

**WORLD ORGANISATION FOR ANIMAL HEALTH**

*Protecting animals, preserving our future*

**TERRESTRIAL ANIMAL  
HEALTH CODE**

**VOLUME II**

Recommendations applicable to OIE listed diseases  
and other diseases of importance to international trade

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## FOREWORD

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*The OIE Terrestrial Animal Health Code (Terrestrial Code) sets out standards for the improvement of terrestrial animal health and welfare and veterinary public health worldwide, including through standards for safe international trade in terrestrial animals (mammals, birds and bees) and their products. The health measures in the Terrestrial Code should be used by the veterinary authorities of importing and exporting countries to provide for early detection, reporting and control agents pathogenic to terrestrial animals and, in the case of zoonoses, for humans, and to prevent their transfer via international trade in terrestrial animals and terrestrial animal products, while avoiding unjustified sanitary barriers to trade.*

*The health measures in the Terrestrial Code have been formally adopted by the World Assembly of OIE Delegates, which constitutes the organisation's highest decision-making body. The 22<sup>nd</sup> edition incorporates modifications to the Terrestrial Code agreed at the 81<sup>th</sup> OIE General Session in May 2013. The 2013 edition includes revised information on the following subjects: glossary; notification of diseases, infections, infestations and epidemiological information; criteria for the inclusion of diseases, infections and infestations on the OIE list; procedures for self declaration and for official recognition by the OIE; evaluation of Veterinary Services; veterinary legislation; collection and processing of bovine, small ruminant and porcine semen; collection and processing of in vivo derived embryos from livestock and horses; official health control of bee diseases; biosecurity procedures in poultry production; responsible and prudent use of antimicrobial agents in veterinary medicine; zoonoses transmissible from non-human primates; introduction to the recommendations for animal welfare; use of animals in research and education; animal welfare and beef cattle production systems; infection with rabies virus; infection with rinderpest virus; infection with *Trichinella* spp.; infestation of honey bees with *Acarapis woodi*; infection of honey bees with *Paenibacillus* larvae (American foulbrood); infection of honey bees with *Melissococcus plutonius* (European foulbrood); infestation with *Aethina tumida* (small hive beetle); infestation of honey bees with *Tropilaelaps* spp.; infestation of honey bees with *Varroa* spp. (varroosis); infection with avian influenza viruses; Newcastle disease; infection with *Mycoplasma mycoides* subsp. *mycoides* SC (contagious bovine pleuropneumonia); infection with equine arteritis virus; infection with *Chlamydia abortus* (enzootic abortion of ewes); infection with peste des petits ruminants virus; and infection with classical swine fever virus.*

*This edition includes three new chapters on infection with *Echinococcus granulosus*, on infection with *Echinococcus multilocularis*, and on animal welfare and broiler chicken production systems.*

*The development of these standards and recommendations is the result of the ongoing work by the OIE Terrestrial Animal Health Standards Commission (the Code Commission). This Commission, which comprises six elected members, meets twice yearly to address its work programme. The Commission draws upon the expertise of internationally renowned scientific experts to prepare draft texts for new texts in the Terrestrial Code and to revise existing texts in the light of advances in veterinary science. The views of OIE National Delegates are systematically sought through the twice yearly circulation of draft texts. The Code Commission collaborates closely with other Specialist Commissions of the OIE, including the Aquatic Animal Health Standards Commission, the Biological Standards Commission and the Scientific Commission for Animal Diseases, to ensure the recommendations contained in the Terrestrial Code are based upon the latest scientific information.*

*The measures recommended in the Terrestrial Code are formally adopted by the World Assembly comprising the plenary meeting of OIE National Delegates, who are in most cases the heads of OIE Member Countries' veterinary authorities. The World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) formally recognises the role of the OIE to specify standards and recommendations as the international references for animal health and zoonotic diseases. The SPS Agreement provides a multilateral framework, incorporating WTO Members' rights and disciplines, to guide the development, adoption and enforcement of sanitary measures to facilitate safe international trade. According to the SPS Agreement, WTO Members should provide a scientific justification for their import health measures. It is preferable that these be based on OIE recommendations. Where there are no OIE recommendations or in cases where a government chooses to apply more restrictive conditions than those recommended by the OIE, the importing country should base its animal health measures on an import risk analysis as described in the Terrestrial Code. The Terrestrial Code is thus a key part of the WTO legal framework for international trade.*

*The Terrestrial Code is published annually in the three official OIE languages (English, French and Spanish). An unofficial translation into Russian is also available from the OIE upon request. The Terrestrial Code may be viewed and downloaded from the OIE Web site at <http://www.oie.int>.*

*The User's Guide, which follows this foreword, is designed to help Veterinary Authorities and other interested parties to use the Terrestrial Code and to promote fair access for all Member Countries, including developing and least developed countries to international markets for animals and animal products.*

*We wish to thank the members of the Code Commission, Delegates and the experts participating in Working Groups and ad hoc Groups and other Commissions for their expert advice. Finally but not least, my thanks go to the staff of the OIE for their dedication in producing this 22<sup>nd</sup> edition of the Terrestrial Code.*

*Dr Bernard Vallat  
Director General  
World Organisation for Animal Health*

*Dr Alejandro Thiermann  
President  
World Organisation for Animal Health*

*Members of the OIE Code Commission (2013):*

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*Members: Dr S.C. MacDiarmid, Dr Salah Hammami and Dr Toshiyuki Tsutsui*

*August 2013*

## USER'S GUIDE

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### **A. General remarks**

- 1) *The purpose of this guide is to assist the Veterinary Authorities of Member Countries to use the OIE Terrestrial Animal Health Code (hereafter referred to as the Terrestrial Code) in the application of animal health measures to international trade in animals and animal products.*
- 2) *The recommendations in each of the disease chapters in Volume II 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. Correctly applied, OIE recommendations provide for trade in animals and animal products to take place with an optimal level of animal health security, based on the most up to date scientific information and available techniques.*
- 3) *The recommendations in the Terrestrial Code make reference only to the animal health situation in the exporting country, and assume that either the disease is either not present in the importing country or is the subject of a control or eradication programme. A Member Country may authorise the importation of animals or animal products into its territory under conditions more or less stringent than those recommended by the Terrestrial Code. Where the conditions are more restrictive, they should be based on a scientific risk analysis conducted in accordance with OIE recommendations. For Members of the World Trade Organization (WTO), international trade measures should be based on a relevant international standard (i.e. for animal health measures, an OIE standard) or an import risk analysis, to meet their obligations under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).*
- 4) *Key terms and expressions used in the Terrestrial Code are defined in the Glossary. When preparing international veterinary health certificates, the importing country should endeavour to use these terms and expressions in accordance with the definitions given in the Terrestrial Code. The Terrestrial Code contains model veterinary health certificates as a further support to Member Countries.*
- 5) *The OIE aims to include, at the beginning of each chapter relating to a specific disease, an article listing either the commodities that are considered safe for trade regardless of the status of the country (or zone) for the disease in question. This is a work in progress and some chapters do not yet contain articles listing safe commodities. In some chapters, the OIE identifies the commodities that are capable of transmitting the disease through international trade and/or those considered not to present a risk.*
- 6) *In many of the Terrestrial Code chapters, the use of specified diagnostic tests and vaccines is recommended and a reference 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 for OIE listed diseases may be found in Chapter 1.3.*
- 7) *Section 5 deals with obligations and ethics in international trade. The OIE recommends that Veterinary Authorities have sufficient copies of the Terrestrial Code to allow all veterinarians directly involved in international trade to familiarise themselves with OIE recommendations. In addition, facilities responsible for disease diagnosis and vaccine production should be fully conversant with the recommendations in the Terrestrial Manual.*
- 8) *The term ('under study') is found in some chapters, with reference to an article or part of an article. This means that the text has not yet been adopted by the World Assembly of OIE Delegates and the particular provisions are not part of the Terrestrial Code. Member Countries may wish to follow such recommendations in part or in full.*
- 9) *The complete text of the Terrestrial Code is available on the OIE Web site and may be downloaded from: <http://www.oie.int>.*

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

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

### **C. International veterinary health certificates**

- 1) *An international veterinary certificate is an official document drawn up by the exporting country in accordance with the terms of Chapter 5.1. and Chapter 5.2., describing the animal health requirements and, where appropriate, public health requirements for the exported commodity. The quality of the exporting country's Veterinary Services,*

*including the ethical approach to the provision of veterinary health certificates, is key in providing assurance to trading partners regarding the safety of exported animals and products.*

- 2) *International veterinary health certificates underpin international trade and provide assurances to the importing country regarding the health status of the animals and products imported. The health measures prescribed should take into account the health status of both exporting and importing countries and be based upon the recommendations in the Terrestrial Code.*
- 3) *The following steps should be taken when drafting international veterinary health certificates:*
  - a) *list the diseases for which the importing country is justified in seeking protection, having regard to the disease status of the importing country and the exporting country. Importing countries should not impose measures in regard to diseases that occur in the importing country and that are not subject to official control or eradication programmes;*
  - b) *list the health requirements for each of these diseases. These can be determined by referring to the relevant articles in the Terrestrial Code. The Terrestrial Code provides for various levels of sanitary status: e.g. disease free country, zone or compartment, disease free herd, vaccinated or non-vaccinated population;*
  - c) *OIE models (see Chapters 5.10. to 5.12.) should be used as the baseline for international veterinary health certificates. The content and form of the final certificate may be modified as required.*
- 4) *As stated in Article 5.2.2., international veterinary health certificates should be kept as simple as possible and should be clearly worded, to avoid misunderstanding of the importing country's requirements.*

#### **D. Guidance notes for importers and exporters**

*To provide a clear understanding of trade requirements, it is advisable to prepare 'guidance notes' to assist importers and exporters. These notes should identify and explain the trade conditions, including the measures to be applied before and after export, during transport and unloading, relevant legal obligations and operational procedures. Exporters should also be reminded of the International Air Transport Association (IATA) rules governing air transport of animals and animal products.*

*The guidance notes should advise on all details to be included in the health certification accompanying the consignment to its destination.*



## GLOSSARY

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For the purposes of the *Terrestrial Code*:

### **Acceptable risk**

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

### **Animal**

means a mammal, bird or bee.

### **Animal for breeding or rearing**

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

### **Animal for slaughter**

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

### **Animal handler**

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

### **Animal health status**

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

### **Animal identification**

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

### **Animal identification system**

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

### **Animal traceability**

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

### **Animal welfare**

means how an *animal* is coping with the conditions in which it lives. An *animal* is in a good state of *welfare* if (as indicated by scientific evidence) it is healthy, comfortable, well nourished, safe, able to express innate behaviour, and if it is not suffering from unpleasant states such as pain, fear and distress. Good *animal welfare* requires *disease* prevention and veterinary treatment, appropriate shelter, management, nutrition, humane handling and human *slaughter/killing*. *Animal welfare* refers to the state of the *animal*; the treatment that an *animal* receives is covered by other terms such as animal care, animal husbandry, and humane treatment.

### **Antimicrobial agent**

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

### **Apiary**

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

**Appropriate level of protection**

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

**Approved**

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

**Artificial insemination centre**

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

**Beehive**

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

**Biosecurity plan**

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

**Border post**

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

**Captive wild animal**

means an *animal* that has a phenotype not significantly affected by human selection but that is captive or otherwise lives under direct human supervision or control, including zoo *animals* and pets.

**Case**

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

**Collection centre**

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

**Commodity**

means live *animals*, products of animal origin, animal genetic material, biological products and *pathological material*.

**Compartment**

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

**Competent Authority**

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

**Container**

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

**Containment zone**

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

**Day-old birds**

means birds aged not more than 72 hours after hatching.

**Death**

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

**Disease**

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

**Disinfection**

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

**Disinfestation**

means the application of procedures intended to eliminate *infestation*.

**Early detection system**

means a system for the timely detection and identification of an incursion or emergence of *diseases/infections* in a country, *zone* or *compartment*. An early detection system should be under the control of the *Veterinary Services* and should include the following characteristics:

- a) representative coverage of target animal *populations* by field services;
- b) ability to undertake effective *disease* investigation and reporting;
- c) access to laboratories capable of diagnosing and differentiating relevant *diseases*;
- d) a training programme for *veterinarians*, *veterinary para-professionals*, livestock owners/keepers and others involved in handling *animals* for detecting and reporting unusual animal health incidents;
- e) the legal obligation of private *veterinarians* to report to the *Veterinary Authority*;
- f) a national chain command.

**Emerging disease**

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

**Epidemiological unit**

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

**Equivalence of sanitary measures**

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

**Eradication**

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

**Establishment**

means the premises in which *animals* are kept.

**Euthanasia**

means the act of inducing *death* using a method that causes a rapid and irreversible loss of consciousness with minimum pain and distress to *animal*.

**Exporting country**

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

**Feral animal**

means an *animal* of a domesticated species that now lives without direct human supervision or control.

**Flock**

means a number of *animals* of one kind kept together under human control or a congregation of gregarious *wild animals*. For the purposes of the *Terrestrial Code*, a *flock* is usually regarded as an *epidemiological unit*.

**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*.

**Good manufacturing practice**

means a production and testing practice recognised by the *Competent Authority* to ensure the quality of a product.

**Greaves**

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

**Hatching eggs**

means fertilised bird eggs, suitable for incubation and hatching.

**Hazard**

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

**Hazard identification**

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

**Headquarters**

means the Permanent Secretariat of the World Organisation for Animal Health located at:

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>

**Herd**

means a number of *animals* of one kind kept together under human control or a congregation of gregarious *wild animals*. For the purposes of the *Terrestrial Code*, a *herd* is usually regarded as an *epidemiological unit*.

**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 a *disease* has been diagnosed.

**Infection**

means the entry and development or multiplication of an infectious agent in the body of humans or *animals*.

**Infective period**

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

**Infestation**

means the external invasion or colonisation of *animals* or their immediate surroundings by arthropods, which may cause *disease* or are potential *vectors* of infectious agents.

**International trade**

means importation, exportation and transit of *commodities*.

**International veterinary certificate**

means a certificate, issued in conformity with the provisions of Chapter 5.2., describing the animal health and/or public health requirements which are fulfilled by the exported *commodities*.

**Journey**

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

**Killing**

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

**Laboratory**

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

**Lairage**

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

**Listed diseases**

means the list of transmissible *disease* agreed by the World Assembly of OIE Delegates and set out in Chapter 1.2.

**Loading/unloading**

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

**Market**

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

**Meat**

means all edible parts of an *animal*.

**Meat-and-bone meal**

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

**Meat products**

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

**Milk**

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

**Milk product**

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

**Modified stamping-out policy**

see *stamping-out policy*.

**Monitoring**

means the intermittent performance and analysis of routine measurements and observations, aimed at detecting changes in the environment or health status of a *population*.

**Notifiable disease**

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

**Notification**

means the procedure by which:

- a) the *Veterinary Authority* informs the *Headquarters*,
- b) the *Headquarters* inform the *Veterinary Authority*,

of the occurrence of an *outbreak* of *disease* or *infection*, according to the provisions of Chapter 1.1.

**Official control programme**

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

**Official Veterinarian**

means a *veterinarian* authorised by the *Veterinary Authority* of the country to perform certain designated official tasks associated with animal health and/or public health and inspections of *commodities* and, when appropriate, to certify in conformity with the provisions of Chapters 5.1. and 5.2.

**Official veterinary control**

means the operations whereby the *Veterinary Services*, knowing the location of the *animals* and after taking appropriate actions to identify their owner or responsible keeper, are able to apply appropriate animal health measures, as required. This does not exclude other responsibilities of the *Veterinary Services* e.g. food safety.

**Outbreak**

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

**Owned dog**

means a dog for which a person claims responsibility.

**Pathological material**

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

**Place of shipment**

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

**Population**

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

**Post-journey period**

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

**Poultry**

means all domesticated birds, including backyard poultry, used for the production of *meat* or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds, as well as fighting cocks used for any purpose.

Birds that are kept in captivity for any reason other than those reasons referred to in the preceding paragraph, including those that are kept for shows, races, exhibitions, competitions or for breeding or selling these categories of birds as well as pet birds, are not considered to be poultry.

**Pre-journey period**

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

**Prevalence**

means the total number of *cases* or *outbreak* 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.

**Protection zone**

means a *zone* established to protect the health status of *animals* in a free country or *free zone*, from those in a country or *zone* of a different *animal health status*, using measures based on the epidemiology of the *disease* under consideration to prevent spread of the causative pathogenic agent into a free country or *free zone*. These measures may include, but are not limited to, *vaccination*, movement control and an intensified degree of *surveillance*.

**Qualitative risk assessment**

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

**Quality**

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

**Quantitative risk assessment**

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

**Quarantine station**

means an establishment under the control of the *Veterinary Authority* where *animals* are maintained in isolation with no direct or indirect contact with other *animals*, to ensure that there is no transmission of specified pathogen(s) outside the establishment while the *animals* are undergoing observation for a specified length of time and, if appropriate, testing and treatment.

**Registration**

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

**Responsible dog ownership**

means the situation whereby a person (as defined above) accepts and commits to perform various duties according to the legislation in place and focused on the satisfaction of the behavioural, environmental and physical needs of a dog and to the prevention of risks (aggression, *disease* transmission or injuries) that the dog may pose to the community, other *animals* or the environment.

**Resting point**

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

**Restraint**

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

**Risk**

means the likelihood of the occurrence and the likely magnitude of the biological and economic consequences of an adverse event or effect to animal or human health.

**Risk analysis**

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

**Risk assessment**

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

**Risk communication**

is the interactive transmission and exchange of information and opinions throughout the *risk analysis* process concerning *risk*, *risk*-related factors and *risk* perceptions among *risk* assessors, *risk* managers, *risk* communicators, the general public and other interested parties.

**Risk management**

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

**Sanitary measure**

means a measure, such as those described in various chapters of the *Terrestrial Code*, destined to protect animal or human health or life within the territory of the Member Country from *risks* arising from the entry, establishment and/or spread of a *hazard*.

**Slaughter**

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

**Slaughterhouse/abattoir**

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

**Space allowance**

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

**Specific surveillance**

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

**Stamping-out policy**

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

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

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

**Stocking density**

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

**Stray dog**

means any dog not under direct control by a person or not prevented from roaming. Types of stray dog:

- a) free-roaming owned dog not under direct control or restriction at a particular time,
- b) free-roaming dog with no owner,
- c) feral dog: domestic dog that has reverted to the wild state and is no longer directly dependent upon humans.



**Stunning**

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

**Subpopulation**

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

**Surveillance**

means the systematic ongoing collection, collation, and analysis of information related to animal health and the timely dissemination of information so that action can be taken.

**Terrestrial Code**

means the OIE *Terrestrial Animal Health Code*.

**Terrestrial Manual**

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

**Transit country**

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

**Transparency**

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

**Transport**

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

**Transporter**

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

**Travel**

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

**Unit**

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

**Vaccination**

means the successful immunisation of susceptible *animals* through the administration, according to the manufacturer's instructions and the *Terrestrial Manual*, where relevant, of a vaccine comprising antigens appropriate to the *disease* to be controlled.

**Vector**

means an insect or any living carrier that transports an infectious agent from an infected individual to a susceptible individual or its food or immediate surroundings. The organism may or may not pass through a development cycle within the *vector*.

**Vehicle/vessel**

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

**Veterinarian**

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

**Veterinary Authority**

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

**Veterinary legislation**

means laws, regulations and all associated legal instruments that pertain to the veterinary domain.

**Veterinary medicinal product**

means any product with approved claim(s) to having a prophylactic, therapeutic or diagnostic effect or to alter physiological functions when administered or applied to an *animal*.

**Veterinary para-professional**

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

**Veterinary Services**

means the governmental and non-governmental organisations that implement animal health and *welfare* measures and other standards and recommendations in the *Terrestrial Code* and the *OIE Aquatic Animal Health Code* in the territory. The Veterinary Services are under the overall control and direction of the *Veterinary Authority*. Private sector organisations, *veterinarians*, *veterinary paraprofessionals* or aquatic animal health professionals are normally accredited or approved by the *Veterinary Authority* to deliver the delegated functions.

**Veterinary statutory body**

means an autonomous regulatory body for *veterinarians* and *veterinary para-professionals*.

**Wild animal**

means an *animal* that has a phenotype unaffected by human selection and lives independent of direct human supervision or control.

**Wildlife**

means *feral animals*, *captive wild animals* and *wild animals*.

**Zone/region**

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

**Zoonosis**

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

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SECTION 8.  
MULTIPLE SPECIES

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CHAPTER 8.1.

ANTHRAX

Article 8.1.1.

**General provisions**

This chapter is intended to manage the human and animal health risks associated with the presence of *Bacillus anthracis* (*B. anthracis*) in *commodities* and the environment.

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*.

When authorising import or transit of *commodities* covered in the chapter, with the exception of those listed in Article 8.1.2., *Veterinary Authorities* should require the conditions prescribed in this chapter.

Article 8.1.2.

**Safe commodities**

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any anthrax related conditions: semen and embryos collected and processed in accordance with Chapters 4.5., 4.6., 4.7., 4.8. and 4.9., as relevant.

Article 8.1.3.

**Recommendations for the importation of ruminants, equines and pigs**

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

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

AND

- 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 12 months prior to shipment in accordance with the *Terrestrial Manual*.

Article 8.1.4.

**Recommendations for the importation of fresh meat and meat products destined for human consumption**

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

- 1) have shown no sign of anthrax during ante- and post-mortem inspections; and
- 2) were not vaccinated against anthrax using live vaccine during the 14 days prior to *slaughter* or a longer period depending on the manufacturer's recommendations; and
- 3) come from *establishments* that are not placed under movement restrictions for the control of anthrax and where there has been no *case* of anthrax during the 20 days prior to *slaughter*.

Article 8.1.5.

**Recommendations for the importation of hides, skins and hair (from ruminants, equines and pigs)**

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

- 1) the products originate from *animals* that:
  - a) have shown no sign of anthrax during ante- and post-mortem inspections; and
  - b) come from *establishments* that are not placed under movement restrictions for the control of anthrax;

OR

- 2) hair from ruminants or equines has been treated in accordance with the recommendations in Article 8.1.11.

Article 8.1.6.

**Recommendations for the importation of wool**

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

- 1) originates from live *animals*; and
- 2) originates from *animals* that, at the time of shearing, were part of a *flock* that was not subject to movement restrictions for the control of anthrax;

OR

- 3) has been treated in accordance with the recommendations in Article 8.1.11.

Article 8.1.7.

**Recommendations for the importation of milk and milk products intended for human consumption**

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

- 1) the *milk* originates from *animals* showing no clinical sign of anthrax at the time of milking;
- 2) if the *milk* originates from *herds* or *flocks* that have had a *case* of anthrax within the previous 20 days, it has been chilled promptly and processed using a heat treatment at least equivalent to pasteurisation.

## Article 8.1.8.

**Recommendations for the importation of bristles (from pigs)**

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

- 1) have shown no sign of anthrax during ante- and post-mortem inspections; and
- 2) come from *establishments* that are not placed under movement restrictions for the control of anthrax;

OR

- 3) have been processed to ensure the destruction of *B. anthracis* by boiling for 60 minutes.

## Article 8.1.9.

**Procedures for the inactivation of *B. anthracis* spores in skins and trophies from wild animals**

In situations in which skins and trophies from *wild animals* may be contaminated with *B. anthracis* spores, the following *disinfection* procedure is recommended:

- 1) fumigation with ethylene oxide 500 mg/litre, at relative humidity 20–40 percent, at 55°C for 30 minutes; or
- 2) fumigation with formaldehyde 400 mg/m<sup>3</sup> at relative humidity 30 percent, at >15°C for 4 hours; or
- 3) gamma irradiation with a dose of 40 kiloGray.

## Article 8.1.10.

**Procedures for the inactivation of *B. anthracis* spores in bone-meal and meat-and-bone meal**

In situations where raw materials used to produce bone meal or *meat-and-bone meal* may be contaminated with *B. anthracis* spores, the following inactivation procedures should be used:

- 1) the raw material should be reduced to a maximum particle size of 50 mm before heating; and
- 2) the raw material should be subjected to moist heat at one of the following temperature and time regimes:
  - a) 105°C for at least 8 minutes; or
  - b) 100°C for at least 10 minutes; or
  - c) 95°C for at least 25 minutes; or
  - d) 90°C for at least 45 minutes;

OR

- 3) the raw material should be subjected to dry heat at one of the following temperature and time regimes:
  - a) 130°C for at least 20 minutes; or
  - b) 125°C for at least 25 minutes; or
  - c) 120°C for at least 45 minutes;

OR

- 4) an industrial process demonstrated to be of equivalent efficacy.

