; including the name of the owner, place of departure and destination.

Article 3.7.1.4.

Type of transport

1. All crates, containers, vehicles, ships and aircraft should be of suitable construction and design so as not to cause injury or suffering, to provide adequate ventilation and allow inspection of all animals during transport and, where necessary, for feeding, watering and treatment. They should be subjected to prior inspection and approval by the competent Veterinary Authority.

2. They should be cleansed and disinfected, and where necessary disinsectised, before each journey.

3. They should be appropriate for the type and numbers of the animals to be transported taking into account their physical characteristics and behavioural needs.

4. Adequate light should be available for the inspection and care of animals.
Appendix 3.7.1. - Principles applicable to all forms of transport

Article 3.7.1.5.

Approval of route

Where necessary, prior approval of the route and all transit/rest stops should be obtained from the relevant authorities.

Article 3.7.1.6.

Loading and unloading

1. Animals should not be loaded until all required health and other necessary documentation has been obtained and completed. This documentation should accompany the consignment.

   Movement documentation should include:
   a) details of the animals;
   b) period of rest prior to journey;
   c) starting time.

2. Loading must be undertaken in a manner which causes minimum distress. All facilities must be of suitable construction and design so as to prevent injury.

3. Excessive use of force must be avoided.

4. When loading takes place over a long period of time (e.g. large consignments by sea), attention must be paid to the health and well-being of those animals already loaded.

5. Where applicable, loading should take place as near to the time of departure as possible.

6. Loading should be supervised, where possible, by a veterinarian. Animals found unfit to travel should be removed and loading density monitored.

7. Animals should be grouped on the basis of uniformity of size to be loaded into each vehicle or compartment.

8. Loading density: animals should be provided with adequate space in accordance with their size, physiological condition (e.g. pregnant animals), and behavioural characteristics. In addition, account should be taken of transport method and length of journey, the climatic conditions to be encountered during the journey and the environmental control available on the means of transport.

9. As unloading also presents problems to animals, attention should be paid to this operation.

Article 3.7.1.7.

During transport

1. Animals should be transported by the most appropriate method, taking the most direct route, that considers their physiological characteristics and the needs of disease control and to maintain their health and welfare. Provision should be made for emergency slaughter.

2. Restraint, including tethering, should only be considered where it is necessary for the welfare of the animal and its companions. Tranquilisation should only be used on the advice and under the direction of a veterinary surgeon.
3. During the journey when disposal of a body, manure or litter 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.

4. During the journey animals should be, where necessary, provided with suitable feed, water and care to maintain their health and welfare.

5. Animals shall be accompanied by a suitable number of adequately trained attendants (which may include the driver of a vehicle).

6. Drivers/attendants should:
   a) ensure the provision of rest, food, water, bedding and veterinary assistance as required;
   b) ensure ventilation is adequate especially at stops;
   c) inspect the animals at frequent intervals;
   d) safeguard the maintenance of the health status of the consignment;
   e) keep a record of each journey in the movement documentation, to include disease problems, injuries and deaths, details of rest periods, transit stops, feeding, watering, treatments and veterinary inspections carried out during the journey.

7. Where possible throughout transport, every care should be taken not to subject the animals to sudden changes of speed or direction.

8. Animals should be rested at appropriate intervals, which, depending on the type of transport, may require unloading into suitable facilities (see point 2 of Article 3.7.1.2).

9. Where disinfestation is necessary, it should be carried out with the minimum of stress to the animals.

Article 3.7.1.8.

Veterinary accompaniment

Where consignments are not accompanied by a veterinarian, personnel accompanying the animal should be experienced in animal husbandry and should seek veterinary assistance whenever necessary.

Article 3.7.1.9.

After arrival

1. Suitable premises for receiving the animals (see point 2 of Article 3.7.1.2.) together with local transport should be available to expedite unloading of the number and types of animals arriving.

2. Where disposal of a body, manure or litter is 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.

3. Vehicles, crates, containers, etc., used to carry the animals should be cleansed and disinfected before reuse.
4. Particular care should be taken to protect the health and welfare of the animals during the period of acclimatisation to different environmental conditions including feed and water. Precautions should also be taken to protect the animals against local diseases.
APPENDIX 3.7.2.

PRINCIPLES APPLICABLE TO SPECIFIC FORMS OF TRANSPORT

Article 3.7.2.1.

Road transport

1. Head room should be sufficient to allow all animals to stand naturally.

2. In multi-tiered vehicles/containers, precautions should be taken to protect animals on lower tiers from the excrement from animals above.

3. Precautions should be taken to prevent litter or animal waste from escaping from the vehicle.

4. Ventilation:
   a) the construction of the vehicle/container should allow for adequate ventilation for the animals during transport;
   b) when parked, extra ventilation and protection from direct sun may be required;
   c) protection against extremes of weather must be provided.

5. The driving of vehicles should take account of the welfare of the animals being transported and drivers should not:
   a) rapidly accelerate or decelerate;
   b) corner at excessive speed;
   and should consider the best available routes and road conditions.

Article 3.7.2.2.

Rail transport

1. Drivers of trains carrying livestock should be made aware of their cargo and its particular needs.

2. Ventilation (see Article 3.7.2.1).

3. If qualified animal attendants are not able to travel with the animals, arrangements should be made for regular inspection, veterinary assistance and feeding and watering where necessary.

4. Railway trucks/containers carrying livestock:
   a) should not be left unattended;
   b) should be assembled, reassembled and moved with due care and attention to the welfare of animals.

Article 3.7.2.3.

Transport by water including sea, lake, canal and river

1. Food and water should be protected to avoid deterioration in quality.
2. Animals should be placed in accommodation which is:
   a) protected from adverse weather conditions;
   b) firmly secured to the vessel and situated away from potential hazards;
   c) adequately ventilated.

3. Precautions should be taken to prevent the transmission of disease both to and from livestock on shore.

4. Extra feed and water should be provided on board in case of mechanical breakdown or delay.

5. Separate accommodation on the vessel should be provided for segregation of animals requiring isolation.

**Article 3.7.2.4.**

**Roll-on-Roll-off**

1. The master of the vessel should be informed of the animal cargo.

2. In general, livestock vehicles should be loaded last and just prior to the departure of the vessel, unless the vehicle can be located in an adequately ventilated position.

3. Livestock vehicles should be firmly secured and situated in such a position on the vessel so that the animals are:
   a) not subjected to noxious gases;
   b) near to the vessel's own ventilation system;
   c) protected from the elements.

4. Special ventilation of the animal container may be required due to the vehicle being stationary within the vessel.

5. Regular inspection of animals by drivers/attendants should be undertaken during the voyage.

6. Where necessary, provision should be made for feeding and watering during the voyage.

**Article 3.7.2.5.**

**Movement on foot**

1. Groups of animals should be accompanied by a sufficient number of experienced drovers familiar with the route of the journey.

2. Movement should be undertaken in the most suitable climatic conditions for the animals.

3. Animals should be fed and watered at least once a day.

4. There should be opportunities for grazing during the journey.

5. Animals should not be driven at a speed greater than normal walking pace.
APPENDIX 3.7.3.

PRINCIPLES APPLICABLE TO AIR TRANSPORT OF SELECTED MAMMALIAN SPECIES

Article 3.7.3.1.

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 3.7.3.2.).

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.
Appendix 3.7.3. - Principles applicable to air transport of selected mammalian species

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 3.7.3.2.

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:

<table>
<thead>
<tr>
<th>Females</th>
<th>Maximum number of days since the last service or exposure to a male</th>
</tr>
</thead>
<tbody>
<tr>
<td>Horses</td>
<td>300</td>
</tr>
<tr>
<td>Cows</td>
<td>250</td>
</tr>
<tr>
<td>Deer (axis, fallow and sika)</td>
<td>170</td>
</tr>
<tr>
<td>(red deer, reindeer)</td>
<td>185</td>
</tr>
<tr>
<td>Ewes (sheep)</td>
<td>115</td>
</tr>
<tr>
<td>Nannies (goats)</td>
<td>115</td>
</tr>
<tr>
<td>Sows (pigs)</td>
<td>90</td>
</tr>
</tbody>
</table>

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 3.7.3.3.

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>
<thead>
<tr>
<th>Species</th>
<th>Weight/kg</th>
<th>Density/kg/m²</th>
<th>Space/animal/m²</th>
<th>No. of animals per 10 m²</th>
<th>Animals per single tier pallet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calves</td>
<td>50</td>
<td>220</td>
<td>0.23</td>
<td>43</td>
<td>26 / 31</td>
</tr>
<tr>
<td></td>
<td>70</td>
<td>246</td>
<td>0.28</td>
<td>36</td>
<td>22 / 25</td>
</tr>
<tr>
<td>Cattle</td>
<td>300</td>
<td>344</td>
<td>0.84</td>
<td>12</td>
<td>7 / 8</td>
</tr>
<tr>
<td></td>
<td>500</td>
<td>393</td>
<td>1.27</td>
<td>8</td>
<td>5 / 6</td>
</tr>
<tr>
<td></td>
<td>600</td>
<td>408</td>
<td>1.47</td>
<td>7</td>
<td>4 / 5</td>
</tr>
<tr>
<td></td>
<td>700</td>
<td>400</td>
<td>1.75</td>
<td>6</td>
<td>3 / 4</td>
</tr>
<tr>
<td>Sheep</td>
<td>25</td>
<td>147</td>
<td>0.20</td>
<td>50</td>
<td>31 / 36</td>
</tr>
<tr>
<td></td>
<td>70</td>
<td>196</td>
<td>0.40</td>
<td>25</td>
<td>15 / 18</td>
</tr>
<tr>
<td>Pigs</td>
<td>25</td>
<td>172</td>
<td>0.15</td>
<td>67</td>
<td>41 / 47</td>
</tr>
<tr>
<td></td>
<td>100</td>
<td>196</td>
<td>0.51</td>
<td>20</td>
<td>12 / 14</td>
</tr>
</tbody>
</table>

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 3.7.3.5.