## Article 8.1.11.

**Procedures for the inactivation of *B. anthracis* spores in wool and hair**

In situations in which wool or hair may be contaminated with *B. anthracis* spores, the following procedures are recommended:

- 1) gamma irradiation with a dose of 25 kiloGray; or
- 2) a five-step washing procedure:
  - a) immersion in 0.25–0.3 percent soda liquor for 10 minutes at 40.5°C;
  - b) immersion in soap liquor for 10 minutes at 40.5°C;

- c) immersion in 2 percent formaldehyde solution for 10 minutes at 40.5°C;
  - d) a second immersion in 2 percent formaldehyde solution for 10 minutes at 40.5°C;
  - e) rinsing on cold water followed by drying in hot air.
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## CHAPTER 8.2.

# INFECTION WITH AUJESZKY'S DISEASE VIRUS

### Article 8.2.1.

#### **General provisions**

Pigs are the natural host for Aujeszky's disease (AD) virus, although it can infect cattle, sheep, cats, dogs and rats causing fatal *disease*. The definition of pig includes all varieties of *Sus scrofa*, both domestic and wild.

For the purposes of the *Terrestrial Code*, AD is defined as an *infection* of domestic pigs or captive wild pigs, which are under direct human supervision or control.

For the purposes of this chapter, a distinction is made between domestic pig and captive wild pig populations on the one hand, and wild pig and feral pig populations on the other hand.

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

A Member Country should not impose trade bans in response to a notification of *infection* pigs according to Article 1.1.3. *Terrestrial Code*

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 8.2.3., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the AD status of the *exporting country or zone*.

### Article 8.2.2.

#### **Determination of the AD status of a country or zone**

The AD free or provisionally free status of a country or *zone* can only be determined after considering the following criteria, as applicable:

- 1) AD is notifiable in the whole country, and all clinical signs suggestive of AD should be subjected to field and *laboratory* investigations;
- 2) an on-going awareness programme should be in place to encourage reporting of all cases suggestive of AD;
- 3) the *Veterinary Authority* should have current knowledge of, and authority over, all domestic and captive wild pig *establishments* in the country or *zone*;
- 4) the *Veterinary Authority* should have current knowledge about the population and habitat of wild and feral pigs in the country or *zone*;
- 5) appropriate *surveillance*, capable of detecting the presence of *infection* even in the absence of clinical signs, is in place; this may be achieved through a *surveillance* programme in accordance with Chapter 1.4.

### Article 8.2.3.

#### **Safe commodities**

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

- 1) *fresh meat* of domestic and wild pigs not containing offal (head, and thoracic and abdominal viscera);
- 2) *meat products* of domestic and wild pigs not containing offal (head, and thoracic and abdominal viscera);
- 3) products of animal origin not containing offal (head, and thoracic and abdominal viscera).

Article 8.2.4.

**AD free country or zone**

1. Qualification

- a) A country or *zone* may be considered free from the *disease* without formally applying a specific *surveillance* programme (historical freedom) if the *disease* has not been reported for at least 25 years, and if for at least the past 10 years:
  - i) it has been a *notifiable disease*;
  - ii) an early detection system has been in place;
  - iii) measures to prevent the introduction of the AD virus into the country or *zone* have been in place;
  - iv) no *vaccination* against the *disease* has been carried out;
  - v) *infection* is not known to be established in wild and feral pigs, or appropriate measures have been implemented to prevent any transmission of the AD virus from wild and feral pigs to domestic and captive wild pigs.
- b) A country or *zone* which does not meet the conditions of the above paragraph may be considered free from AD when:
  - i) animal health regulations to control the movement of *commodities* with the exception of those listed in Article 8.2.3. in order to prevent the introduction of *infection* into the *establishments* of the country or *zone* have been in place for at least two years;
  - ii) *vaccination* against AD has been banned for all domestic and captive wild pigs in the country or *zone* for at least two years unless there are means, validated to OIE standards (Chapter 2.1.2. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs;
  - iii) if AD has never been reported in the country or *zone*, serological surveys, with negative results, have been conducted on a representative sample of all pig *establishments* in conformity with the recommendations in Chapter 1.4. at an acceptable level of confidence, no more than three years prior to qualification; the serological surveys should be directed at the detection of antibodies to the whole virus, and based on the breeding pig population or, for *establishments* that contain no breeding pigs, on a comparable number of fattening pigs; or
  - iv) if AD has been reported in the country or *zone*, a *surveillance* and control programme has been in place to detect every infected *establishment* and eradicate AD from it; the *surveillance* programme should be carried out in conformity with the recommendations in Chapter 1.4. and demonstrate that no *establishments* within the country or *zone* have had any clinical, virological or serological evidence of AD for at least two years.
  - v) In countries or *zones* with wild and feral pigs, measures should be implemented to prevent any transmission of the AD virus from wild and feral pigs to domestic and captive wild pigs.

2. Maintenance of free status

In order to maintain its free status, a country or *zone* should comply with the following requirements:

- a) periodic serological surveys directed at the detection of antibodies to the whole AD virus should be carried out on a statistically significant number of breeding pigs, in conformity with the recommendations in Chapter 1.4.;
- b) the importation of the *commodities* with the exception of those listed in Article 8.2.3. into the country or *zone* is carried out in conformity with the import conditions contained in the relevant articles of the present chapter;
- c) the ban on AD *vaccination* remains in force;
- d) appropriate measures aimed at preventing the transmission of the AD virus from wild and feral pigs to domestic and captive wild pigs remain in force.

3. Recovery of free status

Should an AD *outbreak* occur in an *establishment* of a free country or *zone*, the status of the country or *zone* may be restored if either:

- a) all the pigs in the infected *epidemiological units* have been slaughtered; and, during and after the application of this measure, an epidemiological investigation including clinical examination, and serological or virological testing has been carried out in all pig *establishments* which have been directly or indirectly in contact with the infected *establishment* and in all pig *establishments* located within a prescribed radius from the infected *epidemiological units*, 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) during and after the application of the measures described in points i) to ii) above, a thorough epidemiological investigation including clinical examination and serological or virological testing has been carried out in all pig *establishments* which have been directly or indirectly in contact with the infected *establishment* and in all pig *establishments* located within a prescribed radius from the *outbreak*, demonstrating that these *establishments* are not infected.

## Article 8.2.5.

**AD provisionally free country or zone**1. Qualification

A country or *zone* may be considered as provisionally free from AD if the following conditions are complied with:

- a) animal health regulations to control the movement of *commodities* with the exception of those listed in Article 8.2.3. in order to prevent the introduction of *infection* into the *establishments* of the country or *zone* have been in place for at least two years;
- b) if AD has never been reported in the country or *zone*, a serological survey, with negative results, has been conducted on a representative sample of all pig *establishments* in conformity with the recommendations in Chapter 1.4. (but not at an acceptable level of confidence); the serological survey should be directed at the detection of antibodies to the whole virus, and based on the breeding pig population or, for *establishments* that contain no breeding pigs, on a comparable number of fattening pigs; or
- c) if AD has been reported in the country or *zone*, a *surveillance* and control programme has been in place to detect infected *establishments* and eradicate AD from these *establishments*, the *herd* prevalence rate in the country or *zone* has not exceeded one percent for at least three years (the sampling procedure described in point 1e) of the definition of 'AD free establishment' should be applied within the *establishments* of the country or *zone*), and at least 90 percent of the *establishments* in the country or *zone* are qualified free;
- d) in countries or *zones* with wild and feral pigs, appropriate measures should be taken to prevent any transmission of the AD virus between wild and feral pigs and domestic and captive wild pigs.

2. Maintenance of provisionally free status

In order to maintain its provisionally free status, a country or *zone* should comply with the following requirements:

- a) the measures described in points 1b) and 1d) above should be continued;
- b) the percentage of infected *establishments* remains  $\leq$ one percent;
- c) the importation of the *commodities* with the exception of those listed in Article 8.2.3. into the country or *zone* is carried out in conformity with the import conditions contained in the relevant articles of the present chapter.

3. Recovery of provisionally free status

Should the percentage of infected *establishments* exceed one percent in a provisionally free country or *zone*, the status of the country or *zone* is cancelled and may be restored only once the percentage of infected *establishments* has remained  $\leq$ one percent for at least six months, and this result is confirmed by a serological survey conducted in conformity with point 1c) above.

## Article 8.2.6.

**AD infected country or zone**

For the purposes of this chapter, countries and *zones* which do not fulfil the conditions to be considered free or provisionally free of AD should be considered as infected.

Article 8.2.7.

**AD free establishment**

1. Qualification

To qualify as free from AD, an *establishment* should satisfy the following conditions:

- a) it is under the control of the *Veterinary Authority*;
- b) no clinical, virological or serological evidence of AD has been found for at least one year;
- c) the introduction of pigs, semen and embryos or ova into the *establishment* is carried out in conformity with the import conditions for these *commodities* contained in the relevant articles of the present chapter;
- d) *vaccination* against AD has not been carried out in the *establishment* for at least 12 months, and any previously vaccinated pigs are free from gE antibodies;
- e) a representative sample of breeding pigs from the *establishment* has been subjected, with negative results, to serological tests to the whole AD virus, applying a sampling procedure set out in conformity with the recommendations in Chapter 1.4.; these tests should have been carried out on two occasions, at an interval of two months; for *establishments* that contain no breeding pigs, the tests should be carried out only once on a comparable number of fattening or weaning pigs;
- f) a *surveillance* and control programme has been in place to detect infected *establishments* located within a prescribed radius from the *establishment* and no *establishment* is known to be infected within this *zone*.

2. Maintenance of free status

For *establishments* located in an infected country or *infected zone*, the testing procedure described in point 1e) above should be carried out every four months.

For *establishments* located in a provisionally free country or *zone*, the testing procedure described in point 1e) above should be carried out every year.

3. Recovery of free status

Should a free *establishment* become infected, or should an *outbreak* occur within a prescribed radius from a free *establishment*, the free status of the *establishment* should be suspended until the following conditions are met:

- a) in the infected *establishment*:
  - i) all the pigs in the *establishment* have been slaughtered, or
  - ii) at least 30 days after removal of all infected *animals*, all breeding *animals* have been subjected to a serological test to the whole AD virus, with negative results, on two occasions, at an interval of 2 months;
- b) in other *establishments* located within the prescribed radius: a number of breeding pigs from each *establishment* has been subjected, with negative results, to serological tests to the whole AD virus (non vaccinated *establishments*) or to gE antibodies (vaccinated *establishments*), applying the sampling procedure described in point 1e) above.

Article 8.2.8.

**Recommendations for importation from AD free countries or zones**

For domestic and captive wild pigs

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

- 1) showed no clinical sign of AD on the day of shipment;
- 2) come from an *establishment* located in an AD free country or *zone*;
- 3) have not been vaccinated against AD.

Article 8.2.9.

**Recommendations for importation from AD provisionally free countries or zones**

For domestic and captive wild pigs for breeding or rearing

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

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

- 2) have been kept exclusively in AD free *establishments* since birth;
- 3) have not been vaccinated against AD;
- 4) were subjected to a serological test to the whole AD virus, with negative results, within 15 days prior to shipment.

Article 8.2.10.

**Recommendations for importation from AD infected countries or zones**

For domestic and captive wild pigs for breeding or rearing

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

- 1) showed no clinical sign of AD on the day of shipment;
- 2) were kept exclusively in AD free *establishments* since birth;
- 3) have not been vaccinated against AD;
- 4) were isolated in the *establishment* of origin or a *quarantine station*, and were subjected to a serological test to the whole AD virus, with negative results, on two occasions, at an interval of not less than 30 days between each test, the second test being performed during the 15 days prior to shipment.

Article 8.2.11.

**Recommendations for importation from AD provisionally free countries or zones or AD infected countries or zones**

For domestic and captive wild pigs for slaughter

The pigs should be transported directly from the *place of shipment* to the *slaughterhouse/abattoir* from immediate *slaughter*.

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

- 1) a *surveillance* and control programme is in place in the country or *zone* to detect infected *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; and
    - i) have been kept exclusively in AD free *establishments* since birth; or
    - ii) have been vaccinated against AD at least 15 days prior to shipment.

Article 8.2.12.

**Recommendations for importation from AD free countries or zones**

For wild and feral swine

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

- 1) showed no clinical sign of AD on the day of shipment;
- 2) were captured in an AD free country or *zone*;
- 3) have not been vaccinated against the *disease*;
- 4) were isolated in a *quarantine station*, and were subjected to a serological test to the whole AD virus, with negative results, on two occasions, at an interval of not less than 30 days between each test, the second test being performed during the 15 days prior to shipment.

Article 8.2.13.

**Recommendations for importation from AD free countries or zones**

For semen of pigs

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

- 1) the donor *animals*:
  - a) showed no clinical sign of AD on the day of collection of the semen;
  - b) were kept in an *establishment* or *artificial insemination centre* located in an AD free country or *zone* at the time of semen collection;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.2.14.

**Recommendations for importation from AD provisionally free countries or zones**

For semen of pigs

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

- 1) the donor *animals*:
  - a) have been kept for at least four months prior to semen collection in an *artificial insemination centre* which has the status of AD free *establishment*, and where all boars are subjected to a serological test to the whole AD virus, with negative results, every four months;
  - b) showed no clinical sign of AD on the day of collection;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.2.15.

**Recommendations for importation from AD infected countries or zones**

For semen of pigs

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

- 1) the donor *animals*:
  - a) were kept in an AD free *establishment* for at least six months prior to entering the *artificial insemination centre*;
  - b) have been kept for at least four months prior to semen collection in the *artificial insemination centre* which has the status of AD free *establishment*, and where all boars are subjected to a serological test to the whole AD virus, with negative results, every four months;
  - c) were subjected to a serological test to the whole AD virus, with negative results, within 10 days prior to or 21 days after semen collection;
  - d) showed no clinical sign of AD on the day of collection;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.2.16.

**Recommendations for importation from AD free countries or zones**

For *in vivo* derived embryos of pigs

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

- 1) the donor females:
  - a) showed no clinical sign of AD on the day of collection of the embryos;
  - b) were kept in an *establishment* located in an AD free country or *zone* prior to collection;
- 2) the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 8.2.17.

**Recommendations for importation from AD provisionally free countries or zones**

For *in vivo* derived embryos of pigs

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

- 1) the donor females:
  - a) showed no clinical sign of AD on the day of collection of the embryos;
  - b) were kept in an AD free *establishment* for at least three months prior to collection;
- 2) the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 8.2.18.

**Recommendations for importation from AD infected countries or zones**

For *in vivo* derived embryos of pigs

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

- 1) the donor females:
  - a) showed no clinical sign of AD on the day of collection of the embryos;
  - b) were kept in an AD free *establishment* for at least three months prior to collection;
  - c) were subjected to a serological test to the whole AD virus, with negative results, within ten days prior to collection;
- 2) the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 8.2.19.

**Recommendations for importation from AD free countries or zones**

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

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of offal or products containing pig offal comes from *animals* which come from *establishments* located in an AD free country or *zone*.

Article 8.2.20.

**Recommendations for importation from AD provisionally free countries or zones or from AD infected countries or zones**

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

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

- 1) which have been kept in an AD free *establishment* since birth;
- 2) which have not been in contact with *animals* from *establishments* not considered free from AD during their transport to the approved *abattoir* and therein.

Article 8.2.21.

**Recommendations for importation from AD provisionally free countries or zones or from AD infected countries or zones**

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

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

- 1) either the entire consignment of offal used to prepare the products complied with the conditions referred to in Article 8.2.20.; or
- 2) the products have been processed to ensure the destruction of the AD virus; and
- 3) the necessary precautions were taken after processing to avoid contact of the products with any source of AD virus.

## CHAPTER 8.3.

# BLUETONGUE

### Article 8.3.1.

#### General provisions

For the purposes of the *Terrestrial Code*, the *infective period* for bluetongue virus (BTV) shall be 60 days.

Historically, the global BTV distribution has been confined between the latitudes of approximately 53°N and north of 34°S with a recent extension in Northern Europe.

In the absence of clinical *disease* in a country or *zone*, its BTV status should be determined by an ongoing *surveillance* programme (in accordance with Articles 8.3.16. to 8.3.21.). The programme may need to be adapted to target parts of the country or *zone* at a higher risk due to historical, geographical and climatic factors, ruminant population data and *Culicoides* ecology, or proximity to enzootic or incursional zones as described in Articles 8.3.16. to 8.3.21.

All countries or *zones* adjacent to a country or *zone* not having free status should be subjected to similar *surveillance*. The *surveillance* should be carried out over a distance of at least 100 kilometres from the border with that country or *zone*, but a lesser distance could be acceptable if there are relevant ecological or geographical features likely to interrupt the transmission of BTV or a bluetongue *surveillance* programme (in accordance with Articles 8.3.16. to 8.3.21.) in the country or *zone* not having free status supports a lesser distance.

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

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 8.3.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the BTV status of the ruminant population of the *exporting country* or *zone*.

### Article 8.3.2.

#### Safe commodities

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

- 1) *milk* and *milk products*;
- 2) *meat* and *meat products*;
- 3) hides and skins;
- 4) wool and fibre;
- 5) *in vivo* derived bovine embryos and oocytes collected, processed and stored in conformity with the provisions of Chapter 4.7. except for BTV8 (under study).

### Article 8.3.3.

#### BTV free country or zone

- 1) A country or a *zone* may be considered free from BTV when bluetongue is notifiable in the whole country and either:
  - a) a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21. has demonstrated no evidence of BTV in the country or *zone* during the past two years; or
  - b) an ongoing *surveillance* programme has demonstrated no evidence of *Culicoides* in the country or *zone*.
- 2) A BTV free country or *zone* in which ongoing *vector surveillance*, performed according to point 5 of Article 8.3.19., has found no evidence of *Culicoides* will not lose its free status through the importation of vaccinated, seropositive or infective *animals*, or semen or embryos/ova from infected countries or *infected zones*.

- 3) A BTV free country or *zone* in which *surveillance* has found evidence that *Culicoides* are present will not lose its free status through the importation of vaccinated or seropositive *animals* from infected countries or *infected zones*, provided:
  - a) the *animals* have been vaccinated, at least 60 days prior to dispatch, in accordance with the *Terrestrial Manual* with a vaccine which covers all serotypes whose presence in the source population has been demonstrated through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21., and the *animals* are identified in the accompanying certification as having been vaccinated; or
  - b) the *animals* are not vaccinated and, at least 60 days prior to dispatch, are demonstrated to have specific antibodies against the bluetongue virus serotypes whose presence has been demonstrated in the *exporting country or zone*.
- 4) A BTV free country or *zone* adjacent to an infected country or *infected zone* should include a *zone* as described in Article 8.3.1. in which *surveillance* is conducted in accordance with Articles 8.3.16. to 8.3.21. *Animals* within this *zone* should be subjected to continuing *surveillance*. The boundaries of this *zone* should be clearly defined, and should take account of geographical and epidemiological factors that are relevant to BTV transmission.

#### Article 8.3.4.

##### **BTV seasonally free zone**

A BTV seasonally free *zone* is a part of an infected country or an *infected zone* for which for part of a year, *surveillance* demonstrates no evidence either of BTV transmission or of adult *Culicoides*.

For the application of Articles 8.3.7., 8.3.10. and 8.3.13., the seasonally free period is taken to commence the day following the last evidence of BTV transmission (as demonstrated by the *surveillance* programme), and of the cessation of activity of adult *Culicoides*.

For the application of Articles 8.3.7., 8.3.10. and 8.3.13., the seasonally free period is taken to conclude either:

- 1) at least 28 days before the earliest date that historical data show bluetongue virus activity has recommenced; or
- 2) immediately if current climatic data or data from a *surveillance* programme indicate an earlier resurgence of activity of adult *Culicoides*.

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

#### Article 8.3.5.

##### **BTV infected country or zone**

For the purposes of this chapter, a BTV infected country or *infected zone* is a clearly defined area where evidence of BTV has been reported during the past two years. Such a country or *zone* may contain a BTV seasonally free *zone*.

#### Article 8.3.6.

##### **Recommendations for importation from BTV free countries or zones**

###### For ruminants and other BTV susceptible herbivores

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

- 1) the *animals* were kept in a BTV free country or *zone* since birth or for at least 60 days prior to shipment; or
- 2) the *animals* were kept in a BTV free country or *zone* for at least 28 days, then were subjected, with negative results, to a serological test to detect antibody to the BTV group according to the *Terrestrial Manual* and remained in the BTV free country or *zone* until shipment; or
- 3) the *animals* were kept in a BTV free country or *zone* for at least seven days, then were subjected, with negative results, to an agent identification test according to the *Terrestrial Manual*, and remained in the BTV free country or *zone* until shipment; or
- 4) the *animals*:
  - a) were kept in a BTV free country or *zone* for at least seven days;



- b) were vaccinated, at least 60 days before the introduction into the free country or *zone*, in accordance with the *Terrestrial Manual* against all serotypes whose presence in the source population has been demonstrated through a *surveillance* programme as described in Articles 8.3.16. to 8.3.21.;
- c) were identified as having been vaccinated; and
- d) remained in the BTV free country or *zone* until shipment;

AND

- 5) if the *animals* were exported from a free *zone* within an infected country, either:
  - a) did not transit through an *infected zone* during transportation to the *place of shipment*; or
  - b) were protected from *Culicoides* attacks at all times when transiting through an *infected zone*; or
  - c) had been vaccinated in accordance with point 4 above.

Article 8.3.7.

### **Recommendations for importation from BTV seasonally free zones**

#### For ruminants and other BTV susceptible herbivores

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

- 1) were kept during the seasonally free period in a BTV seasonally free *zone* since birth or for at least 60 days prior to shipment; or
- 2) were kept during the BTV seasonally free period in a BTV seasonally free *zone* for at least 28 days prior to shipment, and were subjected during the residence period in the *zone* to a serological test to detect antibody to the BTV group according to the *Terrestrial Manual*, with negative results, carried out at least 28 days after the commencement of the residence period; or
- 3) were kept during the BTV seasonally free period in a BTV seasonally free *zone* for at least 14 days prior to shipment, and were subjected during the residence period in the *zone* to an agent identification test according to the *Terrestrial Manual*, with negative results, carried out at least 14 days after the commencement of the residence period; or
- 4) were kept during the seasonally free period in a BTV seasonally free *zone* and were vaccinated, at least 60 days before the introduction into the free country or *zone*, in accordance with the *Terrestrial Manual* against all serotypes whose presence in the source population has been demonstrated through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21. and were identified as having been vaccinated and remained in the BTV free country or *zone* until shipment;

AND

- 5) either:
  - a) did not transit through an *infected zone* during transportation to the *place of shipment*; or
  - b) were protected from *Culicoides* attacks at all times when transiting through an *infected zone*; or
  - c) were vaccinated in accordance with point 4 above.

Article 8.3.8.

### **Recommendations for importation from BTV infected countries or zones**

#### For ruminants and other BTV susceptible herbivores

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

- 1) were protected from *Culicoides* attacks in a *vector-protected establishment* for at least 60 days prior to shipment and during transportation to the *place of shipment*; or
- 2) were protected from *Culicoides* attacks in a *vector-protected establishment* for at least 28 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, with negative results, carried out at least 28 days after introduction into the *vector-protected establishment*; or
- 3) were protected from *Culicoides* attacks in a *vector-protected establishment* for at least 14 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to an agent identification test according to the *Terrestrial Manual*, with negative results, carried out at least 14 days after introduction into the *vector-protected establishment*; or

- 4) were vaccinated, at least 60 days before shipment, in accordance with the *Terrestrial Manual* against all serotypes whose presence in the source population has been demonstrated through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21., and were identified in the accompanying certification as having been vaccinated or, if demonstrated to have antibodies, have been protected from vectors for at least 60 days prior to shipment; or
- 5) demonstrated to have antibodies for at least 60 days prior to dispatch against all serotypes whose presence has been demonstrated in the source population through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21.

Article 8.3.9.

**Recommendations for importation from BTV free countries or zones**

For semen of ruminants and other BTV susceptible herbivores

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

- 1) the donor *animals*:
  - a) were kept in a BTV free country or *zone* for at least 60 days before commencement of, and during, collection of the semen; or
  - b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after the last collection for this consignment, with negative results; or
  - c) were subjected to an agent identification test according to the *Terrestrial Manual* on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.3.10.

**Recommendations for importation from BTV seasonally free zones**

For semen of ruminants and other BTV susceptible herbivores

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

- 1) the donor *animals*:
  - a) were kept during the BTV seasonally free period in a seasonally free *zone* for at least 60 days before commencement of, and during, collection of the semen; or
  - b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment; or
  - c) were subjected to an agent identification test according to the *Terrestrial Manual* on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.3.11.

**Recommendations for importation from BTV infected countries or zones**

For semen of ruminants and other BTV susceptible herbivores

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

- 1) the donor *animals*:
  - a) were kept in a *vector-protected establishment* for at least 60 days before commencement of, and during, collection of the semen; or
  - b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment; or

- c) were subjected to an agent identification test according to the *Terrestrial Manual* on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

## Article 8.3.12.

**Recommendations for importation from BTV free countries or zones**For *in vivo* derived embryos of ruminants (other than bovines) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos

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

- 1) the donor females:
  - a) were kept in a BTV free country or *zone* for at least the 60 days prior to, and at the time of, collection of the embryos; or
  - b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after collection, with negative results; or
  - c) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative results;
- 2) the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

## Article 8.3.13.

**Recommendations for importation from BTV seasonally free zones**For *in vivo* derived embryos/oocytes of ruminants (other than bovines) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos

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

- 1) the donor females:
  - a) were kept during the seasonally free period in a seasonally free *zone* for at least 60 days before commencement of, and during, collection of the embryos/oocytes; or
  - b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after collection, with negative results; or
  - c) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative results;
- 2) the embryos/oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

## Article 8.3.14.

**Recommendations for importation from BTV infected countries or zones**For *in vivo* derived embryos/oocytes of ruminants (other than bovines) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos

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

- 1) the donor females:
  - a) were kept in a *vector-protected establishment* for at least 60 days before commencement of, and during, collection of the embryos/oocytes; or
  - b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after collection, with negative results; or
  - c) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative results;

- 2) the embryos/oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 8.3.15.

**Protecting animals from *Culicoides* attacks**

1) Vector-protected establishment or facility

The means of protection of the *establishment* or facility should at least comprise the following:

- a) Appropriate physical barriers at entry and exit points, e.g. double-door entry-exit system;
- b) openings of the building are *vector* screened with mesh of appropriate gauge impregnated regularly with an approved insecticide according to the manufacturers' instructions;
- c) *vector surveillance* and control within and around the building;
- d) measures to limit or eliminate breeding sites for *vectors* in the vicinity of the *establishment* or facility;
- e) standard operating procedures, including description of back-up and alarm systems, for operation of the *establishment* or facility and transport of *animals* to the place of *loading*.

2) During transportation

When transporting *animals* through BTV infected countries or *infected zones*, *Veterinary Authorities* should require strategies to protect *animals* from *Culicoides* attacks during transport, taking into account the local ecology of the *vector*.

Potential *risk management* strategies include:

- a) treating *animals* with insect repellents prior to and during transportation;
- b) *loading*, transporting and *unloading animals* at times of low *vector* activity (i.e. bright sunshine, low temperature);
- c) ensuring *vehicles* do not stop en route during dawn or dusk, or overnight, unless the *animals* are held behind insect proof netting;
- d) darkening the interior of the *vehicle*, for example by covering the roof and/or sides of *vehicles* with shade cloth;
- e) *surveillance* for *vectors* at common stopping and offloading points to gain information on seasonal variations;
- f) using historical information and/or information from appropriately verified and validated BTV epidemiological models to identify low risk ports and transport routes.

Article 8.3.16.

**Surveillance: introduction**

Articles 8.3.16. to 8.3.21. define the principles and provide a guide on the *surveillance* for bluetongue complementary to Chapter 1.4. and for *vectors* complementary to Chapter 1.5., applicable to Member Countries seeking to determine their bluetongue status. This may be for the entire country or *zone*. Guidance for Member Countries seeking free status following an *outbreak* and for the maintenance of bluetongue status is also provided.

Bluetongue is a *vector-borne infection* transmitted by different species of *Culicoides* insects in a range of ecosystems. An important component of bluetongue epidemiology is vectorial capacity which provides a measure of *disease risk* that incorporates *vector* competence, abundance, biting rates, survival rates and extrinsic *incubation period*. However, methods and tools for measuring some of these *vector* factors remain to be developed, particularly in a field context. Therefore, *surveillance* for BT should focus on transmission in domestic ruminants.

The impact and epidemiology of bluetongue differ widely in different regions of the world and therefore it is impossible to provide specific recommendations for all situations. It is incumbent upon Member Countries to provide scientific data that explain the epidemiology of bluetongue in the region concerned and adapt the *surveillance* strategies for defining their *infection* status (free, seasonally free or infected country or *zone*) to the local conditions. There is considerable latitude available to Member Countries to justify their *infection* status at an acceptable level of confidence.

*Surveillance* for bluetongue should be in the form of a continuing programme.

## Article 8.3.17.

**Surveillance: case definition**

For the purposes of *surveillance*, a *case* refers to an *animal* infected with BTV.

For the purposes of *international trade*, a distinction should be made between a *case* as defined below and an *animal* that is potentially infectious to *vectors*. The conditions for trade are defined in Articles 8.3.1. to 8.3.15. of this chapter.

The purpose of *surveillance* is the detection of virus circulation in a country or *zone* and not determination of the status of an individual *animal* or *herds*. *Surveillance* deals not only with the occurrence of clinical signs caused by BTV, but also with the evidence of *infection* with BTV in the absence of clinical signs.

The following defines the occurrence of *infection* with BTV:

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

## Article 8.3.18.

**Surveillance: general conditions and methods**

- 1) A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. In particular:
  - a) a formal and ongoing system for detecting and investigating *outbreaks* of *disease* should be in place;
  - b) a procedure should be in place for the rapid collection and transport of samples from suspect cases of bluetongue to a *laboratory* for bluetongue diagnosis as described in the *Terrestrial Manual*;
  - c) a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.
- 2) The bluetongue *surveillance* programme should:
  - a) in a country/*zone* free or seasonally free, include an early warning system for reporting suspicious cases. Farmers and workers, who have regular contact with domestic ruminants, as well as diagnosticians, should report promptly any suspicion of bluetongue to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private *veterinarians* or *Veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. An effective *surveillance* system will periodically identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is BTV. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. All suspected cases of bluetongue should be investigated immediately and samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment are available for those responsible for *surveillance*;
  - b) conduct random or targeted serological and virological *surveillance* appropriate to the *infection* status of the country or *zone*.

Generally, the conditions to prevent exposure of susceptible *animals* to BTV infected *vectors* will be difficult to apply. However, under specific situations, in establishments such as *artificial insemination centres* or *quarantine stations* exposure to *vectors* may be preventable. The testing requirements for *animals* kept in these facilities are described in Articles 8.3.11. and 8.3.14.

## Article 8.3.19.

**Surveillance strategies**

The target population for *surveillance* aimed at identification of *disease* and/or *infection* should cover susceptible domestic ruminants within the country or *zone*. Active and passive *surveillance* for *infection* with BTV should be ongoing.

*Surveillance* should be composed of random or targeted approaches using virological, serological and clinical methods appropriate for the *infection* status of the country or *zone*.

The strategy employed may be based on *surveillance* using randomised sampling that would demonstrate the absence of BTV *infection* at an acceptable level of confidence. The frequency of sampling should be dependent on the epidemiological situation. Random *surveillance* is conducted using serological tests described in the *Terrestrial Manual*. Positive serological results may be followed up with virological methods as appropriate.

Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. Virological and serological methods may be used concurrently to define the BTV status of targeted populations.

A Member Country should justify the *surveillance* strategy chosen as being adequate to detect the presence of *infection* with BTV in accordance with Chapter 1.4. and the prevailing epidemiological situation. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clinical signs (e.g. sheep). Similarly, virological and serological testing may be targeted to species that rarely show clinical signs (e.g. cattle).

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

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

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

Irrespective of the survey approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the *vaccination/infection* history and the different species in the target population.

Irrespective of the testing system employed, *surveillance* system design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as those which may be epidemiologically linked to it.

The principles involved in *surveillance* for *disease/infection* are technically well defined. The design of *surveillance* programmes to prove the absence of BTV *infection/circulation* needs to be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by international trading partners, or excessively costly and logistically complicated. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.

#### 1. Clinical surveillance

Clinical *surveillance* aims at the detection of clinical signs of bluetongue at the *flock/herd* level. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection should not be underrated, particularly during a newly introduced *infection*. In sheep and occasionally goats, clinical signs may include oedema, hyperaemia of mucosal membranes, coronitis and cyanotic tongue.

Bluetongue suspects detected by clinical *surveillance* should always be confirmed by *laboratory* testing.

#### 2. Serological surveillance

An active programme of *surveillance* of host populations to detect evidence of BTV transmission is essential to establish BTV status in a country or *zone*. Serological testing of ruminants is one of the most effective methods of detecting the presence of BTV. The species tested depends on the epidemiology of BTV *infection*, and the species

available, in the local area. Cattle are usually the most sensitive indicator species. Management variables that may influence likelihood of *infection*, such as the use of insecticides and animal housing, should be considered.

*Surveillance* may include serological surveys, for example *abattoir* surveys, the use of cattle as sentinel *animals* (which should be individually identifiable), or a combination of methods. *Surveillance* may also be conducted by sampling and testing of bulk milk using an ELISA, as prescribed in the *Terrestrial Manual*.

The objective of serological *surveillance* is to detect evidence of BTV circulation. Samples should be examined for antibodies against BTV using tests prescribed in the *Terrestrial Manual*. Positive BTV antibody tests results can have four possible causes:

- a) natural *infection* with BTV,
- b) *vaccination* against BTV,
- c) maternal antibodies,
- d) positive results due to the lack of specificity of the test.

It may be possible to use sera collected for other survey purposes for BTV *surveillance*. However, the principles of survey design described in these recommendations and the requirements for a statistically valid survey for the presence of BTV *infection* should not be compromised.

The results of random or targeted serological surveys are important in providing reliable evidence that no *infection* with BTV is present in a country or *zone*. It is, therefore, essential that the survey is thoroughly documented. It is critical to interpret the results in light of the movement history of the *animals* being sampled.

Serological *surveillance* in a free *zone* should target those areas that are at highest risk of BTV transmission, based on the results of previous *surveillance* and other information. This will usually be towards the boundaries of the free *zone*. In view of the epidemiology of *infection* with BTV, either random or targeted sampling is suitable to select *herds* and/or *animals* for testing.

A *protection zone* within a free country or *zone* should separate it from a potentially infected country or *infected zone*. Serological *surveillance* in a free country or *zone* should be carried out over an appropriate distance from the border with a potentially infected country or *infected zone*, based upon geography, climate, history of *infection* and other relevant factors.

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

### 3. Virological surveillance

Isolation and genetic analysis of BTV from a proportion of infected *animals* is beneficial in terms of providing information on serotype and genetic characteristics of the viruses concerned.

Virological *surveillance* using tests described in the *Terrestrial Manual* can be conducted:

- a) to identify virus circulation in at risk populations,
- b) to confirm clinically suspect cases,
- c) to follow up positive serological results,
- d) to better characterize the genotype of circulating virus in a country or *zone*.

### 4. Sentinel animals

Sentinel *animals* are a form of targeted *surveillance* with a prospective study design. They are the preferred strategy for BTV *surveillance*. They comprise groups of unexposed *animals* managed at fixed locations and sampled regularly to detect new *infections* with BTV.

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

A sentinel animal programme should use *animals* of known source and history of exposure, control management variables such as use of insecticides and animal housing (depending on the epidemiology of BTV in the area under consideration), and be flexible in its design in terms of sampling frequency and choice of tests.

Care is necessary in choosing the sites for the sentinel groups. The aim is to maximise the chance of detecting BTV activity at the geographical location for which the sentinel site acts as a sampling point. The effect of secondary factors that may influence events at each location, such as climate, may also be analysed. To avoid bias, sentinel groups should comprise *animals* selected to be of similar age and susceptibility to *infection* with BTV. Cattle are

the most appropriate sentinels but other domestic ruminant species may be used. The only feature distinguishing groups of sentinels should be their geographical location.

Sera from sentinel animal programmes should be stored methodically in a serum bank to allow retrospective studies to be conducted in the event of new serotypes being isolated.

The frequency of sampling will depend on the reason for choosing the sampling site. In endemic areas, virus isolation will allow monitoring of the serotypes and genotypes of BTV circulating during each time period. The borders between infected and non infected areas can be defined by serological detection of *infective period*. Monthly sampling intervals are frequently used. Sentinels in declared free *zones* add to confidence that *infections* with BTV are not occurring unobserved. In such cases, sampling prior to and after the possible period of transmission is sufficient.

Definitive information on BTVs circulating in a country or *zone* is provided by isolation and identification of the viruses. If virus isolation is required, sentinels should be sampled at sufficiently frequent intervals to ensure that samples are collected during the period of viraemia.

5. Vector surveillance

BTV is transmitted between ruminant hosts by species of *Culicoides* which vary across the world. It is therefore important to be able to identify potential *vector* species accurately although many such species are closely related and difficult to differentiate with certainty.

The main purpose of *vector surveillance* is to determine areas of different levels of risk and local details of seasonality by determining the various *vector* species present in an area, their respective seasonal occurrence, and abundance. *Vector surveillance* has particular relevance to potential areas of spread. Long term *surveillance* can also be used to assess *vector* suppression measures.

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

*Vector surveillance* should be based on scientific sampling techniques. The choice of the number and type of traps to be used in *vector surveillance* and the frequency of their use should take into account the size and ecological characteristics of the area to be surveyed.

The operation of *vector surveillance* sites at the same locations as sentinel *animals* is advisable.

The use of a *vector surveillance* system to detect the presence of circulating virus is not recommended as a routine procedure as the typically low *vector infection* rates mean that such detections can be rare. Other *surveillance* strategies (e.g. the use of sentinel *animals* of domestic ruminants) are preferred to detect virus circulation.

Article 8.3.20.

**Documentation of BTV infection free status**

1. Member Countries declaring freedom from BTV infection for the country or zone: additional surveillance procedures

In addition to the general conditions described in the above-mentioned articles, a Member Country declaring freedom from *infection* with BTV for the entire country or a *zone* should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and should be planned and implemented according to general conditions and methods described in this chapter, to demonstrate absence of *infection* with BTV during the preceding 24 months in susceptible domestic ruminant populations. This requires the support of a *laboratory* able to undertake identification of *infection* with BTV through virus detection and antibody tests described in the *Terrestrial Manual*. This *surveillance* should be targeted to non-vaccinated *animals*. Clinical *surveillance* may be effective in sheep while serological *surveillance* is more appropriate in cattle.

2. Additional requirements for countries or zones that practise vaccination

*Vaccination* to prevent the transmission of BTV may be part of a disease control programme. The level of *flock* or *herd* immunity required to prevent transmission will depend on the *flock* or *herd* size, composition (e.g. species) and density of the susceptible population. It is therefore impossible to be prescriptive. The vaccine should also comply with the provisions stipulated for BTV vaccines in the *Terrestrial Manual*. Based on the epidemiology of *infection* with BTV in the country or *zone*, it may be that a decision is reached to vaccinate only certain species or other subpopulations.



In countries or *zones* that practise *vaccination*, there is a need to perform virological and serological tests to ensure the absence of virus circulation. These tests should be performed on non-vaccinated subpopulations or on sentinels. The tests have to be repeated at appropriate intervals according to the purpose of the *surveillance* programme. For example, longer intervals may be adequate to confirm endemicity, while shorter intervals may allow on-going demonstration of absence of transmission.

#### Article 8.3.21.

### The use and interpretation of serological and virus detection tests

#### 1. Serological testing

Ruminants infected with BTV produce antibodies to structural and non-structural viral proteins, as do *animals* vaccinated with current modified live virus vaccines. Antibodies to the BTV serogroup antigen are detected with high sensitivity and specificity by competitive ELISA (c-ELISA) and to a lesser extent by AGID as described in the *Terrestrial Manual*. Positive c-ELISA results can be confirmed by neutralization assay to identify the infecting serotype(s); however, BTV infected ruminants can produce neutralizing antibodies to serotypes of BTV other than those to which they were exposed (false positive results), especially if they have been infected with multiple serotypes.

#### 2. Virus detection

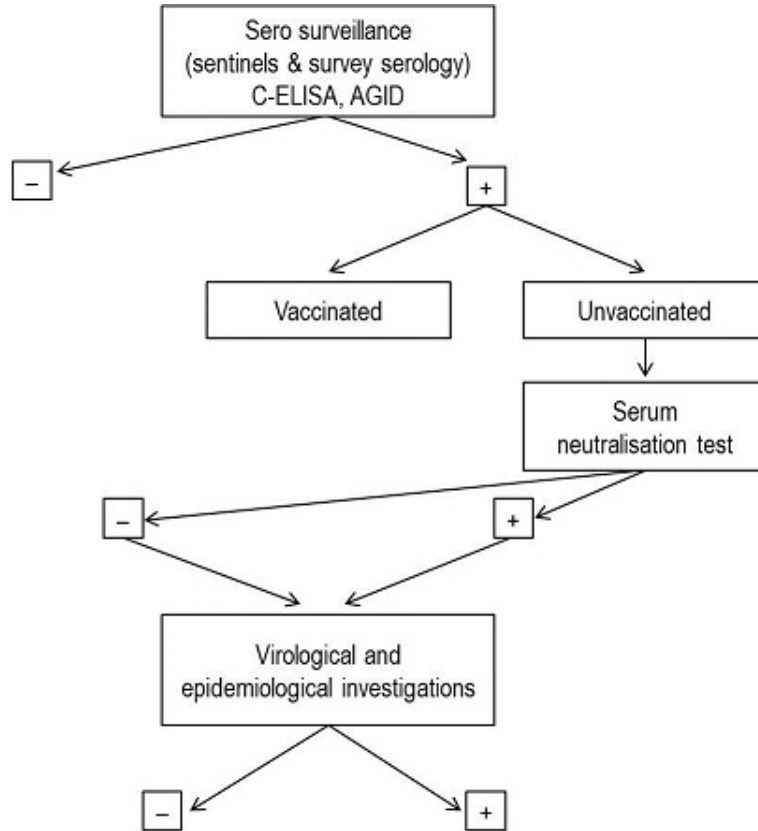
The presence of BTV in ruminant blood and tissues can be detected by virus isolation or polymerase chain reaction (PCR) as described in the *Terrestrial Manual*.

Interpretation of positive and negative results (both true and false) differs markedly between these tests because they detect different aspects of BTV *infection*, specifically (1) infectious BTV (virus isolation) and (2) nucleic acid (PCR). The following are especially relevant to interpretation of PCR assays:

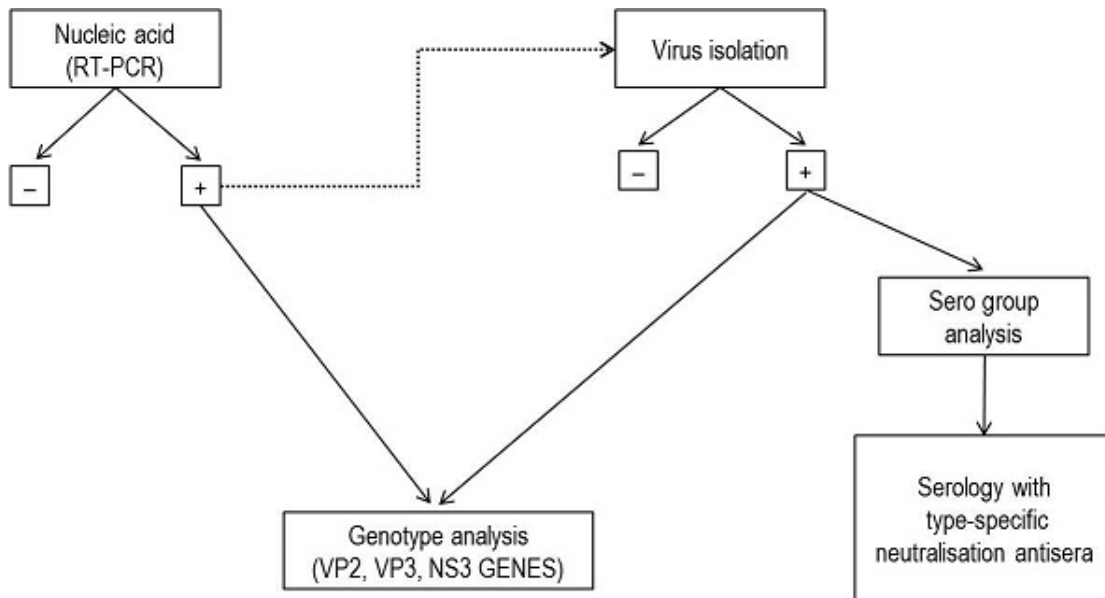
- a) The nested PCR assay detects BTV nucleic acid in ruminants long after the clearance of infectious virus. Thus positive PCR results do not necessarily coincide with active *infection* of ruminants. Furthermore, the nested PCR assay is especially prone to template contamination, thus there is considerable risk of false positive results.
- b) PCR procedures other than real time PCR allow sequence analysis of viral amplicons from ruminant tissues, insect *vectors* or virus isolates. These sequence data are useful for creating data bases to facilitate important epidemiological studies, including the possible distinction of field and vaccine virus strains of BTV, genotype characterization of field strains of BTV, and potential genetic divergence of BTV relevant to vaccine and diagnostic testing strategies.

It is essential that BTV isolates are sent regularly to the OIE Reference Laboratories for genetic and antigenic characterization.

**Fig. 1.** Application of laboratory tests in serological surveillance



**Fig. 2.** Application of laboratory tests in virological surveillance



## CHAPTER 8.4.

# INFECTION WITH *Echinococcus granulosus*

### Article 8.4.1.

#### General provisions

*Echinococcus granulosus* (*E. granulosus*) is a widely distributed cestode (tapeworm). The adult worms occur in the small intestine of canids (definitive host). Larval stages (hydatid) occur in tissues of liver, lung and other organs of other mammals (intermediate host), including humans. Infection with the larval stage of the parasite in the intermediate host, referred to as 'cystic echinococcosis' or 'hydatidosis', is associated with significant economic losses in livestock production and causes a major disease burden in humans.

For the purposes of the *Terrestrial Code*, infection with *E. granulosus* is defined as a zoonotic parasitic infection of canids, ungulates and macropod marsupials with *E. granulosus* (ovine, bovine, cervid, camelid and porcine strains).

For the purposes of this chapter, offal is defined as internal organs of ungulates and macropod marsupials.

Transmission of *E. granulosus* to canids occurs through ingestion of hydatid-infected offal.

Infection in intermediate hosts, as well as in humans, occurs by ingestion of *E. granulosus* eggs from contaminated environments. In humans, infection may also occur following contact with infected canids or by consumption of food or water contaminated with *E. granulosus* eggs from canine faeces.

Infection in humans can be prevented by good food hygiene and personal hygiene, community health education and preventing infection of canids. Collaboration between the *Competent Authority* and the public health authority is an essential component in preventing and controlling *E. granulosus* transmission.

This chapter provides recommendations for prevention of, control of, and surveillance for infection with *E. granulosus* in dogs and livestock.

When authorising the import or transit of the *commodities* covered in this chapter, with the exception of those listed in Article 8.4.2., *Veterinary Authorities* should apply the recommendations in this chapter.

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

### Article 8.4.2.

#### Safe commodities

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

- 1) skeletal muscle *meat* and skeletal muscle *meat products*;
- 2) processed fat;
- 3) casings;
- 4) *milk* and *milk products*;
- 5) hides and skins;
- 6) embryos, oocytes and semen.

### Article 8.4.3.

#### Programmes for the prevention and control of infection with *E. granulosus*

In order to prevent and control infection with *E. granulosus*, the *Veterinary Authority* or other *Competent Authority* should carry out community awareness programmes about the risk factors associated with transmission of

*E. granulosus*, the role of dogs (including *stray dogs*) and the importance of *responsible dog ownership*. The *Veterinary Authority* or other *Competent Authority* should also implement the following prevention and control measures.