Disinfection and disinfestation

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 removable 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. Disinfestation

Where disinfestation is required, the country requesting the action should be consulted for appropriate procedures.


Article 3.7.3.6.

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 3.7.3.7.

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 3.7.3.8.

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 3.7.3.9.

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 3.7.3.7.).
   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 3.7.3.10.

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 3.7.3.11.

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.
SECTION 3.8.

GENERAL PRINCIPLES AND SURVEILLANCE SYSTEMS FOR THE RECOGNITION OF THE DISEASE/INFECTION FREE STATUS

APPENDIX 3.8.1.

GENERAL PRINCIPLES FOR RECOGNISING A COUNTRY OR ZONE FREE FROM A GIVEN DISEASE/INFECTION

Article 3.8.1.1.

Introduction

The present Appendix provides general principles for declaring a country or zone free from disease/infection in relation to the time of last occurrence, and in particular for the recognition of historical freedom.

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 regionalisation.

The provisions of this Appendix are based on the principles developed in Chapter 1.3.6. and the following premises:

1. in the absence of disease and vaccination, the animal population would become susceptible over a period of time;
2. the disease agents to which these provisions apply are likely to produce identifiable clinical signs in susceptible animals;
3. competent and effective Veterinary Services will be able to investigate, diagnose and report disease, if present;
4. 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 the Veterinary Services of an OIE Member Country.

Article 3.8.1.2.

Requirements to declare a country or zone free from infection

1. Historically free

Unless otherwise specified in the relevant disease chapter, a country or zone may be recognised free from infection without formally applying a specific surveillance programme when:
Appendix 3.8.1. - General principles for recognising a country or zone free from a given disease/infection

Appendix 3.8.1. - General principles for recognising a country or zone free from a given disease/infection

a) there has never been occurrence of disease; or
b) 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 and to the present:
   c) it has been a notifiable disease;
   d) an early detection system has been in place;
   e) measures to prevent disease/infection introduction have been in place;
   f) no vaccination against the disease has been carried out;
   g) infection is not known to be established in wildlife.

2. Last occurrence between 10 and 25 years previously
For countries or zones that have achieved eradication (or in which the disease/infection has ceased to occur) between 10 and 25 years previously, in addition to the above conditions, appropriate specific surveillance must have been applied to demonstrate the absence of the agent.

3. Last occurrence within the past 10 years
Countries or zones that have achieved eradication within the past 10 years (or in which the disease/infection has ceased to occur) should follow the specific disease surveillance requirements in the Terrestrial Code if they exist or the general guidelines for surveillance outlined in the Terrestrial Code.

Freedom from infection, OIE list A and B diseases

Historically Free
   Meet requirements for freedom based on non-specific surveillance

Occurrence within last 10-25 years
   Meet requirements for freedom based on non-specific surveillance and
   Appropriate specific surveillance must be applied

Occurrence in past 10 years
   Specific OIE pathway if available
   General guidelines (when available)

Freedom from infection

Article 3.8.1.3.

Guidelines for the discontinuation of specific surveillance after recognition of freedom from infection
A country that has been recognised free from infection following the provisions of the Terrestrial Code may discontinue specific surveillance while maintaining the infection-free status provided that:

1. it is a notifiable disease;
2. an early detection system is in place;
3. measures to prevent disease/infection introduction are in place;
4. vaccination against the disease is not applied;
5. infection is known not to be established in wildlife.

Article 3.8.1.4.

International recognition of disease/infection free status

For diseases for which procedures exist whereby the OIE can officially recognise the existence of a disease free country or zone, a Member Country wishing to apply for recognition of this zone shall, via its Permanent Delegate, send the OIE all the relevant documentation relating to the zone. Such documentation should be presented according to guidelines prescribed by the OIE Scientific Commission for Animal Diseases.
APPENDIX 3.8.2.

RECOMMENDED STANDARDS FOR EPIDEMIOLOGICAL SURVEILLANCE SYSTEMS FOR RINDERPEST

1. Purposes of the document

The document describes the criteria:

a) to prove that a country or a zone is free from rinderpest, and
b) for the declaration of freedom from rinderpest.

2. Definition and purposes of surveillance

Disease surveillance is necessary to provide evidence that a country or region is free from a disease or an infection.

Disease surveillance should be implemented by both:

a) a system of reporting of any signs of disease activity that come to the notice of livestock owners or veterinarians, and
b) an active programme of examination of statistically selected samples from within host populations in order to detect clinical signs or other indications of the occurrence of disease or transmission of infection.

In either case, any suspicion of disease activity should be followed up 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.

3. Steps to be taken to declare a country to be free from rinderpest

The current goal of rinderpest control is to achieve freedom of countries and later of entire world regions from rinderpest 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 and livestock products, but face difficulties due to the presence or past occurrence of rinderpest.

A three-stage process of achieving and proving freedom from rinderpest is, therefore, envisaged. Once a country is satisfied that it is free from rinderpest and that the disease is unlikely to be re-introduced, the country can declare itself provisionally free from rinderpest provided it is satisfied that it meets the criteria listed below.

Subsequent steps are then subject to international verification under the auspices of the OIE. At least 3 years after a country has declared itself provisionally free from rinderpest, a country which meets the criteria stated below may be declared by the OIE to be free from rinderpest disease. At least one year later, a country which meets more stringent criteria with regard to rinderpest may be declared free from rinderpest infection.

The specific criteria proposed for each stage of this process are as follows:

a) Provisional freedom from rinderpest

For a country to declare itself or a zone within the country provisionally free from rinderpest, it must fulfil certain conditions, which are: (see Table 1)
Appendix 3.8.2. - Epidemiological surveillance systems for rinderpest

i) no clinical disease should have been detected for at least 2 years;

ii) there is an effective veterinary service which is able to monitor the animal health situation in the country;

iii) the service investigates all clinical evidence suggestive of rinderpest;

iv) there is an effective reporting system, both from the field to the central veterinary authority, and by that body to the OIE;

v) there is a reliable system for preventing the introduction of infection which is carried out by proper border control, quarantines, etc.;

vi) all vaccinations against rinderpest will cease by the date of the declaration. The OIE and neighbouring countries must be notified of this decision (in writing), giving the date from which vaccination ceased.

b) Freedom from rinderpest disease

A country or a zone which has not vaccinated against rinderpest for at least 5 years and has throughout that period had no evidence of rinderpest may be declared free from rinderpest disease by the OIE based on conclusions of the Foot and Mouth Disease and Other Epizootics Commission, provided that the country has had throughout that period and maintains permanently an adequate disease reporting system.

OR

A country which has declared itself, or a zone within the country, to be provisionally free from rinderpest may be declared by the OIE free from rinderpest disease provided that the following criteria are met: (see table 1)

i) no clinical rinderpest has been detected for at least 5 years;

ii) no rinderpest vaccines have been used for at least 3 years in any susceptible species, and no heterologous vaccines against rinderpest have been used for at least 3 years in cattle, buffaloes or yaks;

iii) the country operates both clinical surveillance and disease reporting systems for rinderpest adequate to detect clinical disease if it were present;

iv) all clinical evidence suggestive of rinderpest is investigated by field and laboratory methods (including serological assessment) to refute a possible diagnosis of rinderpest;

v) there are effective measures in force to prevent the re-introduction of the disease.

On meeting these criteria, a country may apply to the OIE to be declared free from rinderpest disease.

To maintain this status, a country must continue to meet these requirements until it is declared free from rinderpest infection, and must annually report a summary of developments to the OIE.

If it is not practical to achieve national freedom from rinderpest disease in a single step, a country may apply to the OIE for zones within the country to be declared free from rinderpest disease provided that:

i) each proposed zone has well-defined boundaries;

ii) the rinderpest disease free zone is separated from the rest of the country and from neighbouring infected countries by a surveillance zone, or physical or geographical barriers and zoosanitary measures which effectively prevent the entry of infection;

iii) no clinical rinderpest has been detected within the zone for at least 5 years;

iv) no rinderpest vaccines have been used for at least 3 years in any susceptible species, and no heterologous vaccines against rinderpest have been used for at least 3 years in cattle, buffaloes or yaks;

v) the country operates within the zone both clinical surveillance and disease reporting systems for rinderpest, adequate to detect clinical disease if it were present;
vi) all clinical evidence suggestive of rinderpest within the zone is investigated by field and laboratory methods (including serological assessment) to refute a possible diagnosis of rinderpest;

vii) there are effective measures in force to prevent the re-introduction of the disease into the zone from the remainder of the country and from other countries.