1) Prevention of infection in dogs (owned and stray)

- a) Dogs should not be fed offal unless it has been treated in accordance with Article 8.4.6.
- b) Dogs should be prevented from scavenging on dead ungulates and macropod marsupials. Dead *animals* should be disposed of in accordance with provisions in Article 4.12.6.
- c) The *Veterinary Authority* or other *Competent Authority* should ensure that *slaughterhouses/abattoirs* have implemented measures that prevent access of dogs to the premises, and to animal carcasses and waste containing offal.
- d) When livestock cannot be slaughtered in a *slaughterhouse/abattoir* and are slaughtered on-farm, dogs should be prevented from having access to raw offal, and not be fed offal unless it has been treated in accordance with Article 8.4.6.

2) Control of infection in dogs (owned and stray)

- a) For control of *stray dog* populations, the *Veterinary Authority* or other *Competent Authority* should implement relevant aspects of Chapter 7.7.
- b) Dogs known to be infected or suspected of having access to raw offal or in contact with livestock should be dewormed at least every 4-6 weeks with praziquantel (5 mg/kg) or another cestocidal product with comparable efficacy. Where possible, faeces excreted up to 72 hours post treatment should be disposed of by incineration or burial.
- c) In areas of persistent transmission, the *Veterinary Authority* and other *Competent Authority* should collaborate to identify the possible origins of the *infection*, and review and amend the control programme, as appropriate.

3) Control of infection in livestock

- a) The *Veterinary Authority* should ensure that all slaughtered livestock are subjected to post-mortem *meat* inspection in accordance with Chapter 6.2., including inspection of offal for hydatids.
- b) When hydatids are detected during post-mortem *meat* inspection:
  - i) offal containing hydatids should be disposed of in accordance with Article 4.12.6., or treated in accordance with Article 8.4.6.;
  - ii) an investigation should be carried out by the *Veterinary Authority* and other *Competent Authority* to identify the possible origin of the *infection*, and review and amend, as appropriate, the control programme.

Article 8.4.4.

### **Surveillance and monitoring for infection with *E. granulosus***

An *animal identification* and *animal traceability* system should be implemented in accordance with the provisions of Chapters 4.1. and 4.2.

1) Monitoring in dogs

- a) Monitoring for infection with *E. granulosus* in dogs should be undertaken at regular intervals as it is an essential activity for assessing the risk of transmission to dog populations and for evaluating the success of control programmes. This can be achieved through testing of faeces from dogs, and canine faecal samples from the environment.
- b) Monitoring strategies should be appropriate to local conditions, in particular, where large populations of *stray dogs* and wild canids exist. Under these circumstances testing of environmental samples (faeces, soil) may provide a useful indicator of *infection* pressure.

2) Surveillance in slaughterhouses/abattoirs

- a) The *Veterinary Services* should carry out systematic *surveillance* for hydatids in livestock in *slaughterhouses/abattoirs*.
- b) Data collected should be used for the design or amendment of control programmes.

*Veterinary Authorities* should use information from public health authorities on cases of human hydatidosis in initial design and any subsequent modification of *surveillance* and monitoring programmes.

Article 8.4.5.

**Recommendations for the importation of dogs and wild canids from an infected country**

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

- 1) the *animal* has been treated between 24 and 72 hours prior to embarkation with praziquantel (5 mg/kg), or another cestocidal product with comparable efficacy against intestinal forms of *E. granulosus*;
- 2) adequate precautions have been taken to avoid reinfection of the *animal* between treatment and embarkation.

Article 8.4.6.

**Procedures for the inactivation of *E. granulosus* hydatids in offal**

For the inactivation of *E. granulosus* hydatids present in offal, one of the following procedures should be used:

- 1) heat treatment to a core temperature of at least 80°C for ten minutes or an equivalent time and temperature;
  - 2) freezing to minus 20°C or below for at least two days.
-

## CHAPTER 8.5.

# INFECTION WITH *Echinococcus multilocularis*

### Article 8.5.1.

#### General provisions

*Echinococcus multilocularis* (*E. multilocularis*) is a cestode (tapeworm) which is widespread in some parts of the Northern Hemisphere, and it is maintained mainly in wild animal populations. The adult worms occur in the small intestine of canids (definitive hosts), particularly foxes. Larval stages (metacestode) occur in tissues of liver and other organs of other mammals (commonly rodents) (intermediate hosts). Humans are infected occasionally with the larval stage, which causes severe *disease*, referred to as 'alveolar echinococcosis'. *Infection* does not cause discernible health impacts in livestock.

Foxes and some other wild canids are the most important definitive hosts in maintaining the cycle at the *wildlife*-human interface through contaminating both rural and urban environments. Dogs may also act as important and efficient definitive hosts in both rural and urban environments, providing an important potential source for human infections. Even though the potential role of felids in transmission of infection to humans cannot be excluded, their epidemiological role is considered negligible. Pigs may become infected but the parasite remains infertile; therefore, they have no role in transmission of the parasite.

For the purpose of the *Terrestrial Code*, infection with *E. multilocularis* is defined as a zoonotic parasitic *infection* of domestic and wild canids, and rodents.

Transmission of *E. multilocularis* to canids occurs through ingestion of metacestode-infected organs from a range of wild small mammals.

*Infection* in intermediate hosts, as well as in humans, occurs by ingestion of *E. multilocularis* eggs from contaminated environments. In humans, *infection* may also occur following contact with infected definitive hosts or by consumption of food or water contaminated with faeces of canids.

Prevention of infection in humans is difficult, particularly in areas with a high *infection* pressure maintained by rural and urban foxes. Good food hygiene and personal hygiene, community health education and preventing *infection* of dogs reduces the risk of human infection. Good communication and collaboration between the *Competent Authority* and public health authorities is an important component in monitoring the extent of infection with *E. multilocularis* in human and animal populations.

This chapter provides recommendations for prevention, control and monitoring of infection with *E. multilocularis* in dogs, and monitoring in wild canids.

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

### Article 8.5.2.

#### Safe commodities

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

### Article 8.5.3.

#### Programmes for the prevention and control of infection with *E. multilocularis* in owned and stray dogs

In order to achieve success in the prevention and control of infection with *E. multilocularis*, the *Competent Authority* should carry out community awareness programmes to inform people of the risk factors associated with transmission of *E. multilocularis*. Such programmes should include information on the importance of echinococcosis in *animals* and

humans, the role of foxes, other wild canids, and dogs, the need to implement preventive and control measures, and the importance of *responsible dog ownership*.

Whenever the epidemiological situation indicates that a control programme is necessary, the following measures should be undertaken:

- 1) *Owned dogs* should not be allowed to roam freely unless treated according to point 3.
- 2) For control of *stray dog* populations, the *Competent Authority* should ensure compliance with relevant aspects of Chapter 7.7.
- 3) Dogs known to be infected should immediately be treated with praziquantel (5 mg/kg) or another cestocidal product with a comparable efficacy; dogs suspected of having access to rodents or other small mammals should be treated every 21-26 days. Where possible, faeces excreted up to 72 hours post treatment should be disposed of by incineration or burial.

Article 8.5.4.

**Monitoring for infection with *E. multilocularis***

- 1) Monitoring in foxes and other wild canids
  - a) Monitoring for infection with *E. multilocularis* in foxes and other wild canids should be undertaken as it is an essential component for assessing the prevalence of *infection*.
  - b) Monitoring strategies should be appropriate to local conditions, in particular, where large populations of definitive hosts exist. Under these circumstances testing of environmental samples (faeces) may provide a useful indicator of *infection* pressure.
- 2) Surveillance in slaughterhouses/abattoirs

As an indicator of the presence of the parasite in the environment, *Veterinary Services* should consider carrying out targeted *surveillance* for larval lesions of *E. multilocularis* in livers of pigs raised in outdoor conditions.

*Veterinary Authorities* should use information from public health authorities on cases of human infection, in the initial design and any subsequent modification of *surveillance* and monitoring programmes:

Article 8.5.5.

**Recommendations for the importation of dogs and wild canids from an infected country**

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

- 1) the *animal* has been treated between 24 and 72 hours prior to embarkation with praziquantel (5 mg/kg), or another cestocidal product with a comparable efficacy against intestinal forms of *E. multilocularis*;
- 2) adequate precautions have been taken to avoid reinfection of the *animal* between treatment and embarkation.

## CHAPTER 8.6.

# FOOT AND MOUTH DISEASE

### Article 8.6.1.

#### **Introduction**

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 (except *Camelus dromedarius*).

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

The chapter deals not only with the occurrence of clinical signs caused by FMDV, but also with the presence of *infection* with FMDV in the absence of clinical signs.

The following defines the occurrence of FMDV *infection*:

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

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

### Article 8.6.2.

#### **FMD free country where vaccination is not practised**

Susceptible *animals* in the FMD free country where *vaccination* is not practised should be protected from neighbouring infected countries by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a *protection zone*.

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

- 1) have a record of regular and prompt animal *disease* reporting;
- 2) send a declaration to the OIE stating that:
  - a) there has been no *outbreak* of FMD during the past 12 months;
  - b) no evidence of FMDV *infection* has been found during the past 12 months;
  - c) no *vaccination* against FMD has been carried out during the past 12 months;
  - d) no vaccinated *animal* has been introduced since the cessation of *vaccination*;
- 3) supply documented evidence that:
  - a) *surveillance* for FMD and FMDV *infection* in accordance with Articles 8.6.42. to 8.6.47. and Article 8.6.49. is in operation;
  - b) regulatory measures for the early detection, prevention and control of FMD have been implemented;
- 4) describe in detail the boundaries and measures of a *protection zone*, if applicable.

The Member Country will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information in points 2, 3 and 4 above be re-submitted annually and changes in



the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.

#### Article 8.6.3.

##### **FMD free country where vaccination is practised**

Susceptible *animals* in the FMD free country where *vaccination* is practised should be protected from neighbouring infected countries by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a *protection zone*.

To qualify for inclusion in the list of FMD free countries where *vaccination* is practised, a Member 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 two years;
  - b) no evidence of FMDV circulation has been found during the past 12 months;
- 3) supply documented evidence that:
  - a) *surveillance* for FMD and FMDV circulation in accordance with Articles 8.6.42. to 8.6.47. and Article 8.6.49. is in operation;
  - b) regulatory measures for the early detection, prevention and control of FMD have been implemented;
  - c) routine *vaccination* is carried out for the purpose of the prevention of FMD;
  - d) the vaccine used complies with the standards described in the *Terrestrial Manual*;
- 4) describe in detail the boundaries and measures of a *protection zone*, if applicable.

The Member Country will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information in points 2, 3 and 4 above be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.

If a Member Country that meets the requirements of a FMD free country where *vaccination* is practised wishes to change its status to FMD free country where *vaccination* is not practised, the status of this country remains unchanged for a period of at least 12 months after *vaccination* has ceased. Evidence should also be provided showing that FMDV *infection* has not occurred during that period.

#### Article 8.6.4.

##### **FMD free zone where vaccination is not practised**

An FMD free *zone* where *vaccination* is not practised can be established in either an FMD free country where *vaccination* is practised or in a country of which parts are infected. In defining such *zones* the principles of Chapter 4.3. should be followed. Susceptible *animals* in the FMD free *zone* should be protected from the rest of the country and from neighbouring countries if they are of a different *animal health status* by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a *protection zone*.

To qualify for inclusion in the list of FMD free *zones* where *vaccination* is not practised, a Member Country should:

- 1) have a record of regular and prompt animal *disease* reporting;
- 2) send a declaration to the OIE stating that within the proposed FMD free *zone*:
  - a) there has been no *outbreak* of FMD during the past 12 months;
  - b) no evidence of FMDV *infection* has been found during the past 12 months;
  - c) no *vaccination* against FMD has been carried out during the past 12 months;
  - d) no vaccinated *animal* has been introduced into the *zone* since the cessation of *vaccination*, except in accordance with Article 8.6.10.;
- 3) supply documented evidence that:
  - a) *surveillance* for FMD and FMDV *infection* in accordance with Articles 8.6.42. to 8.6.47. and Article 8.6.49. is in operation;

- b) regulatory measures for the early detection, prevention and control of FMD have been implemented;
- 4) describe in detail and supply documented evidence that these are properly implemented and supervised:
  - a) the boundaries of the proposed FMD free zone;
  - b) the boundaries and measures of a *protection zone*, if applicable;
  - c) the system for preventing the entry of the virus (including the control of the movement of susceptible *animals*) into the proposed FMD free zone (in particular if the procedure described in Article 8.6.10. is implemented).

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

The information required in points 2, 3 and 4b)-c) above should be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.

#### Article 8.6.5.

#### **FMD free zone where vaccination is practised**

An FMD free zone where *vaccination* is practised can be established in either an FMD free country where *vaccination* is not practised or in a country of which parts are infected. In defining such zones the principles of Chapter 4.3. should be followed. Susceptible *animals* in the FMD free zone where *vaccination* is practised should be protected from neighbouring countries or zones if they are of a lesser *animal health status* by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a *protection zone*.

To qualify for inclusion in the list of FMD free zones where *vaccination* is practised, a Member Country should:

- 1) have a record of regular and prompt animal *disease* reporting;
- 2) send a declaration to the OIE that within the proposed FMD free zone:
  - a) there has been no *outbreak* of FMD for the past two years;
  - b) no evidence of FMDV circulation has been found during the past 12 months;
- 3) supply documented evidence that:
  - a) *surveillance* for FMD and FMDV *infection/circulation* in accordance with Articles 8.6.42. to 8.6.47. and Article 8.6.49. is in operation;
  - b) regulatory measures for the early detection, prevention and control of FMD have been implemented;
  - c) routine *vaccination* is carried out for the purpose of the prevention of FMD;
  - d) the vaccine used complies with the standards described in the *Terrestrial Manual*;
- 4) describe in detail and supply documented evidence that these are properly implemented and supervised:
  - a) the boundaries of the proposed FMD free zone;
  - b) the boundaries and measures of a *protection zone*, if applicable;
  - c) the system for preventing the entry of the virus (including the control of the movement of susceptible *animals*) into the proposed FMD free zone (in particular if the procedure described in Article 8.6.10. is implemented).

The proposed free zone will be included in the list of FMD free zones where *vaccination* is practised only after the submitted evidence has been accepted by the OIE. The information required in points 2, 3 and 4 b)-c) above should be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3 b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.

If a Member Country that has a zone which meets the requirements of a FMD free zone where *vaccination* is practised wishes to change the status of the zone to FMD free zone where *vaccination* is not practised, the status of this zone remains unchanged for a period of at least 12 months after *vaccination* has ceased. Evidence should also be provided showing that FMDV *infection* has not occurred in the said zone during that period.

## Article 8.6.6.

**FMD free compartment**

A FMD free *compartment* can be established in either a FMD free country or *zone* or in an infected country or *zone*. In defining such a *compartment* the principles of Chapters 4.3. and 4.4. should be followed. Susceptible *animals* in the FMD free *compartment* should be separated from any other susceptible *animals* by the application of an effective biosecurity management system.

A Member Country wishing to establish a FMD free *compartment* should:

- 1) have a record of regular and prompt animal *disease* reporting and if not FMD free, have an official control programme and a *surveillance* system for FMD in place according to Articles 8.6.42. to 8.6.47. and Article 8.6.49. that allows an accurate knowledge of the prevalence of FMD in the country or *zone*;
- 2) declare for the FMD free *compartment* 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) *vaccination* against FMD is prohibited;
  - d) no *animal* vaccinated against FMD within the past 12 months is in the *compartment*;
  - e) *animals*, semen and embryos should only enter the *compartment* in accordance with relevant articles in this chapter;
  - f) documented evidence shows that *surveillance* in accordance with Articles 8.6.42. to 8.6.47. and Article 8.6.49. is in operation for FMD and FMDV *infection*;
  - g) an *animal identification* and *traceability* system in accordance with Chapters 4.1. and 4.2. is in place;
- 3) describe in detail the animal subpopulation in the *compartment* and the biosecurity plan for FMD and FMDV *infection*.

The *compartment* should be approved by the *Veterinary Authority*. The first approval should only be granted when no *outbreak* of FMD has occurred within the *zone* in which the *compartment* is situated, during the last three months.

## Article 8.6.7.

**FMD infected country or zone**

For the purposes of this chapter, 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.

For the purposes of this chapter, 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 8.6.8.

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

In the event of limited *outbreaks* within an FMD free country or *zone*, including within a *protection zone*, with or without *vaccination*, a single *containment zone*, which includes all cases, can be established for the purpose of minimizing the impact on the entire country or *zone*.

For this to be achieved and for the Member Country to take full advantage of this process, the *Veterinary Authority* should submit documented evidence as soon as possible to the OIE that:

- 1) the *outbreaks* are limited based on the following factors:
  - a) immediately on suspicion, a rapid response including notification has been made;
  - b) standstill of animal movements has been imposed, and effective controls on the movement of other *commodities* mentioned in this chapter are in place;
  - c) epidemiological investigation (trace-back, trace-forward) has been completed;
  - d) the *infection* has been confirmed;
  - e) the primary *outbreak* has been identified, and investigations on the likely source of the *outbreak* have been carried out;

- f) all cases have been shown to be epidemiologically linked;
  - g) no new cases have been found in the *containment zone* within a minimum of two *incubation periods* as defined in Article 8.6.1. after the stamping-out of the last detected case is completed;
- 2) a *stamping-out policy* has been applied;
  - 3) the susceptible animal population within the *containment zones* should be clearly identifiable as belonging to the *containment zone*;
  - 4) increased passive and targeted *surveillance* in accordance with Articles 8.6.42. to 8.6.47. and Article 8.6.49. in the rest of the country or *zone* has been carried out and has not detected any evidence of *infection*;
  - 5) animal health measures that effectively prevent the spread of the FMDV to the rest of the country or *zone*, taking into consideration physical and geographical barriers, are in place;
  - 6) ongoing *surveillance* in the *containment zone* is in place.

The free status of the areas outside the *containment zone* would be suspended pending the establishment of the *containment zone*. The free status of these areas could be reinstated irrespective of the provisions of Article 8.6.9., once the *containment zone* is clearly established, by complying with points 1 to 6 above. The *containment zone* should be managed in such a way that it can be demonstrated that *commodities* for *international trade* can be shown to have originated outside the *containment zone*.

The recovery of the FMD free status of the *containment zone* should follow the provisions of Article 8.6.9.

#### Article 8.6.9.

##### 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) three months after the last case where a *stamping-out policy* and serological *surveillance* are applied in accordance with Articles 8.6.42. to 8.6.49.; or
  - b) three months after the *slaughter* of all vaccinated *animals* where a *stamping-out policy*, emergency *vaccination* and serological *surveillance* are applied in accordance with Articles 8.6.42. to 8.6.47. and Article 8.6.49.; or
  - c) six 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 Articles 8.6.42. to 8.6.47. and Article 8.6.49., provided that a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of *infection* in the remaining vaccinated population.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.6.2. or 8.6.4. applies.
- 2) When an FMD *outbreak* or FMDV *infection* occurs in an FMD free country or *zone* where *vaccination* is practised, one of the following waiting periods is required to regain the status of FMD free country or *zone* where *vaccination* is practised:
  - a) 6 months after the last case where a *stamping-out policy*, emergency *vaccination* and serological *surveillance* in accordance with Articles 8.6.42. to 8.6.47. and Article 8.6.49. are applied, provided that the serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation; or
  - b) 18 months after the last case where a *stamping-out policy* is not applied, but emergency *vaccination* and serological *surveillance* in accordance with Articles 8.6.42. to 8.6.47. and Article 8.6.49. are applied, provided that the serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation.
- 3) When a FMD *outbreak* or FMDV *infection* occurs in a FMD free *compartment*, Article 8.6.6. applies.

## Article 8.6.10.

**Direct transfer of FMD susceptible animals from an infected zone for slaughter in a free zone (where vaccination either is or is not practised)**

In order not to jeopardise the status of a free zone, FMD susceptible *animals* should only leave the *infected zone* if transported directly to *slaughter* in the nearest designated *abattoir* 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 three months prior to movement;
- 3) FMD has not occurred within a ten-kilometre radius of the *establishment* of origin for at least three months prior to movement;
- 4) the *animals* should be transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *abattoir* without coming into contact with other susceptible *animals*;
- 5) such an *abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of *animals* from the *infected zone*;
- 6) *vehicles* and the *abattoir* should be subjected to thorough cleansing and *disinfection* immediately after use.

The *meat* should be treated according to Article 8.6.25. or Article 8.6.26. Other products obtained from the *animals* and any products coming into contact with them should be considered infected, and treated in such a way as to destroy any residual virus in accordance with Articles 8.6.34. to 8.6.41.

*Animals* moved into a free zone for other purposes should be moved under the supervision of the *Veterinary Authority* and comply with the conditions in Article 8.6.14.

## Article 8.6.11.

**Transfer directly to slaughter of FMD susceptible animals from a containment zone to a free zone (where vaccination either is or is not practised) within a country**

In order not to jeopardise the status of a free zone, FMD susceptible *animals* should only leave the *containment zone* if moved by mechanised transport directly to *slaughter* in the nearest designated *abattoir* under the following conditions:

- 1) the *containment zone* has been officially established according to the requirements in Article 8.6.8.;
- 2) the *animals* should 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*;
- 3) such an *abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of *animals* from the *containment zone*;
- 4) *vehicles* and the *abattoir* should be subjected to thorough cleansing and *disinfection* immediately after use.

The *meat* should be treated according to point 2 of Article 8.6.25. or Article 8.6.26. Other products obtained from the *animals* and any products coming into contact with them should be treated in such a way as to destroy any residual virus in accordance with Articles 8.6.34. to 8.6.41.

## Article 8.6.12.

**Recommendations for importation from FMD free countries or zones where vaccination is not practised or FMD free compartments**For FMD susceptible animals

*Veterinary Authorities* should require 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 since birth or for at least the past three months in a FMD free country or zone where *vaccination* is not practised or a FMD free *compartment*;
- 3) have not been vaccinated;

- 4) if transiting an *infected zone*, were not exposed to any source of FMD *infection* during transportation to the *place of shipment*.

Article 8.6.13.

**Recommendations for importation from FMD free countries or zones where vaccination is practised**

For domestic ruminants and pigs

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

- 1) showed no clinical sign of FMD on the day of shipment;
- 2) were kept in an FMD free country or *zone* since birth or for at least the past three 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;
- 4) if transiting an *infected zone*, were not exposed to any source of FMD *infection* during transportation to the *place of shipment*.

Article 8.6.14.

**Recommendations for importation from FMD infected countries or zones**

For domestic ruminants and pigs

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

- 1) showed no clinical sign of FMD on the day of shipment;
- 2) were kept in the *establishment* of origin since birth, or
  - a) for the past 30 days, if a *stamping-out policy* is in force in the *exporting country*, or
  - b) for the past 3 months, if a *stamping-out policy* is not in force in the *exporting country*,and that FMD has not occurred within a ten-kilometre radius of the *establishment* of origin for the relevant period as defined in points a) and b) above; and
- 3) were isolated in an *establishment* for the 30 days prior to shipment, and all *animals* in isolation were subjected to diagnostic tests (probang and serology) for evidence of FMDV *infection* with negative results at the end of that period, and that FMD did not occur within a ten-kilometre radius of the *establishment* during that period; or
- 4) were kept in a *quarantine station* for the 30 days prior to shipment, all *animals* in quarantine were subjected to diagnostic tests (probang and serology) for evidence of FMDV *infection* with negative results at the end of that period, and that FMD did not occur within a ten-kilometre radius of the *quarantine station* during that period;
- 5) were not exposed to any source of FMD *infection* during their transportation from the *quarantine station* to the *place of shipment*.

Article 8.6.15.

**Recommendations for importation from FMD free countries or zones where vaccination is not practised or FMD free compartments**

For fresh semen of domestic ruminants and pigs

*Veterinary Authorities* should require 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 for at least three months prior to collection in a FMD free country or *zone* where *vaccination* is not practised or a FMD free *compartment*;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

## Article 8.6.16.

**Recommendations for importation from FMD free countries or zones where vaccination is not practised or FMD free compartments**For frozen semen of domestic ruminants and pigs

*Veterinary Authorities* should require 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 for at least three months prior to collection in an FMD free country or *zone* where *vaccination* is not practised or a FMD free *compartment*;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

## Article 8.6.17.

**Recommendations for importation from FMD free countries or zones where vaccination is practised**For semen of domestic ruminants and pigs

*Veterinary Authorities* should require 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 for at least three months prior to collection in a FMD free country or *zone*;
  - 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 Chapters 4.5. and 4.6.;
  - b) was stored in the country of origin for a period of at least one month following collection, and during this period no *animal* on the *establishment* where the donor *animals* were kept showed any sign of FMD.

## Article 8.6.18.

**Recommendations for importation from FMD infected countries or zones**For semen of domestic ruminants and pigs

*Veterinary Authorities* should require 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 Chapters 4.5. and 4.6.;
  - b) was subjected, with negative results, to a test for FMDV *infection* if the donor *animal* has been vaccinated within the 12 months prior to collection;

- c) was stored in the country of origin for a period of at least one month following collection, and that during this period no *animal* on the *establishment* where the donor *animals* were kept showed any sign of FMD.

Article 8.6.19.

#### **Recommendations for the importation of *in vivo* derived embryos of cattle**

Irrespective of the FMD status of the *exporting country, zone or compartment*, *Veterinary Authorities* should authorise without restriction on account of FMD the import or transit through their territory of *in vivo* derived embryos of cattle subject to the presentation of an *international veterinary certificate* attesting that the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.8. and 4.9., as relevant.

Article 8.6.20.

#### **Recommendations for importation from FMD free countries or zones where vaccination is not practised or FMD free compartments**

##### For *in vitro* produced embryos of cattle

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

- 1) the donor females:
  - a) showed no clinical sign of FMD at the time of collection of the oocytes;
  - b) were kept at the time of collection in a FMD free country or *zone* where *vaccination* is not practised or a FMD free *compartment*;
- 2) fertilisation was achieved with semen meeting the conditions referred to in Articles 8.6.15., 8.6.16., 8.6.17. or 8.6.18., as relevant;
- 3) the oocytes were collected, and the embryos were processed and stored in conformity with the provisions of Chapters 4.8. and 4.9., as relevant.

Article 8.6.21.

#### **Recommendations for importation from FMD free countries or zones where vaccination is practised**

##### For *in vitro* produced embryos of cattle

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

- 1) the donor females:
  - a) showed no clinical sign of FMD at the time of collection of the oocytes;
  - b) were kept for at least three months prior to collection in a FMD free country or *zone* where *vaccination* is practised;
  - c) if destined for an FMD free country or *zone* where *vaccination* is not practised or a FMD free *compartment*:
    - 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 8.6.15., 8.6.16., 8.6.17. or 8.6.18., as relevant;
- 4) the oocytes were collected, and the embryos were processed and stored in conformity with the provisions of Chapters 4.8. and 4.9., as relevant.



## Article 8.6.22.

**Recommendations for importation from FMD free countries or zones where vaccination is not practised or FMD free compartments**For fresh meat or meat products of FMD susceptible animals

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

- 1) have been kept in the FMD free country or *zone* where *vaccination* is not practised or a FMD free *compartment*, or which have been imported in accordance with Article 8.6.12., Article 8.6.13. or Article 8.6.14.;
- 2) have been slaughtered in an approved *abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results.

## Article 8.6.23.

**Recommendations for importation from FMD free countries or zones where vaccination is practised**For fresh meat of cattle and buffaloes (*Bubalus bubalis*) (excluding feet, head and viscera)

*Veterinary Authorities* should require 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, or which have been imported in accordance with Article 8.6.12., Article 8.6.13. or Article 8.6.14.;
- 2) have been slaughtered in an approved *abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results.

## Article 8.6.24.

**Recommendations for importation from FMD free countries or zones where vaccination is practised**For fresh meat or meat products of pigs and ruminants other than cattle and buffaloes

*Veterinary Authorities* should require 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, or which have been imported in accordance with Article 8.6.12., Article 8.6.13. or Article 8.6.14.;
- 2) have been slaughtered in an approved *abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results.

## Article 8.6.25.

**Recommendations for importation from FMD infected countries or zones, where an official control programme for FMD, involving compulsory systematic vaccination of cattle, exists**For fresh meat of cattle and buffaloes (*Bubalus bubalis*) (excluding feet, head and viscera)

*Veterinary Authorities* should require 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 three months prior to *slaughter*;
  - b) have remained, during this period, in a part of the country where cattle are regularly vaccinated against FMD and where official controls are in operation;
  - c) have been vaccinated at least twice with the last *vaccination* not more than 12 months and not less than one month prior to *slaughter*;
  - d) were kept for the past 30 days in an *establishment*, and that FMD has not occurred within a ten-kilometre radius of the *establishment* during that period;

- e) have been transported, in a *vehicle* which was cleansed and disinfected before the cattle were loaded, directly from the *establishment* of origin to the approved *abattoir* without coming into contact with other *animals* which do not fulfil the required conditions for export;
  - f) have been slaughtered in an approved *abattoir*:
    - i) which is officially designated for export;
    - ii) in which no FMD has been detected during the period between the last *disinfection* carried out before *slaughter* and the shipment for export has been dispatched;
  - g) have been subjected to ante- and post-mortem inspections for FMD with favourable results within 24 hours before and after *slaughter*;
- 2) comes from deboned carcasses:
- a) from which the major lymphatic nodes have been removed;
  - b) which, prior to deboning, have been submitted to maturation at a temperature above + 2°C for a minimum period of 24 hours following *slaughter* and in which the pH value was below 6.0 when tested in the middle of both the longissimus dorsi.

Article 8.6.26.

### **Recommendations for importation from FMD infected countries or zones**

#### For meat products of domestic ruminants and pigs

*Veterinary Authorities* should require 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- 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 8.6.34.;
- 3) the necessary precautions were taken after processing to avoid contact of the *meat products* with any potential source of FMD virus.

Article 8.6.27.

### **Recommendations for importation from FMD free countries or zones (where vaccination either is or is not practised) or FMD free compartments**

#### 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

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that these products come from *animals* which have been kept in a FMD free country, *zone* or *compartment*, or which have been imported in accordance with Article 8.6.12., Article 8.6.13. or Article 8.6.14.

Article 8.6.28.

### **Recommendations for importation from FMD infected countries or zones where an official control programme exists**

#### For milk, cream, milk powder and milk products

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

- 1) these products:
  - a) originate from *herds* or *flocks* which were not infected or suspected of being infected with FMD at the time of *milk* collection;
  - b) have been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Article 8.6.38. and in Article 8.6.39.;
- 2) the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMD virus.

## Article 8.6.29.

**Recommendations for importation from FMD infected countries**For blood and meat-meals (from domestic or wild ruminants and pigs)

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the manufacturing method for these products included heating to a minimum core temperature of 70°C for at least 30 minutes.

## Article 8.6.30.

**Recommendations for importation from FMD infected countries**For wool, hair, bristles, raw hides and skins (from domestic or wild ruminants and pigs)

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

- 1) these products have been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Articles 8.6.35., 8.6.36. and 8.6.37.;
- 2) the necessary precautions were taken after collection or processing to avoid contact of the products with any potential source of FMD virus.

*Veterinary Authorities* can authorise, without restriction, the import or transit through their territory of semi-processed hides and skins (limed hides, pickled pelts, and semi-processed leather – e.g. wet blue and crust leather), provided that these products have been submitted to the usual chemical and mechanical processes in use in the tanning industry.

## Article 8.6.31.

**Recommendations for importation from FMD infected countries or zones**For straw and forage

*Veterinary Authorities* should require 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 ten minutes,
  - b) or to the action of formalin fumes (formaldehyde gas) produced by its commercial solution at 35–40 percent in a chamber kept closed for at least eight hours and at a minimum temperature of 19°C;

OR

- 3) have been kept in bond for at least three months (under study) before being released for export.

## Article 8.6.32.

**Recommendations for importation from FMD free countries or zones (where vaccination either is or is not practised)**For skins and trophies derived from FMD susceptible wild animals

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that these products are derived from *animals* that have been killed in such a country or *zone*, or which have been imported from a country or *zone* free of FMD (where *vaccination* either is or is not practised).

Article 8.6.33.

**Recommendations for importation from FMD infected countries or zones**

For skins and trophies derived from FMD susceptible wild animals

*Veterinary Authorities* should require 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 8.6.40.

Article 8.6.34.

**Procedures for the inactivation of the FMD virus in 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 8.6.35.

**Procedures for the inactivation of the FMD virus in 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 four weeks, or 4°C for four months, or 37°C for eight days.

Article 8.6.36.

**Procedures for the inactivation of the FMD virus in bristles**

For the inactivation of viruses present in bristles for industrial use, one of the following procedures should be used:

- 1) boiling for at least one hour;
- 2) immersion for at least 24 hours in a 1 percent solution of formaldehyde prepared from 30 ml commercial formalin per litre of water.

## Article 8.6.37.

**Procedures for the inactivation of the FMD virus in 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 percent sodium carbonate.

## Article 8.6.38.

**Procedures for the inactivation of the FMD virus in 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 8.6.39.

**Procedures for the inactivation of the FMD virus in 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 desiccation;
- 3) UHT combined with another physical treatment referred to in point 2 above.

## Article 8.6.40.

**Procedures for the inactivation of the FMD virus in skins and trophies from wild animals susceptible to the 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 percent (w/v) solution of washing soda (sodium carbonate – Na<sub>2</sub>CO<sub>3</sub>) 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 percent washing soda (sodium carbonate – Na<sub>2</sub>CO<sub>3</sub>).

## Article 8.6.41.

**Procedures for the inactivation of the FMD virus in casings of ruminants and pigs**

For the inactivation of viruses present in casings of ruminants and pigs, the following procedures should be used: salting for at least 30 days either with dry salt (NaCl) or with saturated brine (Aw < 0.80), or with phosphate supplemented dry salt containing 86.5 percent NaCl, 10.7 percent Na<sub>2</sub>HPO<sub>4</sub> and 2.8 percent Na<sub>3</sub>PO<sub>4</sub> (weight/weight/weight), and kept at a temperature of greater than 12°C during this entire period.

Article 8.6.42.

**Surveillance: introduction**

Articles 8.6.42. to 8.6.47. and Article 8.6.49. define the principles and provide a guide for the *surveillance* of FMD in accordance with Chapter 1.4. applicable to Member Countries seeking establishment of freedom from FMD, either with or without the use of *vaccination*. Guidance is provided for Member Countries seeking reestablishment of freedom from FMD for the entire country or for a *zone*, either with or without *vaccination*, or a *compartment*, following an *outbreak* and for the maintenance of FMD status.

The impact and epidemiology of FMD differ widely in different regions of the world and therefore it is impossible to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from FMD at an acceptable level of confidence will need to be adapted to the local situation. For example, the approach to proving freedom from FMD following an *outbreak* caused by a pig-adapted strain of FMD virus (FMDV) should differ significantly from an application designed to prove freedom from FMD for a country or *zone* where African buffaloes (*Syncerus caffer*) provide a potential reservoir of *infection*. It is incumbent upon the Member Country to submit a dossier to the OIE in support of its application that not only explains the epidemiology of FMD in the region concerned but also demonstrates how all the risk factors are managed. This should include provision of scientifically-based supporting data. There is therefore considerable latitude available to Member Countries to provide a well-reasoned argument to prove that the absence of FMDV *infection* (in non-vaccinated populations) or circulation (in vaccinated populations) is assured at an acceptable level of confidence.

*Surveillance* for FMD should be in the form of a continuing programme designed to establish that the whole territory or part of it is free from FMDV *infection/circulation*.

For the purposes of this chapter, virus circulation means transmission of FMDV as demonstrated by clinical signs, serological evidence or virus isolation.

Article 8.6.43.

**Surveillance: general conditions and methods**

- 1) A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. A procedure should be in place for the rapid collection and transport of samples from suspect cases of FMD to a *laboratory* for FMD diagnoses as described in the *Terrestrial Manual*.
- 2) The FMD *surveillance* programme should:
  - a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers who have day-to-day contact with livestock, as well as diagnosticians, should report promptly any suspicion of FMD. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All suspect cases of FMD should be investigated immediately. Where suspicion cannot be resolved by epidemiological and clinical investigation, samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment are available for those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in FMD diagnosis and control;
  - b) implement, when relevant, regular and frequent clinical inspection and serological testing of high-risk groups of *animals*, such as those adjacent to an FMD infected country or *infected zone* (for example, bordering a game park in which infected *wildlife* are present).

An effective *surveillance* system will periodically identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is FMDV. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from FMDV *infection/circulation* should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of *laboratory* testing and the control measures to which the *animals* concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

## Article 8.6.44.

**Surveillance strategies**1. Introduction

The target population for *surveillance* aimed at identifying *disease* and *infection* should cover all the susceptible species within the country, *zone* or *compartment*.

The design of *surveillance* programmes to prove the absence of FMDV *infection/circulation* needs to be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by the OIE or international trading partners, or excessively costly and logistically complicated. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.

The strategy employed may be based on randomised sampling requiring *surveillance* consistent with demonstrating the absence of FMDV *infection/circulation* at an acceptable level of statistical confidence. The frequency of sampling should be dependent on the epidemiological situation. Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. The Member Country should justify the *surveillance* strategy chosen as adequate to detect the presence of FMDV *infection/circulation* in accordance with Chapter 1.4. and the epidemiological situation. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clear clinical signs (e.g. cattle and pigs). If a Member Country wishes to apply for recognition of a specific *zone* within the country as being free from FMDV *infection/circulation*, the design of the survey and the basis for the sampling process would need to be aimed at the population within the *zone*.

For random surveys, the design of the sampling strategy will need to incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect *infection/circulation* if it were to occur at a predetermined minimum rate. The sample size and expected *disease* prevalence determine the level of confidence in the results of the survey. The Member Country must justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the *vaccination/infection* history and production class of *animals* in the target population.

Irrespective of the testing system employed, *surveillance* design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following-up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection/circulation* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as *herds* which may be epidemiologically linked to it.

2. Clinical surveillance

Clinical *surveillance* aims at detecting clinical signs of FMD by close physical examination of susceptible *animals*. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection should not be underrated. It may be able to provide a high level of confidence of detection of *disease* if a sufficiently large number of clinically susceptible *animals* is examined.

Clinical *surveillance* and *laboratory* testing should always be applied in series to clarify the status of FMD suspects detected by either of these complementary diagnostic approaches. *Laboratory* testing may confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive serology. Any sampling unit within which suspicious *animals* are detected should be classified as infected until contrary evidence is produced.

A number of issues must be considered in clinical *surveillance* for FMD. The often underestimated labour intensity and the logistical difficulties involved in conducting clinical examinations should not be underestimated and should be taken into account.

Identification of clinical cases is fundamental to FMD *surveillance*. Establishment of the molecular, antigenic and other biological characteristics of the causative virus, as well as its source, is dependent upon disclosure of such *animals*. It is essential that FMDV isolates are sent regularly to the regional reference *laboratory* for genetic and antigenic characterization.

3. Virological surveillance

Virological *surveillance* using tests described in the *Terrestrial Manual* should be conducted:

- a) to monitor at risk populations;

- b) to confirm clinically suspect cases;
- c) to follow up positive serological results;
- d) to test 'normal' daily mortality, to ensure early detection of *infection* in the face of *vaccination* or in *establishments* epidemiologically linked to an *outbreak*.

#### 4. Serological surveillance

Serological *surveillance* aims at detecting antibodies against FMDV. Positive FMDV antibody test results can have four possible causes:

- a) natural *infection* with FMDV;
- b) *vaccination* against FMD;
- c) maternal antibodies derived from an immune dam (maternal antibodies in cattle are usually found only up to six months of age but in some individuals and in some species, maternal antibodies can be detected for considerably longer periods);
- d) heterophile (cross) reactions.

It is important that serological tests, where applicable, contain antigens appropriate for detecting antibodies against viral variants (types, subtypes, lineages, topotypes, etc.) that have recently occurred in the region concerned. Where the probable identity of FMDVs is unknown or where exotic viruses are suspected to be present, tests able to detect representatives of all serotypes should be employed (e.g. tests based on nonstructural viral proteins – see below).

It may be possible to use serum collected for other survey purposes for FMD *surveillance*. However, the principles of survey design described in this chapter and the requirement for a statistically valid survey for the presence of FMDV should not be compromised.

The discovery of clustering of seropositive reactions should be foreseen. It may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of field strain *infection*. As clustering may signal field strain *infection*, the investigation of all instances must be incorporated in the survey design. If *vaccination* cannot be excluded as the cause of positive serological reactions, diagnostic methods should be employed that detect the presence of antibodies to nonstructural proteins (NSPs) of FMDVs as described in the *Terrestrial Manual*.

The results of random or targeted serological surveys are important in providing reliable evidence that FMDV *infection* is not present in a country, *zone* or *compartment*. It is therefore essential that the survey be thoroughly documented.

#### Article 8.6.45.

#### **Member Countries applying for recognition of freedom from FMD for the whole country or a zone where vaccination is not practised: additional surveillance procedures**

In addition to the general conditions described in the above-mentioned articles, a Member Country applying for recognition of FMD freedom for the country or a *zone* where *vaccination* is not practised should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and will be planned and implemented according to general conditions and methods in this chapter, to demonstrate absence of FMDV *infection*, during the preceding 12 months in susceptible populations. This requires the support of a national or other *laboratory* able to undertake identification of FMDV *infection* through virus/antigen/genome detection and antibody tests described in the *Terrestrial Manual*.

#### Article 8.6.46.

#### **Member Countries applying for recognition of freedom from FMD for the whole country or a zone where vaccination is practised: additional surveillance procedures**

In addition to the general conditions described in the above-mentioned articles, a Member Country applying for recognition of country or *zone* freedom from FMD with *vaccination* should show evidence of an effective *surveillance* programme planned and implemented according to general conditions and methods in this chapter. Absence of clinical *disease* in the country or *zone* for the past two years should be demonstrated. Furthermore, *surveillance* should demonstrate that FMDV has not been circulating in any susceptible population during the past 12 months. This will require serological *surveillance* incorporating tests able to detect antibodies to NSPs as described in the *Terrestrial Manual*. *Vaccination* to prevent the transmission of FMDV may be part of a disease control programme. The level of *herd* immunity required to prevent transmission will depend on the size, composition (e.g. species) and density of the



susceptible population. It is therefore impossible to be prescriptive. However, the aim should be for at least 80 percent of the *animals* in each vaccinated population to have protective immunity. The vaccine must comply with the *Terrestrial Manual*. Based on the epidemiology of FMD in the country or *zone*, it may be that a decision is reached to vaccinate only certain species or other subsets of the total susceptible population. In that case, the rationale should be contained within the dossier accompanying the application to the OIE for recognition of status.

Evidence to show the effectiveness of the *vaccination* programme should be provided.

#### Article 8.6.47.

### **Member Countries re-applying for recognition of freedom from FMD for the whole country or a zone where vaccination is either practised or not practised, following an outbreak: additional surveillance procedures**

In addition to the general conditions described in the above-mentioned articles, a country re-applying for country or *zone* freedom from FMD where *vaccination* is practised or not practised should show evidence of an active *surveillance* programme for FMD as well as absence of FMDV *infection/circulation*. This will require serological *surveillance* incorporating, in the case of a country or a *zone* practising *vaccination*, tests able to detect antibodies to NSPs as described in the *Terrestrial Manual*.

Four strategies are recognised by the OIE in a programme to eradicate FMDV *infection* following an *outbreak*:

- 1) *slaughter* of all clinically affected and in-contact susceptible *animals*;
- 2) *slaughter* of all clinically affected and in-contact susceptible *animals* and *vaccination* of at-risk *animals*, with subsequent *slaughter* of vaccinated *animals*;
- 3) *slaughter* of all clinically affected and in-contact susceptible *animals* and *vaccination* of at-risk *animals*, without subsequent *slaughter* of vaccinated *animals*;
- 4) *vaccination* used without *slaughter* of affected *animals* or subsequent *slaughter* of vaccinated *animals*.

The time periods before which an application can be made for re-instatement of freedom from FMD depends on which of these alternatives is followed. The time periods are prescribed in Article 8.6.9.

In all circumstances, a Member Country re-applying for country or *zone* freedom from FMD with *vaccination* or without *vaccination* should report the results of an active *surveillance* programme implemented according to general conditions and methods in this chapter.

#### Article 8.6.48.

### **OIE endorsed official control programme for FMD**

The overall objective of an OIE endorsed *official control programme* for FMD is for countries to progressively improve the situation and eventually attain free status for FMD.

Member Countries may, on a voluntary basis, apply for endorsement of their *official control programme* for FMD when they have implemented measures in accordance with this article.

For a Member Country's *official control programme* for FMD to be endorsed by the OIE, the Member Country should:

- 1) submit documented evidence on the capacity of the *Veterinary Services* to control FMD; this evidence can be provided by countries following the OIE PVS Pathway;
- 2) submit documentation indicating that the *official control programme* for FMD is applicable to the entire territory;
- 3) have a record of regular and prompt animal *disease* reporting according to the requirements in Chapter 1.1.;
- 4) submit a dossier on the epidemiology of FMD in the country describing the following:
  - a) the general epidemiology in the country highlighting the current knowledge and gaps;
  - b) the measures to prevent introduction of *infection*;
  - c) the main livestock production systems and movement patterns of FMD susceptible *animals* and their products within and into the country;
- 5) submit a detailed plan on the programme to control and eventually eradicate FMD in the country or *zone* including:
  - a) the timeline;
  - b) the performance indicators to assess the efficacy of the control measures to be implemented;

- 6) submit evidence that FMD *surveillance*, taking into account provisions in Chapter 1.4. and the provisions on *surveillance* of this chapter, is in place;
- 7) have diagnostic capability and procedures, including regular submission of samples to a laboratory that carries out diagnosis and further characterisation of strains in accordance with the *Terrestrial Manual*;
- 8) where *vaccination* is practised as a part of the *official control programme* for FMD, provide evidence (such as copies of legislation) that *vaccination* of selected populations is compulsory;
- 9) if applicable, provide detailed information on *vaccination* campaigns, in particular on:
  - a) target populations for *vaccination*;
  - b) monitoring of *vaccination* coverage, including serological monitoring of population immunity;
  - c) technical specification of the vaccines used and description of the licensing procedures in place;
  - d) the proposed timeline for the transition to the use of vaccines, fully compliant with the standards and methods described in the *Terrestrial Manual*;
- 10) provide an emergency preparedness and response plan to be implemented in case of *outbreaks*.

The Member Country's *official control programme* for FMD will be included in the list of programmes endorsed by the OIE only after the submitted evidence has been accepted by the OIE. Retention on the list requires an annual update on the progress of the *official control programme* and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

The OIE may withdraw the endorsement of the *official control programme* if there is evidence of:

- non-compliance with the timelines or performance indicators of the programme; or
- significant problems with the performance of the *Veterinary Services*; or
- an increase in the incidence of FMD that cannot be addressed by the programme.

#### Article 8.6.49.

### The use and interpretation of serological tests (see Figure 3)

The recommended serological tests for FMD *surveillance* are described in the *Terrestrial Manual*.

*Animals* infected with FMDV produce antibodies to both the structural proteins (SP) and the nonstructural proteins (NSP) of the virus. Tests for SP antibodies include SP-ELISAs and the virus neutralisation test (VNT). The SP tests are serotype specific and for optimal sensitivity should utilise an antigen or virus closely related to the field strain against which antibodies are being sought. Tests for NSP antibodies include NSP I-ELISA 3ABC and the electro-immunotransfer blotting technique (EITB) as recommended in the *Terrestrial Manual* or equivalent validated tests. In contrast to SP tests, NSP tests can detect antibodies to all serotypes of FMD virus. *Animals* vaccinated and subsequently infected with FMD virus develop antibodies to NSPs, but in some, the titre may be lower than that found in infected *animals* that have not been vaccinated. Both the NSP I-ELISA 3ABC and EITB tests have been extensively used in cattle. Validation in other species is ongoing. Vaccines used should comply with the standards of the *Terrestrial Manual* insofar as purity is concerned to avoid interference with NSP antibody testing.