The declaration of zones to be free from rinderpest will not remove the requirement for the country to subsequently meet the criteria for declaration of freedom from rinderpest disease for the country as a whole; if it wishes to achieve that status, it will have to meet all the requirements specified earlier before it can apply for a declaration of freedom from rinderpest disease for the entire country.

Should there be a localised temporary outbreak of disease due to re-introduction of rinderpest to a country or zone which is within 2 years of meeting the requirements for declaration of freedom from rinderpest disease, that country may take special measures (including intensive perifocal vaccination) to eradicate the outbreak. In such circumstances, it will then require at least one year from the date of the last case or the last vaccination (whichever occurs later) before the country or zone becomes eligible to apply for a declaration of freedom from rinderpest disease.

In making such an application under these special circumstances, the country must satisfy the Foot and Mouth Disease and Other Epizootics Commission that the outbreak did not represent endemic infection and that the disease has been eradicated by the actions taken.

c) Freedom from rinderpest infection

A country which has not vaccinated against rinderpest for at least 10 years and has throughout that period had no evidence of rinderpest disease or rinderpest virus infection may be declared free from rinderpest infection by the OIE based on conclusions of the Foot and Mouth Disease and Other Epizootics Commission, provided that the country has had throughout that period and maintains permanently an adequate disease reporting system.

OR

A country which has either vaccinated against rinderpest within the last 10 years or has had clinical evidence of rinderpest, may be declared by the OIE to be free from rinderpest infection if the following criteria are met:

i) it should have been declared free from rinderpest disease at least one year earlier, and continues to meet the requirements for this status;

ii) there should have been an effective serosurveillance system in operation for a period of at least 2 years, and the findings must have been consistent with freedom from infection.

This serosurveillance must include other susceptible domestic stock in addition to cattle;

iii) investigations into infection in wild susceptible species must be carried out where these species occur in significant numbers. Where there are opportunities, sampling should be done when possible. Additional strategic sampling of domestic stock should be done in areas adjacent to large game populations to enhance the possibilities of detecting the presence of virus in the game. The findings must be consistent with freedom from infection.

On meeting these criteria, a country may apply to the OIE to be declared free from rinderpest infection.

Declaration of freedom from rinderpest infection can only be made for the country as a whole, and not for zones within a country.
Should there be a localised, temporary outbreak of disease due to re-introduction of rinderpest to a country which is within one year of meeting the requirements for declaration of freedom from rinderpest infection, that country may take special measures to stamp out the outbreak (excluding the use of vaccine). In such circumstances, the country must wait at least one year from the date of the last case before it becomes eligible to apply for declaration of freedom from rinderpest infection. During this year there should be an effective sero-surveillance system in operation in order to prove that the virus has not been disseminated.

In making such an application under these special circumstances, the country must satisfy the Foot and Mouth Disease and Other Epizootics Commission 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 reporting system which would detect rinderpest if it occurred.

Table 1. Requirements for the declaration of freedom from rinderpest disease and freedom from rinderpest infection

<table>
<thead>
<tr>
<th>Possible declarations</th>
<th>Intend to eradicate rinderpest</th>
<th>Provisional freedom from &quot;disease&quot;</th>
<th>Freedom from &quot;disease&quot;</th>
<th>Freedom from &quot;infection&quot;*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serological surveillance*</td>
<td>No clinical disease</td>
<td>No clinical disease and no vaccination</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* If a country wants to be declared free from rinderpest infection at the end of year 4, serological surveillance of unvaccinated animals must be in operation at the end of year 2, in order to prove that there has been no sero-positive case in the country for at least 2 years.

4. Epidemiological methods

a) 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 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 waterpoints. Sampling units should normally be defined so that their size is not less than 50 animals or more than 1,000.

b) Criteria for stratification of host populations

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.

c) 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 to be published in the OIE Scientific and Technical Review, 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 suspicion of disease should be evaluated using epidemiological and laboratory methods.

In carrying out serological surveillance for evidence of rinderpest, the sample size within selected herds shall be sufficient to provide 95% probability of detecting evidence of rinderpest if present in 5% of the animals eligible for serological testing. All animals born after the cessation of vaccination and more than one year old will be eligible for serological testing. Any positive result will be evaluated using epidemiological and laboratory methods to confirm or refute the suspicion of rinderpest virus activity.

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 detecting 1% between-herd prevalence is maintained. The procedures for calculating equivalent within-herd and between-herd sample sizes are described in the Guide to Epidemiological Surveillance for Rinderpest to be published by the OIE.

5. Diagnostic methods for rinderpest and rinderpest related viruses

Where clinical and/or serological surveillance is undertaken in nominally rinderpest-free populations, it is vital to have available a variety of laboratory tests and to use one or more of the methods described in the Terrestrial Manual.

National laboratories should be able to undertake tests for rinderpest antigen and antibody detection such as:

- for antigen detection the agar gel immunodiffusion test and/or the immunocapture ELISA for detection of rinderpest/PPR viruses;
- for serological surveillance the competitive ELISA.
If a national laboratory cannot perform virus isolation and identification, samples should always be sent to Reference Laboratories.

In any case, National Laboratories should submit representative samples to the Reference Laboratories for characterisation.

6. Evaluation of disease status

Evaluation of applications for the status of freedom from disease or freedom from infection will be the responsibility of the Foot and Mouth Disease and Other Epizootics Commission which, if necessary, will ask the Director General of the OIE to appoint an Expert Panel in order to reach an informed decision to present to the International Committee for approval.

The composition and method of selection of the Expert Panel shall be such as to ensure both a high level of expertise in evaluating the evidence and total independence of the Panel in reaching conclusions concerning the disease status of a particular country.
APPENDIX 3.8.3.

RECOMMENDED STANDARDS FOR
EPIDEMIOLOGICAL SURVEILLANCE SYSTEMS
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:

**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 Foot and Mouth Disease and Other Epizootics Commission. 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.
Appendix 3.8.3. - Epidemiological surveillance systems for contagious bovine pleuropneumonia

The Expert Panel will report its findings to the OIE Foot and Mouth Disease and Other Epizootics Commission. 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 accelerated eradication process is summarised in the following chart:

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;

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) 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.
Appendix 3.8.3. - Epidemiological surveillance systems for contagious bovine pleuropneumonia

a) **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.

b) **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.

c) **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.
d) 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.

e) 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 AND MONITORING SYSTEMS FOR BOVINE SPONGIFORM ENCEPHALOPATHY

Article 3.8.4.1.

Introduction

Surveillance for bovine spongiform encephalopathy (BSE) has at least two goals: to determine whether BSE is present in the country, and, if present, to monitor the extent and evolution of the epizootic, thus aiding control measures and monitoring their effectiveness.

The cattle population of a country or zone not free from BSE, will comprise the following sub-populations in order of decreasing size:

1. cattle not exposed to the infective agent;
2. cattle exposed but not infected;
3. infected cattle, which may lie within one of three stages in the progress of BSE:
   a) the majority will die or be killed before reaching a stage at which BSE is detectable by current methods;
   b) some will progress to a stage at which BSE is detectable by testing before clinical signs of disease appear;
   c) the smallest number will show clinical signs of disease.

Surveillance programmes should be determined by, and commensurate with the outcome of the risk assessment referred to in Article 2.3.13.2. and should take into account the diagnostic limitations associated with the above sub-populations and the relative distributions of infected animals among them.

Surveillance programmes developed before the advent of rapid diagnostic tests focused on the sub-population containing cattle displaying clinical signs compatible with BSE as described in Article 3.8.4.2. While surveillance should focus on this sub-population, investigation of other sub-populations using the new diagnostic techniques may provide a more accurate picture of the BSE situation in the country or zone. A surveillance strategy may therefore need to combine several strategies. Recommended strategies for surveying the various sub-populations are described below.

Available data suggest the possibility that a gradient might be established to describe the relative value of surveillance applied to each sub-population. All countries should sample sub-populations identified in Articles 3.8.4.2. and 3.8.4.3. In countries where surveillance of cattle identified in Article 3.8.4.2. is unable to generate the numbers recommended in Table 1, surveillance should be enhanced by testing larger numbers of cattle identified in Article 3.8.4.3. Any shortfall in the first two sub-populations should be addressed by the sampling of normal cattle over 30 months of age at slaughter. Exclusive dependence on random sampling from normal cattle is not recommended, unless the number of samples examined annually is statistically sufficient to detect a disease prevalence of 1 in 1,000,000.

Surveillance for BSE requires laboratory examination of samples in accordance with the methods described in the Terrestrial Manual.

For surveillance purposes, testing a part of the population is consistent with Chapter 1.3.6. on surveillance and monitoring of animal health.
Article 3.8.4.2.

Examination of cattle displaying clinical signs consistent with BSE

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. Since BSE causes no pathognomonic clinical signs, all countries with cattle populations will observe individual animals with compatible clinical signs. 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.

Table 1 indicates the minimum number of animals exhibiting one or more clinical signs of BSE that should be subjected to diagnostic tests according to the total cattle population over 30 months of age. As this sampling is not random, the numbers indicated in this table are a subjective interpretation rather than a strict statistical deduction.

<table>
<thead>
<tr>
<th>Total cattle population over 30 months of age</th>
<th>Minimum number of samples to examine</th>
</tr>
</thead>
<tbody>
<tr>
<td>500,000</td>
<td>50</td>
</tr>
<tr>
<td>700,000</td>
<td>69</td>
</tr>
<tr>
<td>1,000,000</td>
<td>99</td>
</tr>
<tr>
<td>2,500,000</td>
<td>195</td>
</tr>
<tr>
<td>5,000,000</td>
<td>300</td>
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<tr>
<td>30,000,000</td>
<td>425</td>
</tr>
<tr>
<td>40,000,000</td>
<td>433</td>
</tr>
</tbody>
</table>

Article 3.8.4.3.

Examination of targeted cattle displaying clinical signs not necessarily indicative of BSE

Cattle that have died or have been killed for reasons other than routine slaughter should be examined. This population will include cattle which have died on farm or in transit, ‘fallen stock’, and stock sent for emergency slaughter.

Many of these cattle may have exhibited some of the clinical signs listed in Article 3.8.4.2. which were not recognised as being compatible with BSE. Experience in countries where BSE has been identified indicates that this population is the second most appropriate population to target in order to detect BSE.

Article 3.8.4.4.

Examination of cattle subject to normal slaughter

In countries not free from BSE, sampling at routine slaughter is a means of 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.
Within each of the above sub-populations, countries may wish to target cattle identifiable as imported from countries or zones not free from BSE, cattle which have consumed potentially contaminated feedstuffs from countries or zones not free from BSE, offspring of BSE affected cows and cattle which have consumed feedstuffs potentially contaminated with other TSE agents.
APPENDIX 3.8.5.

PRINCIPLES FOR RECOGNISING A COUNTRY OR ZONE HISTORICALLY FREE FROM SCRAPIE

Article 3.8.5.1.

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 regionalisation.

The provisions of this Appendix are based on the principles developed in Chapter 1.3.6. 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 3.8.5.2.

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 the 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

EITHER

i) scrapie has never been reported;

OR

ii) no case of scrapie has been reported for at least 25 years.
APPENDIX 3.8.6.

PRELIMINARY GUIDELINES FOR THE
ESTABLISHMENT OR THE REGAINING OF
RECOGNITION FOR A FOOT AND MOUTH DISEASE
FREE COUNTRY OR ZONE

Article 3.8.6.1.

Introduction

The following are preliminary guidelines for the surveillance of foot and mouth disease (FMD) applicable to countries or zones applying to the OIE for FMD freedom without vaccination, and for countries or zones applying to the OIE for FMD freedom with vaccination. They also provide guidance for countries or zones seeking re-recognition of freedom from FMD, with or without vaccination, following an outbreak. It is not the intention here to exclude other verification strategies, but if an alternative strategy is used it is essential that it be scientifically defensible. These preliminary guidelines are intended to expand on and explain the requirements of Chapter 2.1.1. of the Terrestrial Code.

Surveillance for FMD may be part of a continuing disease surveillance programme involving regular checks on livestock at all stages of the production chain up to slaughter or export, or it may be a specific programme designed to establish that FMDV infection is absent from the national herd in the whole territory or part of it (free zone).

Article 3.8.6.2.

General conditions

1. A surveillance system for FMD should be supported by efficient and adequately funded Veterinary Services (Chapter 1.3.3. of the Terrestrial Code) with expertise in the epidemiology of FMD, access to a diagnostic laboratory capable of undertaking FMD diagnosis and serology, and a farming community committed to the recognition and reporting of FMD. Training of veterinarians, whether state or private practitioner, and animal health auxiliaries, in the clinical recognition of FMD and the collection and dispatch of samples is essential, together with an information programme directed at farmers and other animal workers on the importance of early notification of disease outbreaks. A procedure should be in place for the rapid transport of samples to the laboratory, and access through the laboratory for onward dispatch of samples to the national, regional or world reference laboratories.

2. Passive surveillance is an ongoing programme that should be used by all Veterinary Services to monitor for the appearance of disease in the national livestock populations. Active surveillance is specific in respect of confirmation of the suspect presence of a particular disease and quantification of its prevalence or to demonstrate freedom from a disease/infection for a geographically defined area.

3. An FMD surveillance programme should:

   a) respond to observations and reports made by the public, and from state and private veterinarians, and in particular farmers and animal health workers who have day-to-day contact with the national herds and flocks (passive surveillance). Farmers should be encouraged to report promptly any clinical disease resembling FMD. They should be supported by government information programmes and the Veterinary Services directly or through private veterinarians. All reported suspect cases of FMD should be investigated within 24 hours, and, if still considered suspect, samples should be taken and submitted to the national laboratory by rapid transport. This requires that sampling kits, drugs to sedate animals from which samples are being taken, transport and communications and facilities for the decontamination of
Appendix 3.8.6. - Preliminary guidelines for the establishment or the regaining of recognition for an FMD free country or zone

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equipment and clothing of those involved in disease investigation are available at all times. Both state and private veterinarians who may be involved with investigating suspect outbreaks of FMD should be familiar with the clinical signs and epidemiology of FMD, and have been trained in sample collection. They should also have access to relevant information on the current FMD status of their own and neighbouring countries, and any particular risk factors, and be able to call for additional advice and help from a specialised government FMD epidemiological team. Laboratory results should be sent as soon as possible to the relevant person in the Veterinary Services, and to the veterinarian submitting the sample, to encourage future co-operation;

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).

4. These general requirements apply in all Member Countries submitting their annual request for re-confirmation of FMD free status. Evidence of an enhanced surveillance programme is required from Member Countries and zones applying for the first time for recognition of freedom from FMD with or without vaccination.

Article 3.8.6.3.

Countries or zones applying for freedom from FMD where vaccination is not practised

1. Introduction

In addition to the general conditions, a Member Country applying for recognition of freedom from FMD where vaccination is not practised should show evidence of an effective surveillance programme in which either the FMD susceptible population undergoes regular clinical examination or a statistically significant sample of this population is examined to show that disease has not been present in the population during the past 12 months. In addition, a statistically significant proportion of the population should be subjected to serological surveillance to demonstrate absence of FMD virus (FMDV) infection during the preceding 12 months. This requires the support of a national or other reference laboratory able to undertake serology for FMDV antibody using tests described in the Terrestrial Manual.

2. Survey design

In general, the target population for random surveys for disease and infection will cover the susceptible species within the country or zone to be declared disease-free. Countries wishing to show freedom from FMD in which a pig-specific strain of virus had been prevalent should concentrate on sampling the national pig population. In countries in which an African buffalo population is present, this should also be sampled if included in the proposed FMDV infection free zone.

The objective of the random sample design is to use the minimum level of surveillance consistent with demonstrating the absence of disease/infection at the required level of statistical confidence. The sample should be selected on a random basis during each of the consecutive sampling campaigns; the frequency of sampling is dependent on the epidemiological situation, but should be at least once during the year preceding the application. Every sampling unit should have an equal probability of being selected. The selection of individual sampling units should not affect the probability of selecting any other sampling unit. It should be emphasised that random selection of the sampling units is essential, or the required level of statistical confidence cannot be achieved.

In order to provide representative information on the infection status of the target population, the random sample survey ought to be completed within the shortest possible period of time.
The population may be divided into sections (strata) with similar epidemiological conditions within each stratum. Stratification implies that a suitable system of separating the target population into a series of sections or strata from which random samples can be drawn has been developed. A stratum should be a subpopulation of the total population that is raised using a similar production and husbandry system under similar ecological conditions within geographical or administrative areas (provinces, states, etc.) with a similar likelihood of infection. Which stratification criteria will be most appropriate will depend on the conditions prevailing in the individual country.

During the process of stratification the following two conditions have to be met:

a) all sampling units (village, flock or herd depending on farming system) within a particular stratum can be accessed during the survey and have an equal chance of being selected;

b) an individual sampling unit is included in only one stratum.

The total number of strata required will depend on the country or zone concerned, and additional strata or an increased level of sampling may be applied to areas within a country or zone considered to be at a higher likelihood of FMDV infection. Care should be taken that the number of strata does not exceed the capacity of the field and laboratory service as the required number of random samples will have to be collected from each of the strata. The number of samples is determined, to a considerable extent, by the number of strata. Hence the number of strata should be kept to a minimum but also reflect major epidemiological differences. Further detail may be obtained from suitable epidemiological texts.

If a Member Country wishes to declare a specific zone within the country free from FMDV infection, this should be taken into consideration in the stratification process. The basis for the sampling process would then be the population within each zone.

The objective of the random sample survey is the detection of clinical or serological evidence of FMD within the population, if it is present at a predetermined prevalence. The probability of detecting evidence of FMD or FMDV infection in a given sample depends on the prevalence of FMDV infection in the population and the size of the sample. Hence, the sample size and expected disease prevalence determine the level of confidence in the result of the survey. The lower the prevalence the larger the sample size has to be in order to achieve a given confidence in the outcome of the survey. The sampling strategy should give a 95% probability of detecting evidence of FMD or FMDV infection if it is present in 1% of the primary sampling units. In other words, if at least 1% of herds/flocks are infected with FMD virus, the sample size has to be large enough to give a 95% chance that at least one infected herd/flock will be detected through examination of the random sample of herds/flocks.