Serological testing is a suitable tool for FMD *surveillance*. The choice of a serosurveillance system will depend on, amongst other things, the *vaccination* status of the country. A country, which is free from FMD without *vaccination*, may choose serosurveillance of high-risk subpopulations (e.g. based on geographical risk for exposure to FMDV). SP tests may be used in such situations for screening sera for evidence of FMDV *infection/circulation* if a particular virus of serious threat has been identified and is well characterised. In other cases, NSP testing is recommended in order to cover a broader range of strains and even serotypes. In both cases, serological testing can provide additional support to clinical *surveillance*. Regardless of whether SP or NSP tests are used in countries that do not vaccinate, a diagnostic follow-up protocol should be in place to resolve any presumptive positive serological test results.

In areas where *animals* have been vaccinated, SP antibody tests may be used to monitor the serological response to the *vaccination*. However, NSP antibody tests should be used to monitor for FMDV *infection/circulation*. NSP-ELISAs may be used for screening sera for evidence of *infection/circulation* irrespective of the *vaccination* status of the *animal*. All *herds* with seropositive reactors should be investigated. Epidemiological and supplementary *laboratory* investigation results should document the status of FMDV *infection/circulation* for each positive *herd*. Tests used for confirmation should be of high diagnostic specificity to eliminate as many false positive screening test reactors as possible. The diagnostic sensitivity of the confirmatory test should approach that of the screening test. The EITB or another OIE-accepted test should be used for confirmation.

Information should be provided on the protocols, reagents, performance characteristics and validation of all tests used.

1. The follow-up procedure in case of positive test results if no vaccination is used in order to establish or re-establish FMD free status without vaccination

Any positive test result (regardless of whether SP or NSP tests were used) should be followed up immediately using appropriate clinical, epidemiological, serological and, where possible, virological investigations of the reactor *animal* at hand, of susceptible *animals* of the same *epidemiological unit* and of susceptible *animals* that have been in contact or otherwise epidemiologically associated with the reactor *animal*. If the follow-up investigations provide no evidence for FMDV *infection*, the reactor *animal* shall be classified as FMD negative. In all other cases, including the absence of such follow-up investigations, the reactor *animal* should be classified as FMD positive.

2. The follow-up procedure in case of positive test results if vaccination is used in order to establish or re-establish FMD free status with vaccination

In case of vaccinated populations, one has to exclude that positive test results are indicative of virus circulation. To this end, the following procedure should be followed in the investigation of positive serological test results derived from *surveillance* conducted on FMD vaccinated populations.

The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated, and the results should be collated in the final report.

It is suggested that in the primary sampling units where at least one *animal* reacts positive to the NSP test, the following strategy(ies) should be applied:

- a) Following clinical examination, a second serum sample should be taken from the *animals* tested in the initial survey after an adequate interval of time has lapsed, on the condition that they are individually identified, accessible and have not been vaccinated during this period. The number of *animals* with antibodies against NSP in the population at the time of retest should be statistically either equal to or less than that observed in the initial test if virus is not circulating.

The *animals* sampled should remain in the holding pending test results and should be clearly identifiable. If the three conditions for retesting mentioned above cannot be met, a new serological survey should be carried out in the holding after an adequate period of time, repeating the application of the primary survey design and ensuring that all *animals* tested are individually identified. These *animals* should remain in the holding and should not be vaccinated, so that they can be retested after an adequate period of time.

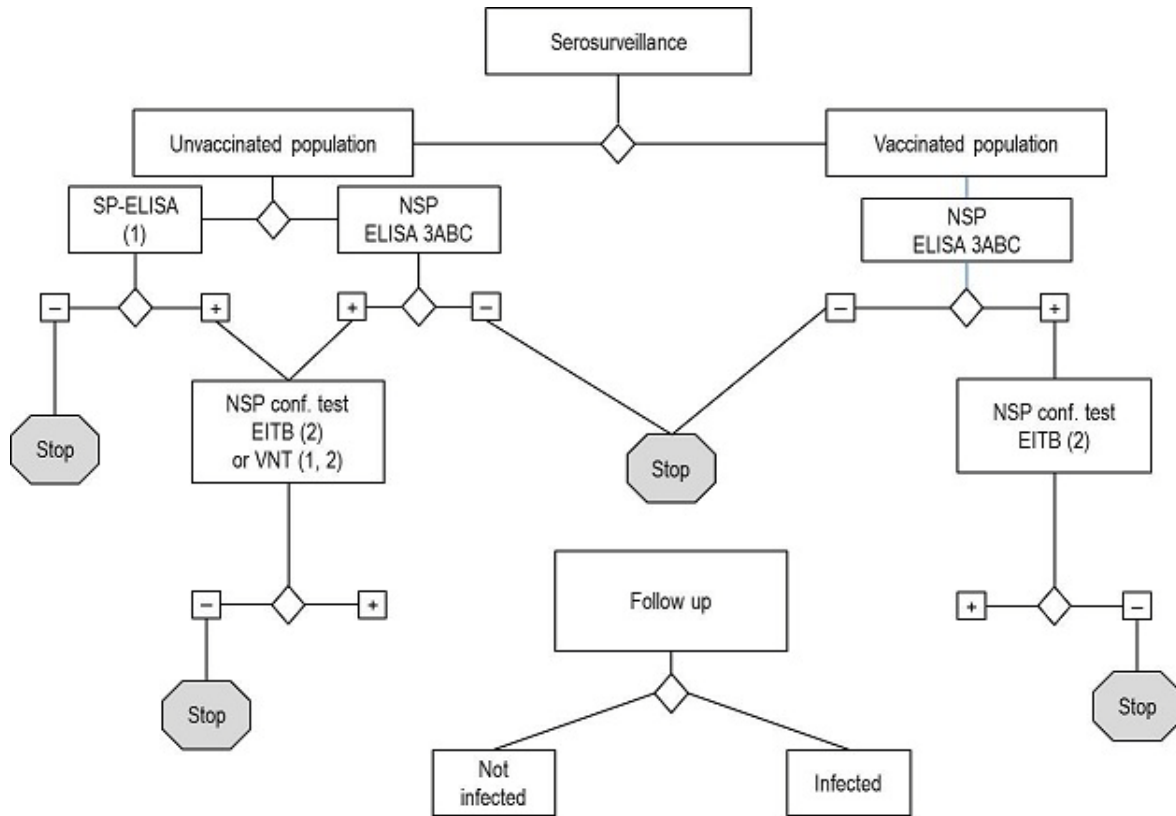
- b) Following clinical examination, serum samples should be collected from representative numbers of susceptible *animals* that were in physical contact with the primary sampling unit. The magnitude and prevalence of antibody reactivity observed should not differ in a statistically significant manner from that of the primary sample if virus is not circulating.
- c) Following clinical examination, epidemiologically linked *herds* should be serologically tested and satisfactory results should be achieved if virus is not circulating.
- d) Sentinel *animals* can also be used. These can be young, unvaccinated *animals* or *animals* in which maternally conferred immunity has lapsed and belonging to the same species resident within the positive initial sampling units. They should be serologically negative if virus is not circulating. If other susceptible, unvaccinated *animals* are present, they could act as sentinels to provide additional serological evidence.

*Laboratory* results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral circulation includes but is not limited to:

- characterization of the existing production systems;
- results of clinical *surveillance* of the suspects and their cohorts;
- quantification of *vaccinations* performed on the affected sites;
- sanitary protocol and history of the *establishments* with positive reactors;
- control of *animal identification* and movements;
- other parameters of regional significance in historic FMDV transmission.

The entire investigative process should be documented as standard operating procedure within the *surveillance* programme.

**Fig. 3.** Schematic representation of laboratory tests for determining evidence of FMDV infection through or following serological surveys



Key:	
ELISA	Enzyme-linked immunosorbent assay
VNT	Virus neutralisation test
NSP	Nonstructural protein(s) of foot and mouth disease virus (FMDV)
3ABC	NSP antibody test
EITB	Electro-immuno transfer blotting technique (Western blot for NSP antibodies of FMDV)
SP	Structural protein test
S	No evidence of FMDV

## CHAPTER 8.7.

# HEARTWATER

Article 8.7.1.

### **General provisions**

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

Article 8.7.2.

### **Trade in commodities**

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

Article 8.7.3.

### **Recommendations for importation from countries considered infected with heartwater**

#### For domestic and wild ruminants

*Veterinary Authorities* should require 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 8.8.  
**JAPANESE ENCEPHALITIS**

Article 8.8.1.

**General provisions**

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 8.8.2.

**Recommendations for importation from countries or zones infected with Japanese encephalitis**

For horses

*Veterinary Authorities* should require 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* attacks during their transportation from the *quarantine station* to the *place of shipment*;

OR

3) were vaccinated against Japanese encephalitis not less than 7 days and no more than 12 months prior to shipment.



## CHAPTER 8.9.

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

#### Article 8.9.1.

#### **Recommendations for importation from countries considered infested with New World or Old World screwworm** For domestic and wild mammals

*Veterinary Authorities* should require 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 prophylactically treated 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 8.9.2.

#### **Quarantine and transportation recommendations**

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

#### Article 8.9.3.

#### **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 8.9.4.

**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.

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CHAPTER 8.10.  
**PARATUBERCULOSIS**

Article 8.10.1.

**General provisions**

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

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## CHAPTER 8.11.

# INFECTION WITH RABIES VIRUS

### Article 8.11.1.

#### General provisions

For the purposes of the *Terrestrial Code*:

- 1) rabies is a *disease* caused by one member of the *Lyssavirus* genus: the *Rabies virus* (formerly referred to as classical rabies virus, genotype-1); all mammals are susceptible to *infection*;
- 2) a *case* is any *animal* infected with the *Rabies virus* species;
- 3) the *incubation period* for rabies is variable, and considered to be six months; the *infective period* for dogs, cats and ferrets is considered to start ten days before the onset of the first apparent clinical signs.

Globally, the most common source of exposure of humans to rabies virus is the dog. Other mammals, particularly members of the Orders Carnivora and Chiroptera, also present a risk.

The aim of this chapter is to mitigate the risk of rabies to human and animal health and to prevent the international spread of the *disease*.

For the purpose of the *Terrestrial Code*, a country that does not fulfil the requirements in Article 8.11.3. is considered to be infected with *Rabies virus*.

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

### Article 8.11.2.

#### Control of rabies in dogs

In order to minimise public health risks due to rabies, and eventually eradicate rabies in dogs, *Veterinary Authorities* should implement the following:

- 1) rabies should be notifiable in the whole country and any change in the epidemiological situation or relevant events should be reported in accordance with Chapter 1.1.;
- 2) an effective system of *disease surveillance* in accordance with Chapter 1.4. should be in operation, with a minimum requirement being an ongoing early detection programme to ensure investigation and reporting of suspected cases of rabies in *animals*;
- 3) specific regulatory measures for the prevention and control of rabies should be implemented consistent with the recommendations in the *Terrestrial Code*, including *vaccination*, identification and effective procedures for the importation of dogs, cats and ferrets;
- 4) a programme for the management of stray dog populations consistent with Chapter 7.7. should be implemented and maintained.

### Article 8.11.3.

#### Rabies free country

A country may be considered free from rabies when:

- 1) the *disease* is notifiable and any change in the epidemiological situation or relevant events are reported in accordance with Chapter 1.1.;
- 2) an ongoing system of *disease surveillance* in accordance with Chapter 1.4. has been in operation for the past two years, with a minimum requirement being an ongoing early detection programme to ensure investigation and reporting of rabies suspect *animals*;

- 3) regulatory measures for the prevention of rabies are implemented consistent with the recommendations in the *Terrestrial Code*, including for the importation of *animals*;
- 4) no case of indigenously acquired rabies virus *infection* has been confirmed during the past two years;
- 5) no imported case in the Orders Carnivora or Chiroptera has been confirmed outside a *quarantine station* for the past six months.

An imported human case of rabies does not affect the rabies free status.

Article 8.11.4.

#### **Recommendations for importation from rabies free countries**

##### For domestic mammals, and captive wild mammals

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

- 1) showed no clinical sign of rabies the day prior to or on the day of shipment;
- 2) and either:
  - a) were kept since birth or at least six months prior to shipment in a free country; or
  - b) were imported in conformity with the regulations stipulated in Articles 8.11.6., 8.11.7., 8.11.8. or 8.11.9.

Article 8.11.5.

#### **Recommendations for importation from rabies free countries**

##### For wild mammals

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

- 1) showed no clinical sign of rabies the day prior to or on the day of shipment;
- 2) and either:
  - a) have been captured at a distance that precludes any contact with *animals* in an infected country. The distance should be defined according to the biology of the species exported, including home range and long distance movements; or
  - b) have been kept in captivity for the six months prior to shipment in a rabies free country.

Article 8.11.6.

#### **Recommendations for importation of dogs, cats and ferrets from countries considered infected with rabies**

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* complying with the model of Chapter 5.11. attesting that the *animals*:

- 1) showed no clinical sign of rabies the day prior to or on the day of shipment;
- 2) were permanently identified and their identification number stated in the *certificate*;

AND EITHER:

- 3) were vaccinated or revaccinated, in accordance with the recommendations of the manufacturer. The vaccine should have been produced and used in accordance with the *Terrestrial Manual*; and
- 4) were subjected not less than 3 months and not more than 12 months prior to shipment to an antibody titration test as prescribed in the *Terrestrial Manual* with a positive result of at least 0.5IU/ml;

OR

- 5) were kept in a *quarantine station* for six months prior to export.

Article 8.11.7.

**Recommendations for importation of domestic ruminants, equids, camelids and suids from countries considered infected with rabies**

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

- 1) showed no clinical sign of rabies the day prior to or on the day of shipment;
- 2) were permanently identified and the identification number stated in the *certificate*;
- 3) EITHER
  - a) were kept for the 6 months prior to shipment in an *establishment* where there has been no case of rabies for at least 12 months prior to shipment;OR
  - b) were vaccinated or revaccinated in accordance with the recommendations of the manufacturer. The vaccine was produced and used in accordance with the *Terrestrial Manual*.

Article 8.11.8.

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

For rodents and lagomorphs born and reared in a biosecure facility

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

- 1) showed no clinical sign of rabies on the day of shipment;
- 2) were kept since birth in a biosecure facility where there has been no case of rabies for at least 12 months prior to shipment.

Article 8.11.9.

**Recommendations for importation of wildlife from countries considered infected with rabies**

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

- 1) showed no clinical sign of rabies the day prior to or on the day of shipment;
  - 2) were kept for the six months prior to shipment in an *establishment* where separation from susceptible *animals* was maintained and where there has been no case of rabies for at least 12 months prior to shipment.
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## CHAPTER 8.12.

# RIFT VALLEY FEVER

### Article 8.12.1.

#### General provisions

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.

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* programme (carried out in accordance with Chapter 1.4.) focusing on mosquitoes and serology of susceptible mammals. The programme should concentrate on parts of the country or *zone* at high risk because of historical, geographic and climatic factors, ruminant and mosquito population distribution, and proximity to areas where epidemics have recently occurred.

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

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

### Article 8.12.2.

#### Safe commodities

When authorising import or transit of the following *commodities* and any products made from them, *Veterinary Authorities* should not require any RVF related conditions, regardless of the RVF status of the ruminant population of the *exporting country* or *zone*:

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

### Article 8.12.3.

#### RVF infection free country or zone

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

- 1) the country or *zone* lies outside the historically infected regions, and not adjacent to historically *infections*; or
- 2) a *surveillance* programme as described in Article 8.12.1. has demonstrated no evidence of RVF *infection* in humans, *animals* or mosquitoes in the country or *zone* during the past four years following a RVF epidemic.

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

A 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 8.12.4.

#### **RVF infected country or zone without disease**

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

Article 8.12.5.

#### **RVF infected country or zone with disease**

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

Article 8.12.6.

#### **Recommendations for importation from RVF infection free countries or zones**

##### For ruminants

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

- 1) were kept in a RVF free country or *zone* 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 attacks at all times when transiting through an *infected zone*.

Article 8.12.7.

#### **Recommendations for importation from RVF infection free countries or zones**

##### For meat and meat products of domestic and wild ruminants

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

Article 8.12.8.

#### **Recommendations for importation from RVF infected countries/zones without disease**

##### For ruminants

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

- 1) showed no evidence of RVF on the day of shipment;
- 2) met one of the following conditions:
  - a) were kept in a RVF infected country/*zone* free of *disease* since birth or for the last six months providing that climatic changes predisposing to *outbreaks* of RVF have not occurred during this time; or
  - b) were vaccinated against RVF at least 21 days prior to shipment with a modified live virus vaccine; or
  - c) were held in a mosquito-proof *quarantine station* for at least 30 days prior to shipment during which the *animals* showed no clinical sign of RVF and were protected from mosquitoes between quarantine and the *place of shipment* as well as at the *place of shipment*;

AND

- 3) did not transit through an *infected zone* with *disease* during transportation of the *place of shipment*.

Article 8.12.9.

**Recommendations for importation from RVF infected countries or zones without disease**

For meat and meat products of domestic and wild ruminants

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

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

Article 8.12.10.

**Recommendations for importation from RVF infected countries or zones with disease**

For ruminants

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

- 1) showed no evidence of RVF on the day of shipment;
- 2) were vaccinated against RVF at least 21 days prior to shipment with a modified live virus vaccine;

OR

- 3) were held in a mosquito-proof *quarantine station* for at least 30 days prior to shipment during which the *animals* showed no clinical sign of RVF and were protected from mosquito attacks between quarantine and the *place of shipment* as well as at the *place of shipment*.

Article 8.12.11.

**Recommendations for importation from RVF infected countries or zones with disease**

For meat and meat products of domestic and wild ruminants

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

- 1) are from *animals* which have been slaughtered in an approved *abattoir* and have been subjected to ante- and post-mortem inspections for RVF with favourable results; and
- 2) have been fully eviscerated and submitted to maturation at a temperature above +2°C for a minimum period of 24 hours following *slaughter*.

Article 8.12.12.

**Recommendations for importation from RVF infected countries or zones with disease**

For *in vivo* derived embryos of ruminants

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

- 1) showed no evidence of RVF within the period from 28 days prior to 28 days following collection of the embryos;
- 2) were vaccinated against RVF at least 21 days prior to collection with a modified live virus vaccine;

OR

- 3) were serologically tested on the day of collection and at least 14 days following collection and showed no significant rise in titre.

Article 8.12.13.

**(Under study) Recommendations for importation from RVF infected countries or zones with disease or from RVF infected countries or zones without disease**

For milk and milk products

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

- 1) was subjected to pasteurization; or
  - 2) was subjected to a combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.
-



## CHAPTER 8.13.

# INFECTION WITH RINDERPEST VIRUS

### Article 8.13.1.

#### Preamble

The global eradication of rinderpest has been achieved and was announced in mid-2011 based on the following:

- 1) Evidence demonstrates that there is no significant risk that rinderpest virus (RPV) remains in susceptible domesticated or wild host populations anywhere in the world.
- 2) All OIE Member and non-member countries have completed the pathway defined by the OIE for recognition of national rinderpest freedom and have been officially recognised by the OIE as free from the *infection*.
- 3) All *vaccinations* against rinderpest have ceased throughout the world.

However, RPV containing material including live vaccines continue to be held in a number of institutions around the world and this poses a risk of virus re-introduction into susceptible *animals*.

As sequestration and destruction of virus stocks proceed, the risks of re-introduction of *infection* into *animals* is expected to progressively diminish. The possibility of deliberate or accidental release of virus demands continuing vigilance, especially in the case of those countries known to host an institution holding RPV containing material. This chapter takes into account the new global status and provides recommendations to prevent re-emergence of the *disease* and to ensure adequate *surveillance* and protection of livestock.

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

### Article 8.13.2.

#### Definitions and general provisions

For the purpose of the *Terrestrial Code*:

- 1) RPV containing material means field and laboratory strains of RPV; vaccine strains of RPV including valid and expired vaccine stocks; tissues, sera and other clinical material from *animals* known or suspected to be infected; diagnostic material containing or encoding live virus, recombinant morbilliviruses (segmented or non-segmented) containing unique RPV nucleic acid or amino acid sequences, and full length genomic material including virus ribonucleic acid (RNA) and cDNA copies of virus RNA. Sub-genomic fragments of morbillivirus nucleic acid that are not capable of being incorporated in a replicating morbillivirus or morbillivirus-like virus are not considered as RPV containing material;
- 2) ban on *vaccination* against rinderpest means a ban on administering any vaccine containing RPV or RPV components to any *animal*;
- 3) the *incubation period* for rinderpest shall be 21 days;
- 4) a *case* is defined as an *animal* infected with RPV whether or not showing clinical signs; and
- 5) for the purpose of this chapter, 'susceptible *animals*' means domestic, feral and wild artiodactyls.

### Article 8.13.3.

#### Ongoing surveillance post global freedom

All countries in the world, whether or not Member Countries of the OIE, have completed all the procedures necessary to be recognised as free from rinderpest *infection* and annual re-confirmation of rinderpest absence is no longer required. However, countries are still required to carry out general *surveillance* in accordance with Chapter 1.4. to detect rinderpest should it recur and to comply with OIE reporting obligations concerning the occurrence of unusual epidemiological events in accordance with Chapter 1.1. Countries should also maintain national contingency plans for responding to events suggestive of rinderpest.

Article 8.13.4.

**Recommendations for international trade in livestock and their products**

When authorising import or transit of livestock and their products, *Veterinary Authorities* should not require any rinderpest related conditions.

Article 8.13.5.

**Response to recurrence of rinderpest**

1. Definition of a suspected case of rinderpest

Rinderpest should be suspected if one or more *animals* of a susceptible species is found to be exhibiting clinical signs consistent with 'stomatitis-enteritis syndrome'.

Stomatitis-enteritis syndrome is defined as fever with ocular and nasal discharges in combination with:

- a) clinical signs of erosions in the oral cavity with diarrhoea, dysentery, dehydration or *death*;
- or
- b) necropsy findings of haemorrhages on serosal surfaces, haemorrhages and erosions on alimentary mucosal surfaces and lymphadenopathy.

Stomatitis-enteritis syndrome could indicate a number of *diseases* from which rinderpest should be differentiated by appropriate laboratory investigation.

The detection of RPV specific antibodies in an *animal* of a susceptible species with or without clinical signs is considered a suspected case of rinderpest.

2. Procedures to be followed in the event of the suspicion of rinderpest

Any direct or indirect detection of RPV in an *animal* or animal product shall be notified immediately.

Upon detection of a suspected case, the national contingency plan should be implemented immediately. If the presence of rinderpest cannot be ruled out, samples should be collected in accordance with Chapter 2.1.15. of the *Terrestrial Manual* and dispatched to one of the appointed OIE-FAO Reference Laboratories for rinderpest for confirmation and, if applicable, for molecular characterisation of the virus to facilitate identification of its source. A full epidemiological investigation should be conducted simultaneously to provide supporting information and to assist in identifying the possible source and spread of the virus.

3. Definition of a case of rinderpest

Rinderpest should be considered as confirmed when, based on a report from an appointed OIE-FAO Reference Laboratory for rinderpest:

- a) RPV has been isolated from an *animal* or a product derived from that *animal* and identified; or
- b) viral antigen or viral RNA specific to RPV has been identified in samples from one or more *animals*; or
- c) antibodies to RPV have been identified in one or more *animals* with either epidemiological links to a confirmed or suspected *outbreak* of rinderpest, or showing clinical signs consistent with recent *infection* with RPV.

4. Procedures to be followed after confirmation of rinderpest

A *case* of rinderpest confirmed in an appointed OIE-FAO Reference Laboratory using a prescribed test shall constitute a global emergency requiring immediate, concerted action for its investigation and elimination.

Immediately following the confirmation of the presence of RPV, viral RNA or antibody, the appointed OIE-FAO Reference Laboratory should inform the country concerned, the OIE and the FAO, allowing the initiation of the international contingency plan.

In the event of the confirmation of rinderpest, the entire country is considered to be infected. When epidemiological investigation has indicated the extent of the infected area, *infected* and *protection zones* can be defined for the purposes of disease control. In the event of limited *outbreaks*, a single *containment zone*, which includes all *cases*, may be established for the purpose of minimising the impact on the country. The *containment zone* should be established in accordance with Chapter 4.3. and may cross international boundaries.

Emergency *vaccination* is acceptable only with live-attenuated tissue culture rinderpest vaccine, produced in accordance with the *Terrestrial Manual*. Vaccinated *animals* should always be clearly identified at a *herd* or individual level.

- 5) Global rinderpest freedom is suspended and the sanitary measures for trade with the infected country or countries shall revert to those in Articles 8.12.5. to 8.12.9. of the *Terrestrial Animal Health Code* 2010 Edition.