3. Clinical surveillance

Clinical surveillance aims at the detection of clinical signs of FMD by close inspection of the mouth, feet and udder of a randomly selected sample. It is essential that all animals within the selected primary sampling unit are examined for signs of FMD. Any herd/flock where suspicious animals are detected should be classified as infected until contrary evidence is produced.

4. Serological surveillance

Serological surveillance aims at the detection of antibodies against FMDV. A positive reaction to an FMDV antibody detection test can have four possible causes:

a) natural infection with FMDV;

b) vaccination;

c) maternal antibodies from an immune dam (maternal antibodies in cattle are usually found only up to 6 months of age, however, in some individuals and in buffalo calves, maternal antibody can be detected for longer);

d) non-specific reactions, for example to some other unrelated antigen (heterophile reactions).
Appendix 3.8.6. - Preliminary guidelines for the establishment or the regaining of recognition for an FMD free country or zone

Thus antibodies detected in animals (other than African buffalo) over 6 months of age and born after a country or region has ceased vaccination should be in response to natural infection and be indicative of circulating virus. This group of animals will be considered eligible as secondary sample units for the purpose of serological surveillance. It may be possible to use serum collected for other survey purposes, but the objective of a statistically valid random survey for the specific presence of FMDV should not be compromised.

If vaccination cannot be excluded as the cause of positive serological reactions, additional testing for the presence of antibodies to the nonstructural proteins (NSPs) of FMDV could indicate the previous presence of live FMDV.

It is unusual to find only one or two sero-positive animals in an infected herd/flock. For this reason and for practical as well as economic reasons, it is considered acceptable to include only a random sample of animals from each primary sampling unit in the serological surveillance. The sample size has to be sufficient to achieve a 95% probability of detecting sero-positive animals. If a herd is infected a significant time after the cessation of vaccination, it would be expected that the serological prevalence will exceed 20%.

FMDV persists in the pharyngeal region of recovered ruminants for up to 3 years in cattle and 9 months in sheep, and therefore oesophageal–pharyngeal (OP) fluid sampling is an additional valuable tool in surveillance for FMDV. OP samples should be collected from herds and flocks selected by positive serology. The collection of OP samples will depend on the availability of collection equipment (e.g. probang), facilities for storing the OP material until testing, and access to a laboratory able to work with live FMDV. Sheep can also be sampled by collecting OP fluid, and a similar sampling strategy can be applied, bearing in mind that the carrier state is shorter in this species.

Staff collecting OP samples should be given specific training on the techniques for the collection, transport and storage of OP fluid. It is essential that the OP fluid is placed in a neutral buffer and immediately frozen in or over liquid nitrogen or solid CO₂ after collection, and kept in this state until thawed in the diagnostic laboratory and placed on susceptible tissue culture (see the Terrestrial Manual).

It is preferable to stratify the sampling frame to reflect the possibility of FMD having been present up to 3 years previously. OP samples should be collected from each group of yearlings, 2-year-old and 3-year-old cattle/sheep in the selected herds and flocks.

The results of the random sample survey will provide evidence both to the national authorities and to the OIE that no FMDV infection is present in the country or zone. It is therefore essential that the random sample survey can be audited through clear documentation and the presence of complete records.

Article 3.8.6.4.

Countries or zones applying for freedom from FMD where vaccination is practised

In addition to the general conditions, a country or zone applying for recognition of freedom from FMD with vaccination should show evidence of an effective surveillance programme for clinical disease and demonstrate that FMD has not occurred in the country or zone for the past 2 years. Furthermore, surveillance for FMDV infection should show that FMDV has not been circulating in the vaccinated population within the past 12 months. This will require serological surveillance incorporating tests able to detect antibodies to NSPs as described in these guidelines.

Evidence to show the effectiveness of the vaccination programme is recommended.

Article 3.8.6.5.

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, a country re-applying for freedom from FMD where vaccination is practised should show evidence of an active surveillance programme for FMD as well as FMDV infection.
Four strategies are recognised by 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, and 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 all 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 depending on which of these alternatives is followed are indicated in Article 2.1.1.7. of the Terrestrial Code.

In all circumstances, a Member Country re-applying for freedom from FMD with vaccination in a country or zone should report the results of an active surveillance programme in which the FMD susceptible population undergoes regular clinical examination or where active surveillance has targeted a statistically significant sample of the susceptible population. In addition, a statistically significant sample, based on the susceptible population at risk during the outbreak, would need to be tested for absence of FMDV infection. The procedures to follow are described above, but when a country or zone has used vaccination to help control the outbreak, and not subsequently slaughtered the vaccinated animals, it will be necessary to demonstrate that the sampling scheme employed takes into account the sensitivity of the diagnostic system used for the detection of vaccinated animals which may have been infected following exposure to live virus.

Article 3.8.6.6.

The use and interpretation of serological tests (see Fig 1)

The recommended serological tests for FMD surveillance are described in the Terrestrial Manual. In unvaccinated populations, the screening can be carried out using the liquid-phase blocking ELISA (LPBE) or the solid phase competition ELISA (SPCE). The sensitivity of the LPBE approaches 100% but it can have a specificity in cattle as low as 95%, and will therefore give up to 5% false positive results at a titre greater than 40. Because the objective of the survey is to discover evidence of infection if the latter is present, it is acceptable for the purposes of the survey to raise the cut-off value for negative/positive sera. The rationale for raising or lowering the cut-off titre should be given in reports of tests for which this has been used. Raising of the cut-off value may still result in false positive results, and therefore positive sera should be re-tested by the virus neutralisation test (VNT), in which a titre of 45 or greater is classified as positive. Any animals whose sera are positive by the VNT should be re-sampled to confirm this status, and if still positive they should be tested for evidence of infection. The remaining animals in the herd/flock should also be tested for the presence of antibodies to FMDV and, if found positive, sampled by collection of OP material using a probang cup. The SPCE has been shown to have a higher specificity, but similar sensitivity to the LPBE, and should be used in preference to the LPBE where possible.

For serological surveillance in countries or zones in which vaccine is, or has been used, the LPBE or SPCE can still be the test of choice in those FMD susceptible species not included in the vaccination programme. Animals that have been vaccinated will have antibodies to the structural proteins of FMD virus, and some may have antibodies to the NSPs, depending on the number of times they have been vaccinated, and the amount of the NSPs present in the vaccine used. However, animals that have recovered from infection with FMD virus will have high levels of antibody to the NSPs. There are eight NSPs associated with the replication of FMD virus, namely 1, 2A, 2B, 2C, 3A, 3B, 3C and 3D, and antibodies can be found to all of these in most recovered animals. Some do not persist for more than a few months, and some animals may fail to produce detectable levels to all of them. ELISA tests have been developed to detect 2C, 3B or 3ABC antibodies, the former being detectable for up to one year after infection, and the latter for up to 2 years. A western blot technique (EITB) has also been used to detect the NSP antibodies to 2C, 3ABC, 3A, 3B and 3D; it is particularly specific and sensitive in identifying animals previously infected. All these tests have been validated in cattle.
Fig. 1 Schematic representation of laboratory tests for determining evidence of FMDV infection through, or following serological surveys

The above diagram indicates the tests which are recommended for use in the investigation of sampling units in which a positive test result has been obtained.

Key:
- ELISA: enzyme-linked immunosorbant assay
- LPBE: liquid-phase blocking ELISA
- SPCE: solid-phase competition ELISA
- VNT: virus neutralisation test
- NSP: nonstructural protein(s) of FMDV
- 3ABC: NSP antibody test
- EITB: western blot for NSP antibodies of FMDV
- OP: oesophageal–pharyngeal sample
Appendix 3.8.6. - Preliminary guidelines for the establishment or the regaining of recognition for an FMD free country or zone

A class of animal exists, however, that has been infected with FMD virus and could remain carrying the virus without developing detectable antibodies to the NSPs. These are animals which have received highly potent vaccine and then had contact with the virus during an outbreak, but, because of their level of immunity, suppress viral replication and show no evidence of disease. Because the virus does not replicate significantly in these animals, there is little expression of the NSPs and therefore development of detectable levels of antibodies may not occur. However, on a herd basis there are always less protected animals following vaccination, and if these animals are challenged with the virus, they will produce antibodies to the NSPs, and can develop clinical disease. It is therefore important that NSP antibody tests be interpreted by assessing the level of these antibodies in the sera of a representative sample from the whole herd.

There is the option to use the NSP antibody test together with the LPBE or SPCE, particularly in areas where vaccination has been used and virus activity is suspected. LPBE titres or SPCE inhibition higher than would be expected from vaccination alone may suggest FMDV infection and this can be confirmed by testing for the presence of antibodies to the NSPs, and by taking OP samples.

The diagnostic sensitivity of tests used influences the numbers of animals that need to be sampled in a survey to provide evidence of absence of infection. The diagnostic specificity of the test influences the proportion and number of positive results to be expected in the absence or presence of infection, and therefore the selection and use of confirmatory tests. Results of surveys which indicate a significantly higher proportion of positive test results in comparison with that expected from the estimate of the false positive rate derived from the diagnostic specificity (i.e. 100 minus diagnostic specificity) may be interpreted as evidence of infection in the population and therefore a confirmatory test of high specificity, and where appropriate other investigations, should be conducted.

Figure 1 provides a flowchart of the test protocol that could be used to test the samples collected in the random survey. If the population being tested has not been previously vaccinated against FMD, the serum samples can be tested using the LPBE or SPCE. Sera positive on the test used should be retested using the VNT, which is the “gold standard” test for FMDV antibodies. In addition, or in place of the VNT if the laboratory is not able to manipulate live FMDV, the positive sera may be retested using a NSP antibody test, such as the 3B, 3ABC or EITB. If the positive sera are from a ruminant species, OP samples may also be collected and tested for the presence of live FMDV. A positive VNT or NSP test would indicate that live virus had been circulating, and would require further investigation of the herd or flock to show whether it was still present; a positive OP sample would provide definitive evidence. Further investigation should include serum testing of the whole herd or flock from which the positive samples were obtained, in addition to taking further OP samples to show whether live virus is still present.

NSP tests should be used for testing sera from vaccinated herds or flocks, as such sera will be positive by VNT. LPBE and SPCE can be used in addition, as described above. 3ABC or 3B positive samples may be repeat tested using the EITB for confirmation. All animals from herds and flocks from which positive samples are obtained should be re-tested for antibodies to NSP’s, and OP samples collected for detection of live FMDV.

Data on the sensitivity and specificity of the NSP tests currently available is not fully documented, in particular for species other than cattle, or for vaccinated animals carrying live FMDV. However, this is under investigation in a number of laboratories worldwide. Member Countries submitting data to the OIE Scientific Commission for Animal Diseases derived using commercial or other NSP tests should provide information on the characteristics of the test being used, and adjust the number of samples collected to accommodate the test parameters. In addition, the testing of OP samples for the presence of FMDV may be less than 50% sensitive, even using very sensitive tissue culture such as primary bovine thyroid cells or lamb kidney cells. Repeat OP samples should be collected from serum-antibody positive animals after a 2-week interval, if the initial attempt at virus isolation is negative, or further tests such as PCR carried out on the samples.
SECTION 3.9.
ANTIMICROBIAL RESISTANCE

APPENDIX 3.9.1.
GUIDELINES FOR THE HARMONISATION OF 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. 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 shall follow standard operating procedures.
Table 1. Sample size estimates for prevalence of antimicrobial resistance in a large population

<table>
<thead>
<tr>
<th>Level of confidence</th>
<th>Expected prevalence</th>
<th>90% desired precision</th>
<th>95% desired precision</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10%</td>
<td>5%</td>
<td>1%</td>
</tr>
<tr>
<td>10%</td>
<td>24</td>
<td>97</td>
<td>2,429</td>
</tr>
<tr>
<td>20%</td>
<td>43</td>
<td>173</td>
<td>4,310</td>
</tr>
<tr>
<td>30%</td>
<td>57</td>
<td>227</td>
<td>5,650</td>
</tr>
<tr>
<td>40%</td>
<td>65</td>
<td>260</td>
<td>6,451</td>
</tr>
<tr>
<td>50%</td>
<td>68</td>
<td>270</td>
<td>6,718</td>
</tr>
<tr>
<td>60%</td>
<td>65</td>
<td>260</td>
<td>6,451</td>
</tr>
<tr>
<td>70%</td>
<td>57</td>
<td>227</td>
<td>5,650</td>
</tr>
<tr>
<td>80%</td>
<td>43</td>
<td>173</td>
<td>4,310</td>
</tr>
<tr>
<td>90%</td>
<td>24</td>
<td>97</td>
<td>2,429</td>
</tr>
</tbody>
</table>


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 2. Examples of sampling sources, sample types and outcome of monitoring

<table>
<thead>
<tr>
<th>Source</th>
<th>Sample type</th>
<th>Outcome</th>
<th>Additional information required/additional stratification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Herd of origin</td>
<td></td>
<td>Prevalence of resistance in bacteria originating from animal populations (of different production types)</td>
<td>Per age categories, production types, etc. Antibiotic use over time</td>
</tr>
<tr>
<td>Abattoir</td>
<td>Faecal</td>
<td>Prevalence of resistance in bacterial populations originating from animals at slaughter age</td>
<td></td>
</tr>
<tr>
<td>Intestine</td>
<td></td>
<td>As above</td>
<td></td>
</tr>
<tr>
<td>Carcass</td>
<td></td>
<td>Hygiene, contamination during slaughter</td>
<td></td>
</tr>
<tr>
<td>Processing, packing</td>
<td>Meat products</td>
<td>Hygiene, contamination during processing and handling</td>
<td></td>
</tr>
<tr>
<td>Retail</td>
<td>Meat products</td>
<td>Prevalence of resistance in bacteria originating from food, exposure data for consumers</td>
<td></td>
</tr>
<tr>
<td>Vegetables</td>
<td></td>
<td>Prevalence of resistance in bacteria originating from vegetables, exposure data for consumers</td>
<td></td>
</tr>
<tr>
<td>Various origin</td>
<td>Animal feed</td>
<td>Prevalence of resistance in bacteria originating from animal feed, exposure data for animals</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 3.9.1. - Guidelines for the harmonisation of antimicrobial resistance surveillance and monitoring programmes

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 failures, may provide biased information.

Table 3. Examples of animal bacterial pathogens that may be included in resistance surveillance and monitoring

<table>
<thead>
<tr>
<th>Target animals</th>
<th>Respiratory pathogens</th>
<th>Enteric pathogens</th>
<th>Udder pathogens</th>
<th>Other pathogens</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cattle</td>
<td><em>Pasteurella</em> spp.</td>
<td><em>Escherichia coli</em></td>
<td><em>Staphylococcus aureus</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Haemophilus somnus</em></td>
<td><em>Salmonella</em> spp.</td>
<td><em>Streptococcus spp.</em></td>
<td></td>
</tr>
<tr>
<td>Pigs</td>
<td><em>Actinobacillus pleuropneumoniae</em></td>
<td><em>Escherichia coli</em></td>
<td><em>Brachyspira</em> spp.</td>
<td><em>Streptococcus suis</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>Salmonella</em> spp.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poultry</td>
<td><em>Escherichia coli</em></td>
<td></td>
<td></td>
<td><em>Vibrio</em> spp.</td>
</tr>
<tr>
<td>Fish</td>
<td></td>
<td></td>
<td></td>
<td><em>Aeromonas</em> spp.</td>
</tr>
</tbody>
</table>

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.
Appendix 3.9.1. - Guidelines for the harmonisation of antimicrobial resistance surveillance and monitoring programmes

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, when 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.

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.

b) 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.
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 within 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 antimicrobials 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 bacteria (with their resistance determinants) within animal populations;
4. maintain the efficacy of antimicrobial agents used in livestock;
5. prevent or reduce the transfer of resistant bacteria 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.

Article 3.9.3.3.

Responsibilities of the regulatory authorities

1. Marketing authorisation

The national regulatory authorities are responsible for granting marketing authorisation. 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 risk to both the animal and the consumer resulting from the use of antimicrobial agents in food-producing animals must be carried out. The evaluation should focus on each individual antimicrobial product and not be generalised to the class of antimicrobials to which the particular active principle belongs. If dose ranges or different durations of treatment are suggested, guidance on the usage should be provided.

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, must 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 country;

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 country. All countries should make every effort to actively combat the trade, distribution and use of unlicensed and counterfeit 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. Control 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);
Appendix 3.9.3. - Guidelines for the responsible and prudent use of antimicrobial agents in veterinary medicine

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– assess the ability of the antimicrobial agent to select for resistant bacteria 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-resistant bacteria.

ii) The activity of antimicrobial agents towards the targeted bacteria should be established by pharmacodynamics. The following criteria should be taken into account:

– mode of action;

– minimum inhibitory and bactericidal concentrations;

– time- or concentration-dependent activity;

– 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 justified.

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;

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 resistant bacteria

Other studies may be requested in support of the assessment of the potential of antimicrobials to select for resistant bacteria. The interpretation of their results should be undertaken with great caution.

The party applying for market authorisation should, where possible, supply data derived in target animal species under the intended conditions of use.

Considerations may include:

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 level of human exposure to food-borne resistant bacteria;

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).

Other studies may be requested in support of the assessment of the potential of antimicrobials to select for resistant bacteria. The interpretation of their results should be undertaken with great caution.

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 environmental contamination with antimicrobials is restricted to a minimum.

10. Establishment of a summary of product characteristics for each veterinary medicinal product

The summary of product characteristics contains the information necessary for the appropriate use of VMPs and constitutes the official reference for their labelling and package insert. This summary always contains the following items:

a) pharmacological properties,

b) target animal species,

c) therapeutic indications,

d) target bacteria,

e) dosage and administration route,

f) withdrawal periods,
Appendix 3.9.3. - Guidelines for the responsible and prudent use of antimicrobial agents in veterinary medicine

- g) incompatibilities,
- h) expiry date,
- i) operator safety,
- j) particular precautions before use,
- k) particular precautions for the proper disposal of un-used products.

Antimicrobials that are considered to be important in treating critical diseases in humans should only be used in animals when alternatives are either unavailable or inappropriate.

Consideration should be given to providing such guidance by means of the product label and data sheet.

The oral route should be used with caution.