## Article 8.13.6.

**Recovery of free status**

Should there be a confirmed occurrence of rinderpest, as defined above, a country or *zone* shall be considered as RPV infected until shown to be free through targeted *surveillance* involving clinical, serological and virological testing procedure.

The time needed to recover rinderpest free status of a country or *zone*, or of a *containment zone* if one is established, depends on the methods employed to achieve the elimination of *infection*.

One of the following waiting periods applies:

- 1) three months after the last case where a *stamping-out policy* and serological *surveillance* are applied in accordance with Article 8.13.8.; or
- 2) three months after the *slaughter* of all vaccinated *animals* where a *stamping-out policy*, emergency *vaccination* and serological *surveillance* are applied in accordance with Article 8.13.8.

The recovery of rinderpest free status requires an international expert mission to verify the successful application of containment and eradication measures, as well as a review of documented evidence by the OIE.

The country or *zone* shall be considered free only after the submitted evidence has been accepted by the OIE

## Article 8.13.7.

**Recovery of global freedom**

Global rinderpest freedom shall be reinstated provided that within six months of the confirmation of an *outbreak*, the following conditions have been met:

- 1) the *outbreak* was recognised in a timely manner and handled in accordance with the international contingency plan;
- 2) reliable epidemiological information clearly demonstrated that there was minimal spread of virus;
- 3) robust control measures consisting of stamping out *herds* containing infected *animals*, and any vaccinated *animals*, combined with sanitary procedures including movement controls were rapidly implemented and were successful in eliminating the RPV;
- 4) the origin of the virus was established, and it did not relate to an undetected reservoir of *infection*;
- 5) a *risk assessment* indicates that there is negligible risk of recurrence;
- 6) if *vaccination* was applied, all vaccinated *animals* were slaughtered or destroyed;
- 7) the affected country or *zone* has regained free status in accordance with Article 8.13.6.

If the conditions above are not met, the global rinderpest freedom is lost and Chapter 8.12. and Article 1.6.4. of the *Terrestrial Animal Health Code* 2010 Edition are reinstated. Recovery of global rinderpest freedom would then require re-establishment of an internationally coordinated rinderpest eradication programme and assessments of rinderpest free country status.

## Article 8.13.8.

**Surveillance for recovery of rinderpest free status**

A Member Country applying for reinstatement of rinderpest free status in accordance with Article 8.12.6. should provide evidence demonstrating effective *surveillance* in accordance with Chapter 1.4.

- 1) The target for *surveillance* should be all populations of rinderpest susceptible species within the country. In certain areas some *wildlife* populations, such as African buffaloes, act as sentinels for rinderpest *infection*.
- 2) Given that rinderpest is an acute *infection* with no known carrier state, virological *surveillance* should be conducted to confirm clinically suspected cases. A procedure should be established for the rapid collection and transport of samples from suspect cases to an appointed OIE-FAO Reference Laboratory for diagnosis.

- 3) An awareness programme should be established for all animal health professionals including *veterinarians*, both official and private, and livestock owners to ensure that rinderpest's clinical and epidemiological characteristics and risks of its recurrence are understood. Farmers and workers who have day-to-day contact with livestock, as well as diagnosticians, should report promptly any suspicion of rinderpest.
- 4) Differing clinical presentations can result from variations in levels of innate host resistance (*Bos indicus* breeds being more resistant than *B. taurus*), and variations in the virulence of the attacking strain. In the case of sub-acute (mild) cases, clinical signs are irregularly displayed and difficult to detect. Experience has shown that syndromic *surveillance* strategies i.e. *surveillance* based on a predefined set of clinical signs (e.g. searching for 'stomatitis-enteritis syndrome') are useful to increase the sensitivity of the system.

Article 8.13.9.

**Annual update on RPV containing material**

Annual reports on RPV containing material should be submitted to the OIE by the end of November each year by the *Veterinary Authority* of a Member Country hosting an institution or institutions holding RPV containing material. A separate report, drawn up in accordance with the model below, should be produced for each institution. A final report should be submitted to the OIE for each institution when all materials have been destroyed and no new activities are foreseen for the future.

Model annual report on rinderpest virus (RPV)-containing material as of 1 November [year]

Name of institution:

Biosecurity level of the facility holding RPV containing material:

Postal address:

Title and name of contact person:

E-mail/phone/fax:

**1) RPV containing material currently held as of 1 November [year]**

Type	Live viruses, including field isolates but excluding vaccine strains	Vaccine stocks including seed strains	Other potentially infectious materials
Check [x] if yes	[ ]	[ ]	[ ]
Strain/genetic characterisation			
Quantity/doses (if applicable)			
Ownership (if other institution)			

**2) RPV containing material destroyed during the past 12 months**

Type	Live viruses, including field isolates but excluding vaccine strains	Vaccine stocks including seed strains	Other potentially infectious materials
Check [x] if yes	[ ]	[ ]	[ ]
Strain/genetic characterisation			
Quantity/doses (if applicable)			

3) **RPV containing material transferred to another institution during the past 12 months**

Type	Live viruses, including field isolates but excluding vaccine strains	Vaccine stocks including seed strains	Other potentially infectious materials
Check [x] if yes	[ ]	[ ]	[ ]
Transferred to			
Strain/genetic characterisation			
Quantity/doses (if applicable)			

4) **RPV containing material received from another institution during the past 12 months**

Type	Live viruses, including field isolates but excluding vaccine strains	Vaccine stocks including seed strains	Other potentially infectious materials
Check [x] if yes	[ ]	[ ]	[ ]
Received from			
Strain/genetic characterisation			
Quantity/doses (if applicable)			

5) **Research or any other use conducted on RPV containing material during the past 12 months**

[Please specify.]

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## CHAPTER 8.14.

# INFECTION WITH *Trichinella* SPP.

### Article 8.14.1.

#### General provisions

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

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

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

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

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

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

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

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

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

### Article 8.14.2.

#### Safe commodities

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

- 1) hides, skins, hair and bristles;
- 2) semen, embryos and oocytes.

### Article 8.14.3.

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

- 1) Prevention of *infection* is dependent on minimising exposure to potential sources of *Trichinella*:
  - a) facilities and the surrounding environment should be managed to prevent exposure of pigs to rodents and *wildlife*;
  - b) raw food waste of animal origin should not be present at the farm level;

- c) feed should comply with the requirements in Chapter 6.3. and should be stored in a manner to prevent access by rodents and *wildlife*;
  - d) a rodent control programme should be in place;
  - e) dead *animals* should be immediately removed and disposed of in accordance with provisions of Chapter 4.12.;
  - f) introduced pigs should originate from *herds* officially recognised as being under controlled management conditions as described in point 2, or from *herds* of a *compartment* with a negligible risk of *Trichinella* infection, as described in Article 8.14.5.
- 2) The *Veterinary Authority* may officially recognise pig *herds* as being under controlled management conditions if:
- a) all management practices described in point 1 are complied with and recorded;
  - b) visits by approved auditors have been made periodically to verify compliance with good management practices described in point 1; the frequency of inspections should be *risk*-based, taking into account historical information, *slaughterhouse* monitoring results, knowledge of established farm management practices and the presence of susceptible *wildlife*;
  - c) a subsequent programme of audits is conducted, taking into account the factors described in point b.

## Article 8.14.4.

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

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

- 1) *Trichinella* infection is notifiable in the whole territory and communication procedures on the occurrence of *Trichinella* infection are established between the *Veterinary Authority* and the public health authority;
- 2) the *Veterinary Authority* has knowledge of, and authority over, all domestic pigs;
- 3) the *Veterinary Authority* has knowledge of the distribution of susceptible species of *wildlife*;
- 4) an *animal identification* and *animal traceability* system for domestic pigs is implemented in accordance with the provisions of Chapters 4.1. and 4.2.;
- 5) *Veterinary Services* have the capability to assess the epidemiological situation, detect the presence of *Trichinella* infection (including genotype, if relevant) in domestic pigs and identify exposure pathways.

## Article 8.14.5.

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

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

- 1) all *herds* of the *compartment* comply with the requirements in Article 8.14.3.;
- 2) Article 8.14.4. has been complied with for at least 24 months;
- 3) the absence of *Trichinella* infection in the *compartment* has been demonstrated by a *surveillance* programme which takes into account current and historical information, and *slaughterhouse* monitoring results, as appropriate, in accordance with Chapter 1.4.;
- 4) once a *compartment* is established, a subsequent programme of audits of all *herds* within the *compartment* is in place to ensure compliance with Article 8.14.3.;
- 5) if an audit identifies a lack of compliance with the criteria described in Article 8.14.3. and the *Veterinary Authority* determines this to be a significant breach of biosecurity, the *herd(s)* concerned should be removed from the *compartment* until compliance is re-established.

Article 8.14.6.

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

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

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

AND

- 2) either:

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

OR

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

OR

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

Article 8.14.7.

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

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

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

AND

- 2) either:

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

OR

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

Article 8.14.8.

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

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

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

AND

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

Article 8.14.9.

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

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

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



AND

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

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## CHAPTER 8.15.

### TULAREMIA

Article 8.15.1.

#### General provisions

For the purposes of the *Terrestrial Code*, the *incubation period* for tularemia (in hares, genus *Lepus*) shall be 15 days.

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

Article 8.15.2.

#### Tularemia free country

A country may be considered free from tularemia when it has been shown that tularemia has not been present for at least the past two years and when bacteriological or serological surveys in previously *infected zones* have given negative results.

Article 8.15.3.

#### Tularemia infected zone

A *zone* shall be considered as infected with tularemia:

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 8.15.4.

#### Trade in commodities

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

Article 8.15.5.

#### Recommendations for importation from countries considered infected with tularemia

##### For live hares

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

- 1) showed no clinical sign of tularemia on the day of shipment;
- 2) were not kept in a tularemia *infected zone*;
- 3) have been treated against parasites (ticks); and
- 4) were kept in a *quarantine station* for the 15 days prior to shipment.

## CHAPTER 8.16.

# VESICULAR STOMATITIS

### Article 8.16.1.

#### General provisions and safe commodities

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

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

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

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

### Article 8.16.2.

#### VS free country

A country may be considered free from VS when:

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

### Article 8.16.3.

#### Trade in commodities

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

### Article 8.16.4.

#### Recommendations for importation from VS free countries

For domestic cattle, sheep, goats, pigs and horses

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

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

### Article 8.16.5.

#### Recommendations for importation from VS free countries

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

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

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

- 2) come from a VS free country;

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

- 3) were kept in a *quarantine station* for the 30 days prior to shipment and were subjected to a diagnostic test for VS with negative results at least 21 days after the commencement of quarantine;
- 4) were protected from insect *vectors* during quarantine and transportation to the *place of shipment*.

Article 8.16.6.

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

For domestic cattle, sheep, goats, pigs and horses

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

- 1) showed no clinical sign of VS on the day of shipment;
- 2) were kept, since birth or for the past 21 days, in an *establishment* where no case of VS was officially reported during that period;
- 3) were kept in a *quarantine station* for the 30 days prior to shipment and were subjected to a diagnostic test for VS with negative results at least 21 days after the commencement of quarantine;
- 4) were protected from insect *vectors* during quarantine and transportation to the *place of shipment*.

Article 8.16.7.

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

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

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

- 1) showed no clinical sign of VS on the day of shipment;
- 2) were kept in a *quarantine station* for the 30 days prior to shipment and were subjected to a diagnostic test for VS with negative results at least 21 days after the commencement of quarantine;
- 3) were protected from insect *vectors* during quarantine and transportation to the *place of shipment*.

Article 8.16.8.

#### **Recommendations for importation from VS free countries or zones**

For *in vivo* derived embryos of ruminants, swine and horses

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

- 1) the donor females were kept in an *establishment* located in a VS free country or *zone* at the time of collection;
- 2) the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 8.16.9.

#### **Recommendations for importation from countries or zones considered infected with VS**

For *in vivo* derived embryos of ruminants, swine and horses

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

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

- 2) the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.
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## CHAPTER 8.17.

# WEST NILE FEVER

### Article 8.17.1.

#### General provisions

West Nile fever (WNF) is a zoonotic *disease* caused by certain strains of the mosquito transmitted West Nile virus (WNV).

For the purpose of this chapter, the susceptible species are equidae, geese, ducks (under study) and birds other than *poultry*.

WNV is maintained in a mosquito–bird–mosquito transmission cycle, whereas humans and equidae are considered dead-end hosts. Most human *infections* occur by natural transmission from mosquitoes.

In relation to domestic animal trade, geese and ducks pose a *risk* for the spread of the WNV as some species have been documented to develop a viraemia sufficient to infect mosquitoes.

*Surveillance* for WNF should be carried out according to Chapter X.X.

The following criteria define the occurrence of WNF:

- 1) WNV has been isolated from an *animal* that shows signs consistent with WNF; or
- 2) viral antigen or viral ribonucleic acid (RNA) specific to WNV has been identified in samples from one or more *animals* that show clinical signs consistent with WNF, or that is epidemiologically linked to a confirmed or suspected *outbreak* of WNF; or
- 3) antibodies to WNV have been identified in an unvaccinated *animal* that shows clinical signs consistent with WNF, or that is epidemiologically linked to a confirmed or suspected *outbreak* of WNF.

For the purposes of the *Terrestrial Code*, the *incubation period* for WNF shall be 15 days.

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

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 8.17.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the WNF status of the *exporting country* or *zone*.

### Article 8.17.2.

#### Safe commodities

Member Countries should not impose trade restrictions on dead-end hosts such as horses.

When authorising import or transit of the following *commodities* and any products made from these, *Veterinary Authorities* should not require any WNV related conditions, regardless of the WNF status of the *exporting country* or *zone*:

- 1) *hatching eggs*;
- 2) eggs for human consumption;
- 3) egg products;
- 4) *poultry* semen;
- 5) *fresh meat* and *meat products* of *poultry*;
- 6) products of *poultry* origin intended for use in animal feeding, or for agricultural or industrial use;
- 7) feathers and down from *poultry*;
- 8) semen of horses;
- 9) *meat* and *meat products* of horses.

## Article 8.17.3.

**WNF free country or zone**

- 1) A country or *zone* may be considered free from WNF when WNF is notifiable in the whole country and either:
  - a) no occurrence of WNF *cases*, where *infection* occurred within the territory of the Member Country, have been recorded for the past two years; or
  - b) a *surveillance* programme in accordance with Chapter X.X. has demonstrated no evidence of WNV in the country or *zone* during the past two years.
- 2) A WNF free country or *zone* will not lose its free status through the importation from WNF infected countries or *infected zones* of:
  - a) seropositive *animals*;
  - b) semen, embryo or ova;
  - c) *animals* vaccinated in accordance with the *Terrestrial Manual* at least 30 days prior to dispatch, and are identified in the accompanying certification as having been vaccinated; or
  - d) *animals* not vaccinated if a *surveillance* programme in accordance with Chapter X.X. has been in place in the source population for a period of 30 days immediately prior to dispatch, and no evidence of WNV transmission has been detected.

## Article 8.17.4.

**WNF seasonally free country or zone**

- 1) A WNF seasonally free country or *zone* is one in which for part of a year, *surveillance* demonstrates no evidence either of WNV transmission or presence of mosquitoes likely to be competent WNV *vectors*.
- 2) For the application of Article 8.17.6., the seasonally free period is taken to commence 21 days following the last evidence of WNV transmission (as demonstrated by the *surveillance* programme), or the cessation of activity of mosquitoes likely to be competent WNV *vectors*.
- 3) For the application of Article 8.17.6., the seasonally free period is taken to conclude either:
  - a) at least 21 days before the earliest date that historical data show WNV transmission cycle has recommenced; or
  - b) immediately if current climatic data or data from a *surveillance* programme indicate an earlier resurgence of activity of mosquitoes likely to be competent WNV *vectors*.
- 4) A WNF seasonally free country or *zone* will not lose its free status through the importation from WNF infected countries or *infected zones* of:
  - a) seropositive *animals*;
  - b) semen, embryo or ova;
  - c) *animals* vaccinated in accordance with the *Terrestrial Manual* at least 30 days prior to dispatch, and are identified in the accompanying certification as having been vaccinated; or
  - d) *animals* not vaccinated if a *surveillance* programme in accordance with Chapter X.X. has been in place in the source population for a period of 30 days immediately prior to dispatch, and no evidence of WNV transmission has been detected.

## Article 8.17.5.

**Recommendations for importation from WNF free countries or zones**For ducks (under study), geese and birds other than poultry

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

- 1) the *animals* were kept in a WNF free country or *zone* since birth or for at least 30 days prior to shipment; or
- 2) the *animals* were kept in a WNF free country or *zone* for at least 15 days, were subjected, with negative results, to an agent identification test according to the *Terrestrial Manual* carried out on a sample collected at least 3 days after the commencement of the residence period and remained in the WNF free country or *zone* until shipment; or
- 3) the *animals*:
  - a) were vaccinated in accordance with the *Terrestrial Manual* 30 days before introduction into the free country or *zone*; and

- b) were identified as having been vaccinated; and
- c) were kept in a WNF free country or *zone* for at least 15 days; and
- d) remained in the WNF free country or *zone* until shipment;

AND

- 4) if the *animals* were exported from a WNF free *zone*, either:
  - a) did not transit through an infected country or *infected zone* during transportation to the *place of shipment*; or
  - b) were protected from mosquito attacks at all times when transiting through an infected country or *infected zone*; or
  - c) had been vaccinated in accordance with point 3 above.

Article 8.17.6.

**Recommendations for importation from WNF seasonally free countries or zones**

For ducks (under study), geese and birds other than poultry

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

- 1) were kept during the seasonally free period in a WNF seasonally free country or *zone* since birth or for at least 30 days prior to shipment; or
- 2) were kept during the WNF seasonally free period in a WNF seasonally free country or *zone* for at least 15 days prior to shipment, and were subjected during the residence period in the country or *zone* to an agent identification test according to the *Terrestrial Manual*, with negative results, carried out on a sample collected at least 3 days after the commencement of the residence period and remained in the WNF seasonally free country or *zone* until shipment; or
- 3) were kept during the seasonally free period in a WNF seasonally free country or *zone* for at least 15 days prior to shipment, and were vaccinated in accordance with the *Terrestrial Manual* 30 days before introduction into the free country or *zone* against WNF, were identified as having been vaccinated and remained in the WNF seasonally free country or *zone* until shipment;

AND

- 4) if the *animals* were exported from a WNF seasonally free country or *zone*, either:
  - a) did not transit through an infected country or *infected zone* during transportation to the *place of shipment*; or
  - b) were protected from mosquito attacks at all times when transiting through an infected country or *infected zone*; or
  - c) were vaccinated in accordance with point 3 above.

Article 8.17.7.

**Recommendations for importation from WNF infected countries or infected zones**

For ducks (under study) and geese

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

- 1) were protected from mosquito attacks for at least 30 days prior to shipment; or
- 2) were subjected to a serological test according to the *Terrestrial Manual* to detect WNV neutralizing antibodies with positive results; or
- 3) were protected from mosquito attacks for at least 15 days prior to shipment, and were subjected during that period to an agent identification test according to the *Terrestrial Manual*, with negative results, carried out on a sample collected at least 3 days after being introduced in the mosquito-free *zone*; or
- 4) were vaccinated at least 30 days before shipment in accordance with the *Terrestrial Manual* against WNV and were identified in the accompanying certification as having been vaccinated; or
- 5) are not vaccinated and a *surveillance* programme in accordance with Chapter X.X. has been in place in the source population for a period of 30 days immediately prior to shipment, and no evidence of WNV transmission has been detected;



AND

- 6) were protected from mosquito attacks during transportation to the *place of shipment*.

Article 8.17.8.

**Recommendations for the importation from WNF infected countries or zones**

For birds other than poultry

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

- 1) the birds showed no clinical sign of WNF on the day of shipment; and
- 2) the birds were kept in a *quarantine station* in a mosquito-free environment for 30 days prior to shipment and a statistically valid sample was subjected, with negative results, to an agent identification test according to the *Terrestrial Manual* at least 3 days after the commencement of the residence period.

Article 8.17.9.

**Protecting animals from mosquito attacks**

When transporting *animals* through WNF infected countries or *infected zones*, *Veterinary Authorities* should require strategies to protect susceptible *animals* from mosquito attacks during transport, taking into account the local ecology of the mosquitoes.

Potential *risk management* strategies include:

- 1) treating *animals* with insect repellents prior to and during transportation;
  - 2) ensuring *vehicles* do not stop en route unless the *animals* are held behind insect-proof netting;
  - 3) *surveillance* for *vectors* at common stopping and offloading points to gain information on seasonal variations;
  - 4) integrated pest management practices at holding, common stopping and offloading points;
  - 5) using historical, ongoing and/or WNF modelling information to identify low risk ports and transport routes.
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## SECTION 9.

### APIDAE

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#### CHAPTER 9.1.

### INFESTATION OF HONEY BEES WITH *Acarapis woodi*

#### Article 9.1.1.

##### General provisions

For the purposes of the *Terrestrial Code*, acarapisosis, also known as acarine disease or tracheal mite *infestation*, is an *infestation* of adult honey bees (species of the genus *Apis*), primarily *Apis mellifera* L. with the mite *Acarapis woodi*, an internal obligate parasite of the respiratory system which spreads by direct contact from adult honey bee to adult honey bee.

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.1.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the acarapisosis status of the honey bee population of the *exporting country or zone*.

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

#### Article 9.1.2.

##### Safe commodities

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

- 1) pre-imagos (eggs, larvae and pupae) of honey bees;
- 2) honey bee semen;
- 3) honey bee venom;
- 4) used apicultural equipment;
- 5) honey;
- 6) bee-collected pollen;
- 7) propolis;
- 8) beeswax;
- 9) royal jelly.

Article 9.1.3.

**Determination of the acarapisosis status of a country or zone**

The acarapisosis status of a country or zone can only be determined after considering the following criteria:

- 1) a *risk assessment* has been conducted, identifying all potential factors for acarapisosis occurrence and their historic perspective;
- 2) acarapisosis should be notifiable in the whole country or zone and all clinical signs suggestive of acarapisosis should be subjected to field and *laboratory* investigations;
- 3) an ongoing awareness programme should be in place to encourage reporting of all cases suggestive of acarapisosis;
- 4) the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the whole country.

Article 9.1.4.

**Country or zone free from acarapisosis**

1) Historically free status

A country or zone may be considered free from acarapisosis after conducting a *risk assessment* as referred to in Article 9.1.3. but without formally applying a specific *surveillance* programme if the country or zone complies with the provisions of Chapter 1.4.

2) Free status as a result of an eradication programme

A country or zone which does not meet the conditions of point 1 above may be considered free from acarapisosis after conducting a *risk assessment* as referred to in Article 9.1.3. and when:

- a) the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees has current knowledge of, and authority over, all domesticated *apiaries* existing in the country or zone;
- b) acarapisosis is notifiable in the whole country or zone, and any clinical cases suggestive of acarapisosis are subjected to field and *laboratory* investigations;
- c) for the three years following the past reported case of acarapisosis, annual surveys supervised by the *Veterinary Authority* or other *Competent Authority*, with no positive results, have been carried out on a representative sample of *apiaries* in the country or zone to provide a confidence level of at least 95% of detecting acarapisosis if at least 1% of the *apiaries* were infected at a within-*apiary* prevalence rate of at least 5% of the hives; such surveys may be targeted towards *apiaries*, areas and seasons with a higher likelihood of *disease*;
- d) to maintain free status, an annual survey supervised by the *Veterinary Authority*, with no positive results, is carried out on a representative sample of *apiaries* in the country or zone to indicate that there has been no new cases; such surveys may be targeted towards areas with a higher likelihood of *disease*;
- e) either there is no wild or self-sustaining feral population of species of the genus *Apis* in the country or zone, or there is an ongoing *surveillance* programme of the wild or self-sustaining feral population of species of the genus *Apis* which demonstrates no evidence of the presence of the *disease* in the country or zone;
- f) the importation of the *commodities* listed in this chapter into the country or zone is carried out in conformity with the recommendations of this chapter.

Article 9.1.5.