11. Post-marketing antimicrobial surveillance

The information collected through pharmacovigilance programmes, including lack of efficacy, should form part of the comprehensive strategy to minimise antimicrobial resistance.

- a) 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.

- b) General epidemiological surveillance

The surveillance of animal bacteria resistant to antimicrobial agents is essential. The relevant authorities should implement a programme according to the Terrestrial Code.

12. Distribution 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 suitably trained and authorised person;
- b) delivered by an authorised animal health professional;
- c) supplied only through licensed/authorised distribution systems;
- d) administered to animals by a veterinarian or under the supervision of a veterinarian or by other authorised persons.

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 antibiotic users

Training of antibiotic users should focus on:

a) information on disease prevention and management strategies,
b) the ability of antimicrobials to select for resistant bacteria 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 VMPs

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 VMPS

For the marketing and export of VMPs:

a) only licensed and officially approved VMPs should be sold and supplied, and then only through licensed/authorised distribution systems;
b) only VMPs that have been authorised in the (exporting) country in which the product(s) is approved for sale or the quality of which is certified by a regulatory authority should be exported;
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 livestock 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.
Responsibilities of pharmacists

1. Pharmacists should only distribute veterinary antimicrobials on prescription. All products should be appropriately labelled (see point 5 of Article 3.9.3.6.).

2. The guidelines on the responsible use of antimicrobials should be reinforced by pharmacists 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. Pharmacists should also be involved in training programmes on the responsible use of antimicrobials, as defined in point 14 of Article 3.9.3.3.

Responsibilities of veterinarians

The prime concern of the veterinarian is to encourage good farming practice in order to minimise the need for antimicrobial use in livestock.

Veterinarians should only prescribe antimicrobials for animals under their care.

1. Use of antimicrobial agents

   The responsibilities of veterinarians in this area 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.

   On certain occasions, a group of animals that may have been exposed to pathogenic bacteria 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.

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 pathogenic bacteria 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 pathogenic bacteria involved;

vi) Should a first line antibiotic 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 bacteria likely to be the cause of infection.

b) Combinations of antimicrobials are used for their synergistic effect to increase therapeutic efficacy or to broaden the spectrum of activity. Furthermore, the use of combinations of antimicrobials can be protective against the selection of resistance in cases in which bacteria exhibit a high mutation rate against a given antimicrobial.

Some combinations of antimicrobials may, in certain cases, lead to an increase in the selection of resistance.

3. Appropriate use of the antimicrobial agent chosen

A prescription for antimicrobial agents must indicate precisely the treatment regime, the dose, the dosage 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.

As far as ‘Off label use’ (extra-label use) of veterinary medicinal products is concerned, although all medicinal products should be prescribed and used in accordance with the specifications of the marketing authorisation, the prescriber should have the discretion to adapt these in exceptional circumstances.

4. Recording

All available information should be consolidated into one form or database. This information should:

a) allow monitoring of the quantities of medication used;

b) contain a list of all medicines supplied to each livestock holding;

c) contain a list of medicine withdrawal periods and a system for allowing information to be updated;

d) contain a record of antimicrobial susceptibilities;

e) provide comments concerning the response of animals to medication;

f) allow 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.

5. Labelling

All medicines supplied by a veterinarian should be adequately labelled with the following minimum information:

a) the name of the owner/keeper or person who has control of the animal(s);

b) the address of the premises where the animal(s) is kept;

c) the name and address of the prescribing veterinarian;
d) identification of the animal or group of animals to which the antimicrobial agent was administered;

e) the date of supply;

f) the indication ‘For animal treatment only’;

g) the warning ‘Keep out of the reach of children’;

h) the relevant withdrawal period, even if this is nil.

The label should not obscure the expiry date of the preparation, batch number or other important information supplied by the manufacturer.

6. **Training**

Veterinary professional organisations should participate in the training programmes as defined in point 14 of Article 3.9.3.3.

**Article 3.9.3.7.**

**Responsibilities of livestock producers**

1. Livestock producers with the assistance of a veterinarian, where possible, are responsible for preventing outbreaks of disease and implementing health and welfare programmes on their farms.

2. Livestock producers have to:

   a) draw up a health plan with the veterinarian in charge of the animals that outlines preventative measures (mastitis plan, worming 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 doses 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 resistant bacteria;

   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; partially-used 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;
Appendix 3.9.3. - Guidelines for the responsible and prudent use of antimicrobial agents in veterinary medicine

j) keep adequate records of all medicines used, including the following:
   i) name of the product/active substance and batch number,
   ii) name of supplier,
   iii) date of administration,
   iv) identification of the animal or group of animals to which the antimicrobial agent was administered,
   v) diagnosis/clinical conditions treated,
   vi) quantity of the antimicrobial agent administered,
   vii) withdrawal periods,
   viii) result of laboratory tests,
   ix) effectiveness of therapy;

k) inform the responsible veterinarian of recurrent disease problems.
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.

<table>
<thead>
<tr>
<th>Date of vaccination (dd/mm/yy)</th>
<th>Name of inactivated virus vaccine (see note 2)</th>
<th>1. Manufacturing laboratory</th>
<th>Name (in capital letters) and signature of the veterinarian (see note 6)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>2. Batch number</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Expiry date</td>
<td></td>
</tr>
</tbody>
</table>

**PERIOD OF VALIDITY OF VACCINATION FOR INTERNATIONAL MOVEMENT**

(see note 3)

<table>
<thead>
<tr>
<th>Name (in capital letters) and signature of the Official Veterinarian</th>
</tr>
</thead>
<tbody>
<tr>
<td>from (dd/mm/yy) to (dd/mm/yy)</td>
</tr>
</tbody>
</table>
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).

<table>
<thead>
<tr>
<th>Date of sampling (dd/mm/yy)</th>
<th>Name and address of the official diagnostic laboratory</th>
<th>Result of the antibody titration test (in International Units [IU]/ml)</th>
<th>Name (in capital letters) and signature of the veterinarian (see note 6)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

PERIOD OF VALIDITY OF SEROLOGICAL TESTING FOR INTERNATIONAL MOVEMENT (see note 3)

<table>
<thead>
<tr>
<th>from (dd/mm/yy)</th>
<th>to (dd/mm/yy)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Name (in capital letters) and signature of the Official Veterinarian
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).

<table>
<thead>
<tr>
<th>Date (dd/mm/yy)</th>
<th>Name (in capital letters) and signature of the veterinarian (see note 6)</th>
<th>Name (in capital letters) and signature of the Official Veterinarian</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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 Administration 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

<table>
<thead>
<tr>
<th>Official ear mark</th>
<th>Breed</th>
<th>Sex</th>
<th>Age</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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:**
Official stamp:

Issued at.................................. on ...........................................................
Name and address of Veterinarian...............................................................

Signature: ......................................................................................................

* It is recommended that individual certificates be drawn up for breeding animals.

** These conditions are agreed between the Veterinary Services of the importing and exporting countries in accordance with the options provided in the 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*

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*

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:**

---

Appendix 4.1.3. - Model international veterinary certificate: Semen
Appendix 4.1.3. - Model international veterinary certificate: Semen

Official stamp:

Issued at........................................on .................................................................
Name and address of Veterinarian.................................................................
..............................................................................................................................
..............................................................................................................................

Signature: .............................................................................................................

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

* Zootechnical information supplied by: .................................................................
..............................................................................................................................
..............................................................................................................................

** These conditions are agreed between the Veterinary Services of the importing and exporting countries in accordance with the options provided in the 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.: ............................................................................................................................................................

<table>
<thead>
<tr>
<th>Species</th>
<th>Age</th>
<th>Sex</th>
<th>Breed</th>
<th>Marks and description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**I. Identification of the animal/s**

**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:**
Official stamp:

Issued at.............................. on .........................

Name and address of Veterinarian..............................................................................................
................................................................................................................................................
................................................................................................................................................

Signature: ..................................................................................................................................

* It is recommended that individual certificates be drawn up for breeding animals.

** These conditions are agreed between the Veterinary Services of the importing and exporting
countries in accordance with the options provided in the Terrestrial Code.
APPENDIX 4.1.5.

MODEL PASSPORT FOR INTERNATIONAL MOVEMENT OF COMPETITION HORSES
MODERN 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.
<table>
<thead>
<tr>
<th>Date of registration by the National Equestrian Federation</th>
<th>Name of owner</th>
<th>Address of owner</th>
<th>Nationality of owner</th>
<th>Signature of owner</th>
<th>National Equestrian Federation stamp and signature of the secretary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fecha de registro por la Federación Ecuestre Nacional</td>
<td>Nombre del propietario</td>
<td>Dirección del propietario</td>
<td>Nacionalidad del propietario</td>
<td>Firma del propietario</td>
<td>Sello de la Federación Ecuestre Nacional y firma oficial</td>
</tr>
</tbody>
</table>
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):
### Appendix 4.1.5. - Model passport for international movement of competition horses

<table>
<thead>
<tr>
<th>Line</th>
<th>French</th>
<th>English</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>Certificat d'origine validé le:</td>
<td>Origin certificate validated on:</td>
</tr>
<tr>
<td></td>
<td>par:</td>
<td>by:</td>
</tr>
<tr>
<td></td>
<td>Certificado de origen visado el:</td>
<td>por:</td>
</tr>
<tr>
<td>13</td>
<td>- Nom de l'autorité compétente:</td>
<td>- Name of the competent authority:</td>
</tr>
<tr>
<td></td>
<td>Name of the competent authority:</td>
<td>Nombre de la autoridad competente:</td>
</tr>
<tr>
<td>14</td>
<td>- Adresse:</td>
<td>- Address:</td>
</tr>
<tr>
<td></td>
<td>Dirección:</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>- N° de téléphone:</td>
<td>- Telephone No.:</td>
</tr>
<tr>
<td></td>
<td>- Téléphone No.:</td>
<td>- Telecopy No.:</td>
</tr>
<tr>
<td></td>
<td>- N° de télefono:</td>
<td>- N° de fax:</td>
</tr>
<tr>
<td>16</td>
<td>- Signature:</td>
<td>- Signature:</td>
</tr>
<tr>
<td></td>
<td>(nom en lettres capitales et qualité du signataire)</td>
<td>(Name in capital letters and capacity of signatory)</td>
</tr>
<tr>
<td></td>
<td>Signature:</td>
<td>Firma:</td>
</tr>
<tr>
<td></td>
<td>(Nombre en letras mayúsculas y calidad del firmante)</td>
<td>(Nombre en letras mayúsculas y calidad del firmante)</td>
</tr>
<tr>
<td>17</td>
<td>- Cachet</td>
<td>- Stamp</td>
</tr>
<tr>
<td></td>
<td>Stamp</td>
<td>Sello</td>
</tr>
</tbody>
</table>
Appendix 4.1.5. - Model passport for international movement of competition horses

(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. L. :

Foreleg R. :
Ant. D. :

Post. G. :
Hindleg L. :
Post. L. :

Post. D. :
Hindleg R. :

Corps :
Body:
Cuerpo:

Signature et cachet du vétérinaire agréé
(o de l'autorité compétente)
Signature and stamp of qualified veterinary surgeon
(or competent authority)

Firma y sello del veterinario autorizado
(o de la autoridad competente)

Marques :
Markings:
Marcas:

(signature in capital letters)

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.

<table>
<thead>
<tr>
<th>Date</th>
<th>Ville et pays</th>
<th>Motif du contrôle (concours, certificat sanitaire, etc.)</th>
<th>Signature, nom en lettres capitales et position de la personne ayant vérifié l'identité</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>Town and country</td>
<td>Purpose of control (event, veterinary certificate, etc.)</td>
<td>Signature, name (in capital letters) and status of official verifying the identification</td>
</tr>
<tr>
<td>Fecha</td>
<td>Ciudad y país</td>
<td>Motivo del control (concurso, certificado sanitario, etc)</td>
<td>Firma, nombre (en letras mayúsculas) y calidad de la persona que controla la identidad</td>
</tr>
</tbody>
</table>
**Appendix E**

**GRIPE ÉQUINE SEULEMENT**
Enregistrement des vaccinations

**EQUINE INFLUENZA ONLY**
Vaccination record

**GRIPE EQUINA SOLAMENTE**
Registro de vacunas

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.

<table>
<thead>
<tr>
<th>Date</th>
<th>Lieu</th>
<th>Pays</th>
<th>Vaccin/Vaccine/Vacuna</th>
<th>Nom en lettres capitales et signature du vétérinaire</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Nom</td>
<td>Name (in capital letters) and signature of the veterinarian</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Numéro de lot</td>
<td>Nombre (en letras mayúsculas) y firma del veterinario</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Número de lote</td>
<td></td>
</tr>
</tbody>
</table>
### Appendix F

<table>
<thead>
<tr>
<th>Date</th>
<th>Lieu</th>
<th>Pays</th>
<th>Vaccin/Vaccine/Vacuna</th>
<th>Nom en lettres capitales et signature du vétérinaire</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date</th>
<th>Place</th>
<th>Country</th>
<th>Nom Nombre</th>
<th>Numéro de lot Número de lote</th>
<th>Maladie(s) Enfermedad(es)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**MALADIES AUTRES QUE LA GRIPPE ÉQUINE**

Enregistrement des vaccinations

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.

**DISEASES OTHER THAN EQUINE INFLUENZA**

Vaccination record

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.

**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.
Appendix 4.1.5. - Model passport for international movement of competition horses

Appendix G

<table>
<thead>
<tr>
<th>Date</th>
<th>Maladies transmissibles concernées</th>
<th>Nature de l'examen</th>
<th>Résultat de l'examen</th>
<th>Laboratoire officiel ayant analysé le prélèvement</th>
<th>Nom en lettres capitales et signature du vétérinaire</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>Transmissible diseases tested for</td>
<td>Type of test</td>
<td>Result of test</td>
<td>Official laboratory to which sample transmitted</td>
<td>Name (in capital letters) and signature of Veterinarian</td>
</tr>
<tr>
<td>Fecha</td>
<td>Enfermedades transmisibles examinadas</td>
<td>Tipo de examen</td>
<td>Resultado del examen</td>
<td>Laboratorio oficial que ha analizado la muestra</td>
<td>Nombre (en letras mayúsculas) y firma del veterinario</td>
</tr>
</tbody>
</table>

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.

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.
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.
Appendix 4.1.5. - Model passport for international movement of competition horses

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.

<table>
<thead>
<tr>
<th>Date</th>
<th>Lieu</th>
<th>Nom en lettres capitales et signature du vétérinaire officiel</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Pour des raisons épidémiologiques particulières, un certificat sanitaire séparé accompagne le présent passeport.</td>
</tr>
<tr>
<td>Date</td>
<td>Place</td>
<td>Name (in capital letters) and signature of official veterinarian</td>
</tr>
<tr>
<td></td>
<td></td>
<td>For special epizootic reasons a separate veterinary certificate accompanies this passport.</td>
</tr>
<tr>
<td>Fecha</td>
<td>Lugar</td>
<td>Nombre en letras mayúsculas y firma del veterinario oficial</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Por razones epidemiológicas particulares se adjunta al presente pasaporte un certificado sanitario.</td>
</tr>
</tbody>
</table>

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

[Note: 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

<table>
<thead>
<tr>
<th>Number</th>
<th>Mark</th>
<th>Species</th>
<th>Sex</th>
<th>Age</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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:*
Appendix 4.1.6. - Model international veterinary certificate: Birds

Official stamp:

Issued at.....................................on ...........................................................
Name and address of Veterinarian.................................................................
.....................................................................................................................
.....................................................................................................................

Signature: .....................................................................................................

* These conditions are agreed between the Veterinary Services of the importing and exporting countries in accordance with the options provided in the 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

<table>
<thead>
<tr>
<th>Number</th>
<th>Mark</th>
<th>Species</th>
<th>Breed</th>
</tr>
</thead>
</table>

II. Origin of the birds or hatching eggs

Name and address of the establishment of origin*: ..................................................................................................
..............................................................................................................................................................................
or of the hatchery*: ................................................................................................................................................
..............................................................................................................................................................................
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* or hatching eggs*:

a) come from an establishment* or a hatchery* which is regularly inspected;

b) come from an establishment* or a hatchery* which satisfies the following requirements:**
Official stamp:

Issued at........................................on ..................................................................................
Name and address of Veterinarian..................................................................................
..............................................................................................................................................
..............................................................................................................................................
..............................................................................................................................................

Signature: ...................................................................................................................................
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

<table>
<thead>
<tr>
<th>Number</th>
<th>Breed</th>
<th>Sex</th>
<th>Age</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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:*
Official stamp:

Issued at....................................on .................................................................
Name and address of Veterinarian.................................................................
..............................................................................................................................
..............................................................................................................................

Signature: ..............................................................................................................

* These conditions are agreed between the Veterinary Services of the importing and exporting countries in accordance with the options provided in the 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

<table>
<thead>
<tr>
<th>Kind*</th>
<th>Number and variety</th>
<th>Breed</th>
<th>Peculiarities</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Marks or age or weight or surface, etc.</td>
<td>Packing material</td>
</tr>
</tbody>
</table>

* Hive with bees, swarm, consignment of bees (worker bees, drones), queen bees, brood-combs, royal cells, etc.

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 in List B;
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 in List B;

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: .............................................................................................................
SECTION 4.2.

MODEL INTERNATIONAL VETERINARY CERTIFICATES 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
Appendix 4.2.1. - Model international veterinary certificate: Meat

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

*Address/es and number/s of veterinary approval of the abattoir/s: .......................................................... ..........
...........................................................................................................................................................................................
...........................................................................................................................................................................................

*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*, packages of meat* 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:**
Official stamp:

Issued at..................................on ...........................................................
Name and address of Veterinarian..............................................................
....................................................................................................................
....................................................................................................................

Signature: ......................................................................................................

* Delete where not applicable.

** These conditions are agreed between the Veterinary Services of the importing and exporting countries in accordance with the options provided in the 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-mentioned 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:*
Official stamp:

Issued at........................................ on ...............................................................
Name and address of Veterinarian.................................................................
.........................................................................................................................
.........................................................................................................................
Signature: .............................................................................................................

* These conditions are agreed between the Veterinary Services of the importing and exporting countries in accordance with the options provided in the Terrestrial Code.