**Recommendations for the importation of live queen, worker and drone honey bees with or without associated brood combs**

*Veterinary Authorities* of importing countries should require the presentation of an *international veterinary certificate* attesting that the honey bees come from *apiaries* situated in a country or zone free from acarapisosis or the *apiaries* meet the conditions prescribed in Chapter 4.14. (Article 4.14.5.). With regards to the provisions detailed in point 2 of

Article 4.14.5., this will be achieved by a statistically valid number of honey bees per colony being examined by any method complying with the relevant chapter of the *Terrestrial Manual* and found free of all life stages of *A. woodi*.

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## CHAPTER 9.2.

# INFECTION OF HONEY BEES WITH *Paenibacillus larvae* (AMERICAN FOULBROOD)

### Article 9.2.1.

#### General provisions

For the purposes of the *Terrestrial Code*, American foulbrood is a *disease* of the larval and pupal stages of honey bees (species of the genus *Apis*) caused by *Paenibacillus larvae*, which is widely distributed. *Paenibacillus larvae* is a bacterium that can produce over one billion spores in each infected larva. The spores are very long-living and extremely resistant to heat and chemical agents, and only the spores are capable of inducing the *disease*.

Combs with American foulbrood infected pre-imago of honey bees show distinctive clinical signs which can allow the *disease* to be diagnosed in the field. However, subclinical *infections* are common and require *laboratory* diagnosis.

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.2.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the American foulbrood status of the honey bee population of the *exporting country* or *zone*.

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

### Article 9.2.2.

#### Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any American foulbrood related conditions, regardless of the American foulbrood status of the honey bee population of the *exporting country* or *zone*:

- 1) honey bee semen;
- 2) honey bee venom;
- 3) honey bee eggs.

### Article 9.2.3.

#### Determination of the American foulbrood status of a country or zone

The American foulbrood status of a country or *zone* can only be determined after considering the following criteria:

- 1) a *risk assessment* has been conducted, identifying all potential factors for American foulbrood occurrence and their historic perspective;
- 2) American foulbrood should be notifiable in the whole country or *zone* and all clinical signs suggestive of American foulbrood should be subjected to field and *laboratory* investigations;
- 3) an ongoing awareness programme should be in place to encourage reporting of all cases suggestive of American foulbrood;
- 4) the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the country.

Article 9.2.4.

**Country or zone free from American foulbrood**

1) Historically free status

A country or *zone* may be considered free from the *disease* after conducting a *risk assessment* as referred to in Article 9.2.3. but without formally applying a specific *surveillance* programme if the country or *zone* complies with the provisions of Chapter 1.4.

2) Free status as a result of an eradication programme

A country or *zone* which does not meet the conditions of point 1 above may be considered free from American foulbrood after conducting a *risk assessment* as referred to in Article 9.2.3. and when:

- a) the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees has current knowledge of, and authority over, all domesticated *apiaries* existing in the country or *zone*;
- b) American foulbrood is notifiable in the whole country or *zone*, and any clinical cases suggestive of American foulbrood are subjected to field and *laboratory* investigations;
- c) for the five years following the last reported isolation of the American foulbrood agent, annual surveys supervised by the *Veterinary Authority* or other *Competent Authority*, with no positive results, have been carried out on a representative sample of *apiaries* in the country or *zone* to provide a confidence level of at least 95% of detecting American foulbrood if at least 1% of the *apiaries* were infected at a within-*apiary* prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with the last reported isolation of the American foulbrood agent;
- d) to maintain free status, an annual survey supervised by the *Veterinary Authority* or other *Competent Authority*, with no positive results, is carried out on a representative sample of hives in the country or *zone* to indicate that there has been no new isolations; such surveys may be targeted towards areas with a higher likelihood of isolation;
- e) either there is no wild or self-sustaining feral population of species of the genus *Apis* in the country or *zone*, or there is an ongoing *surveillance* programme of the wild or self-sustaining feral population of species of the genus *Apis* which demonstrates no evidence of the presence of the *disease* in the country or *zone*;
- f) all equipment associated with previously infected *apiaries* has been sterilised or destroyed;
- g) the importation of the *commodities* listed in this chapter into the country or *zone* is carried out in conformity with the recommendations of this chapter.

Article 9.2.5.

**Recommendations for the importation of live queen, worker and drone honey bees with or without associated brood combs**

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

- 1) the honey bees come from *apiaries* situated in a country or *zone* free from American foulbrood; or
- 2) the shipment comprises only honey bees without associated brood combs and:
  - a) the honey bees come from *apiaries* meeting the conditions prescribed in Article 4.14.5.; and
  - b) the *apiaries* where the honey bees come from are situated in the centre of an area with a radius of 3 kilometres where there has been no *outbreak* of American foulbrood during the past 30 days.

Article 9.2.6.

**Recommendations for the importation of larvae and pupae of honey bees**

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

- 1) come from *apiaries* situated in a country or *zone* free from American foulbrood; or
- 2) have been isolated from queens in a *quarantine station*, and all workers which accompanied the queen or a representative sample of larvae were examined for the presence of *P. larvae* by bacterial culture or PCR in accordance with the *Terrestrial Manual*.

Article 9.2.7.

**Recommendations for the importation of used apicultural equipment**

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

- 1) comes from *apiaries* situated in a country or *zone* free from American foulbrood; or
- 2) was sterilised under the supervision of the *Veterinary Authority* in conformity with one of the following procedures:
  - a) by irradiation with 10 kGy (suitable for all the used equipment); or
  - b) by either immersion in 1% sodium hypochlorite for at least 30 minutes (suitable only for non-porous materials such as plastic and metal); or
  - c) by immersion for at least 10 minutes in molten paraffin wax heated to 160°C (suitable only for wooden equipment); or
  - d) by any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing* and *exporting countries*.

Article 9.2.8.

**Recommendations for the importation of honey, honey bee-collected pollen, beeswax, propolis and royal jelly for use in apiculture**

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

- 1) come from *apiaries* situated in a country or *zone* free from American foulbrood; or
- 2) have been processed to ensure the destruction of both bacillary and spore forms of *P. larvae* by irradiation with ten kGy or any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing* and *exporting countries*; or
- 3) have been found free from spore forms of *P. larvae* by a test method described in the relevant chapter of the *Terrestrial Manual*.

Article 9.2.9.

**Recommendations for the importation of honey, honey bee-collected pollen, beeswax, propolis and royal jelly for human consumption**

*Veterinary Authorities of importing countries* free from American foulbrood should require the presentation of an *international veterinary certificate* attesting that the products:

- 1) come from *apiaries* situated in a country or *zone* free from American foulbrood; or
  - 2) have been processed to ensure the destruction of both bacillary and spore forms of *P. larvae* by irradiation with ten kGy or any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing* and *exporting countries*; or
  - 3) have been found free from spore forms of *P. larvae* by a test method described in the relevant chapter of the *Terrestrial Manual*.
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CHAPTER 9.3.

**INFECTION OF HONEY BEES WITH  
*Melissococcus plutonius*  
(EUROPEAN FOULBROOD)**

Article 9.3.1.

**General provisions**

For the purposes of the *Terrestrial Code*, European foulbrood is a *disease* of the larval and pupal stages of honey bees (species of the genus *Apis*), caused by *Melissococcus plutonius*, a non-sporulating bacterium, which is widely distributed. Subclinical *infections* are common and require *laboratory* diagnosis. *Infection* remains enzootic because of mechanical contamination of the honeycombs. Recurrences of *disease* can therefore be expected in subsequent years.

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.3.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the European foulbrood status of the honey bee population of the *exporting country or zone*.

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

Article 9.3.2.

**Safe commodities**

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any European foulbrood related conditions, regardless of the European foulbrood status of the honey bee population of the *exporting country or zone*:

- 1) honey bee semen;
- 2) honey bee venom.

Article 9.3.3.

**Determination of the European foulbrood status of a country or zone**

The European foulbrood status of a country or *zone* can only be determined after considering the following criteria:

- 1) a *risk assessment* has been conducted, identifying all potential factors for European foulbrood occurrence and their historic perspective;
- 2) European foulbrood should be notifiable in the whole country or *zone* and all clinical signs suggestive of European foulbrood should be subjected to field and *laboratory* investigations;
- 3) an ongoing awareness programme should be in place to encourage reporting of all cases suggestive of European foulbrood;
- 4) the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all *apiaries* in the whole country.

Article 9.3.4.

**Country or zone free from European foulbrood**

- 1) Historically free status

A country or *zone* may be considered free from the *disease* after conducting a *risk assessment* as referred to in Article 9.3.3. but without formally applying a specific *surveillance* programme if the country or *zone* complies with the provisions of Chapter 1.4.

2) Free status as a result of an eradication programme

A country or *zone* which does not meet the conditions of point 1 above may be considered free from European foulbrood after conducting a *risk assessment* as referred to in Article 9.3.3. and when:

- a) the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees has current knowledge of, and authority over, all domesticated *apiaries* existing in the country or *zone*;
- b) European foulbrood is notifiable in the whole country or *zone*, and any clinical cases suggestive of European foulbrood are subjected to field and *laboratory* investigations;
- c) for the three years following the last reported isolation of the European foulbrood agent, an annual survey supervised by the *Veterinary Authority* or other *Competent Authority*, with no positive results, have been carried out on a representative sample of *apiaries* in the country or *zone* to provide a confidence level of at least 95% of detecting European foulbrood if at least 1% of the *apiaries* were infected at a within-*apiary* prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with the last reported isolation of the European foulbrood agent;
- d) to maintain free status, an annual survey supervised by the *Veterinary Authority* or other *Competent Authority*, with no positive results, is carried out on a representative sample of hives in the country or *zone* to indicate that there has been no new isolations; such surveys may be targeted towards areas with a higher likelihood of isolation;
- e) either there is no wild or self-sustaining feral population of species of the genus *Apis* in the country or *zone*, or there is an ongoing *surveillance* programme of the wild or self-sustaining feral population of species of the genus *Apis* which demonstrates no evidence of the presence of the *disease* in the country or *zone*;
- f) the importation of the *commodities* listed in this chapter into the country or *zone* is carried out in conformity with the recommendations of this chapter.

Article 9.3.5.

**Recommendations for the importation of live queen, worker and drone honey bees with or without associated brood combs**

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

- 1) the honey bees come from *apiaries* situated in a country or *zone* free from European foulbrood; or
- 2) the shipment comprises only honey bees without associated brood combs and:
  - a) the honey bees come from *apiaries* meeting the conditions prescribed in Article 4.14.5.; and
  - b) the *apiaries* where the honey bees come from are situated in the centre of an area with a radius of 3 kilometres where there has been no *outbreak* of European foulbrood during the past 30 days.

Article 9.3.6.

**Recommendations for the importation of eggs, larvae and pupae of honey bees**

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

- 1) come from *apiaries* situated in a country or *zone* free from European foulbrood; or
- 2) have been isolated from queens in a *quarantine station*, and all workers which accompanied the queen or a representative sample of eggs or larvae were examined for the presence of *M. plutonius* by bacterial culture or PCR in accordance with the *Terrestrial Manual*.

Article 9.3.7.

**Recommendations for the importation of used apicultural equipment**

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

- 1) comes from *apiaries* situated in a country or *zone* free from European foulbrood; or

- 2) was sterilised under the supervision of the *Veterinary Authority* in conformity with one of the following procedures:
  - a) by immersion in 0.5% sodium hypochlorite for at least 20 minutes (suitable only for non-porous materials such as plastic and metal); or
  - b) by irradiation with 15 kGy; or
  - c) by any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing* and *exporting countries*.

Article 9.3.8.

**Recommendations for the importation of honey, honey bee-collected pollen, beeswax, propolis and royal jelly for use in apiculture**

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

- 1) come from *apiaries* situated in a country or *zone* free from European foulbrood; or
- 2) have been processed to ensure the destruction of *M. plutonius* by irradiation with 15 kGy or any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing* and *exporting countries*; or
- 3) have been found free of *M. plutonius* by a test method described in the relevant chapter of the *Terrestrial Manual*.

Article 9.3.9.

**Recommendations for the importation of honey, honey bee-collected pollen, beeswax, propolis and royal jelly for human consumption**

*Veterinary Authorities* of *importing countries* free from European foulbrood should require the presentation of an *international veterinary certificate* attesting that the *commodities*:

- 1) come from *apiaries* situated in a country or *zone* free from European foulbrood; or
  - 2) have been processed to ensure the destruction of *M. plutonius* by irradiation with 15 kGy or any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing* and *exporting countries*; or
  - 3) have been found free of *M. plutonius* by a test method described in the relevant chapter of the *Terrestrial Manual*.
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CHAPTER 9.4.

**INFESTATION WITH *Aethina tumida***  
**(SMALL HIVE BEETLE)**

Article 9.4.1.

**General provisions**

For the purposes of the *Terrestrial Code*, infestation with *Aethina tumida* (also known as small hive beetle) is an *infestation* of bee colonies (species of the genera *Apis* and *Bombus* and also stingless bees) by the beetle *A. tumida*, which is a free-living predator and scavenger affecting bee populations.

The adult beetle is attracted to bee colonies to reproduce, although it can potentially survive and reproduce independently in other natural environments, using other food sources, including certain types of fruit. Hence once it is established within a localised environment, it is extremely difficult to eradicate.

The life span of an adult beetle depends on environmental conditions such as temperature and humidity but, in practice, adult female beetles can live for at least six months and, in favourable reproductive conditions, the female is capable of producing up to a thousand eggs over a lifespan of four to six months. The beetle is able to survive at least two weeks without food.

Early signs of *infestation* and reproduction may go unnoticed. When the bees cannot prevent beetle mass reproduction on the combs, this leads to abandonment or collapse of the colony. Because *A. tumida* can be found and can thrive within the natural environment, and can fly up to 6-13 km from its nest site, it is capable of dispersing rapidly and directly invading new hives. Spread of *infestation* does not require contact between adult bees. The movement of adult bees, honeycomb and other apiculture products and used apicultural equipment may all cause *infestations* to spread to previously unaffected colonies.

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.4.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the *A. tumida* status of the honey bee and bumble bee population of the *exporting country or zone*.

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

Article 9.4.2.

**Safe commodities**

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any *A. tumida* related conditions, regardless of the *A. tumida* status of the *exporting country or zone*:

- 1) honey bee semen;
- 2) honey bee venom.

Article 9.4.3.

**Determination of the *A. tumida* status of a country or zone**

The *A. tumida* status of a country or *zone* can only be determined after considering the following criteria:

- 1) a *risk assessment* has been conducted, identifying all potential factors for *A. tumida* occurrence and their historic perspective;
- 2) the presence of *A. tumida* should be notifiable in the whole country, and all signs suggestive of *A. tumida infestation* should be subjected to field and *laboratory* investigations;
- 3) ongoing awareness and training programmes should be in place to encourage reporting of all cases suggestive of *A. tumida infestation*;

- 4) the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the country.

## Article 9.4.4.

**Country or zone free from *A. tumida***1) Historically free status

A country or *zone* may be considered free from *A. tumida* after conducting a *risk assessment* as referred to in Article 9.4.3. but without formally applying a specific *surveillance* programme if the country or *zone* complies with the provisions of Chapter 1.4.

2) Free status as a result of an eradication programme

A country or *zone* which does not meet the conditions of point 1 above may be considered free from *A. tumida* after conducting a *risk assessment* as referred to in Article 9.4.3. and when:

- a) the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees has current knowledge of, and authority over, all domesticated *apiaries* existing in the country or *zone*;
- b) the presence of *A. tumida* is notifiable in the whole country or *zone*, and any clinical cases suggestive of *A. tumida* infestation are subjected to field and *laboratory* investigations; a contingency plan is in place describing controls and inspection activities;
- c) for the five years following the last report of the presence of *A. tumida*, an annual survey supervised by the *Veterinary Authority* or other *Competent Authority*, with no positive results, has been carried out on a representative sample of *apiaries* in the country or *zone* to provide a confidence level of at least 95% of detecting *A. tumida* if at least 1% of the *apiaries* were infested at a within-*apiary* prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with a higher likelihood of *infestation*;
- d) to maintain free status, an annual survey supervised by the *Veterinary Authority* or other *Competent Authority*, with no positive results, is carried out on a representative sample of *apiaries* to indicate that there have been no presence of *A. tumida*; such surveys may be targeted towards areas with a higher likelihood of *infestation*;
- e) all equipment associated with previously infested *apiaries* has been destroyed, or cleaned and sterilised to ensure the destruction of *A. tumida*, in conformity with one of the following procedures:
  - i) heating to 50°C core temperature and holding at that temperature for 24 hours; or
  - ii) freezing at core temperature of -12°C or less for at least 24 hours; or
  - iii) irradiation with 400 Gy; or
  - iv) by any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing* and *exporting* countries;
- f) the soil and undergrowth in the immediate vicinity of all infested *apiaries* has been treated with a soil drench or similar suitable treatment that is efficacious in destroying incubating *A. tumida* larvae and pupae;
- g) the importation of the *commodities* listed in this chapter into the country or *zone* is carried out, in conformity with the recommendations of this chapter.

## Article 9.4.5.

**Recommendations for the importation of individual consignments containing a single live queen bee, accompanied by a small number of associated attendants (a maximum of 20 attendants per queen)**

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

- 1) the bees come from *apiaries* situated in a country or *zone* free from *A. tumida*;

OR

- 2) the bees come from hives or colonies which were inspected immediately prior to dispatch and show no evidence of the presence of *A. tumida* based on a visual inspection and the use of one of the methods described in the relevant chapter of the *Terrestrial Manual*; and
- 3) the bees come from an area of at least 100 km radius where no *apiary* has been subject to any restrictions associated with the occurrence of *A. tumida* for the previous six months; and

- 4) the bees and accompanying packaging presented for export have been thoroughly and individually inspected and do not contain *A. tumida*; and
- 5) the packaging material, containers, accompanying products and food are new; and
- 6) all precautions have been taken to prevent *infestation* or contamination with *A. tumida*, in particular, measures that prevent *infestation* of queen cages such as no long term storage of queens prior to shipment and covering the consignment of bees with fine mesh through which a live beetle cannot enter.

Article 9.4.6.

**Recommendations for the importation of live worker and drone bees with or without associated brood combs**

*Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that the bees come from *apiaries* situated in a country or *zone* free from *A. tumida*.

Article 9.4.7.

**Recommendations for the importation of eggs, larvae and pupae of bees**

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

- 1) the *commodities* come from *apiaries* situated in a country or *zone* free from *A. tumida*;

OR

- 2) the *commodities* have been bred and kept under a controlled environment within a recognised establishment which is supervised and controlled by the *Veterinary Authority* or other *Competent Authority*; and
- 3) the establishment was inspected immediately prior to dispatch and all eggs, larvae and pupae show no evidence of the presence of *A. tumida*; and
- 4) the packaging material, containers, accompanying products and food are new and all precautions have been taken to prevent *infestation* or contamination with *A. tumida*.

Article 9.4.8.

**Recommendations for the importation of used apicultural equipment**

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

- 1) the equipment:

EITHER

- a) comes from *apiaries* situated in a country or *zone* free from *A. tumida*;

OR

- b) has been thoroughly cleaned, and treated to ensure the destruction of *A. tumida*, in conformity with one of the following procedures:
  - i) heating to 50°C core temperature and holding at that temperature for 24 hours; or
  - ii) freezing at core temperature of -12°C or less for at least 24 hours; or
  - iii) irradiation with 400 Gy; or
  - iv) by any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing and exporting countries*;

AND

- 2) all precautions have been taken to prevent contamination with *A. tumida*.

Article 9.4.9.

**Recommendations for the importation of honey**

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

1) the honey:

EITHER

a) comes from *apiaries* situated in a country or *zone* free from *A. tumida*;

OR

b) has been strained through a filter of pore size no greater than 0.42 mm;

OR

c) has been treated to ensure the destruction of *A. tumida*, in conformity with one of the following procedures:

i) heating to 50°C core temperature and holding at that temperature for 24 hours; or

ii) freezing at core temperature of -12°C or less for at least 24 hours; or

iii) irradiation with 400 Gy; or

iv) by any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing* and *exporting countries*;

AND

2) all precautions have been taken to prevent contamination with *A. tumida*.

Article 9.4.10.

**Recommendations for the importation of bee-collected pollen**

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

1) the bee-collected pollen:

EITHER

a) comes from *apiaries* situated in a country or *zone* free from *A. tumida*;

OR

b) contains no live bees or bee brood; and

c) has been treated to ensure the destruction of *A. tumida*, in conformity with one of the following procedures:

i) freezing at core temperature of -12°C or less for at least 24 hours; or

ii) irradiation with 400 Gy; or

iii) desiccation by freeze drying or equivalent; or

iv) by any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing* and *exporting countries*;

AND

2) all precautions have been taken to prevent contamination with *A. tumida*.

Article 9.4.11.

**Recommendations for the importation of beeswax and propolis**

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

1) the *commodities*:

EITHER

a) come from *apiaries* situated in a country or *zone* free from *A. tumida*;

OR

b) contain no live bees or bee brood; and

c) are processed propolis or processed beeswax;

OR

d) contain no live bees or bee brood; and

e) have been treated to ensure the destruction of *A. tumida*, in conformity with one of the following procedures:

i) freezing at core temperature of -12°C or less for at least 24 hours; or

ii) irradiation with 400 Gy; or

iii) by any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing and exporting countries*;

AND

2) all precautions have been taken to prevent contamination with *A. tumida*.

Article 9.4.12.

**Recommendations for the importation of royal jelly**

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

1) the royal jelly:

EITHER

a) comes from *apiaries* situated in a country or *zone* free from *A. tumida*;

OR

b) is encapsulated for human consumption;

OR

c) has been treated to ensure the destruction of *A. tumida*, in conformity with one of the following procedures:

i) heating to 50°C core temperature and holding at that temperature for 24 hours; or

ii) freezing at core temperature of -12°C or less for at least 24 hours; or

iii) desiccation by freeze drying or equivalent; or

iv) irradiation with 400 Gy; or

v) by any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing and exporting countries*;

AND

2) all precautions have been taken to prevent contamination with *A. tumida*.

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CHAPTER 9.5.

**INFESTATION OF HONEY BEES WITH  
*TROPILAEELAPS* SPP.**

Article 9.5.1.

**General provisions**

For the purposes of the *Terrestrial Code*, *Tropilaelaps* infestation of honey bees (species of the genus *Apis*) is caused by different species of *Tropilaelaps* mites (including the mites ***Tropilaelaps clareae***, *T. koenigerum*, *T. thajii* and *T. mercedesae*). The mite is an ectoparasite of brood of honey bees, and cannot survive for periods of more than 21 days away from bee brood.

Early signs of infestation normally go unnoticed, but the growth in the mite population is rapid leading to high hive mortality. The infestation spreads by direct contact from adult honey bee to adult honey bee, and by the movement of infested honey bees and bee brood. The mite can also act as a vector for viruses of the honey bee.

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

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.5.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the *Tropilaelaps* spp. status of the honey bee population of the *exporting country* or *zone*.

Article 9.5.2.

**Safe commodities**

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any *Tropilaelaps* spp. related conditions, regardless of the *Tropilaelaps* spp. status of the *exporting country* or *zone*:

- 1) honey bee semen;
- 2) honey bee venom;
- 3) honey bee eggs;
- 4) royal jelly.

Article 9.5.3.

**Determination of the *Tropilaelaps* spp. status of a country or zone**

The *Tropilaelaps* spp. status of a country or *zone* can only be determined after considering the following criteria:

- 1) a *risk assessment* has been conducted, identifying all potential factors for *Tropilaelaps* spp. occurrence and their historic perspective;
- 2) the presence of *Tropilaelaps* spp. should be notifiable in the whole country or *zone* and all clinical signs suggestive of *Tropilaelaps* spp. infestation should be subjected to field and *laboratory* investigations;
- 3) an ongoing awareness programme should be in place to encourage reporting of all cases suggestive of *Tropilaelaps* spp. infestation;
- 4) the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the country.

Article 9.5.4.

**Country or zone free from *Tropilaelaps* spp.**

1) Historically free status

A country or *zone* may be considered free from *Tropilaelaps* spp. after conducting a *risk assessment* as referred to in Article 9.5.3. but without formally applying a specific *surveillance* programme if the country or *zone* complies with the provisions of Chapter 1.4.

2) Free status as a result of an eradication programme

A country or *zone* which does not meet the conditions of point 1 above may be considered free from *Tropilaelaps* spp. after conducting a *risk assessment* as referred to in Article 9.5.3. and when:

- a) the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees has current knowledge of, and authority over, all domesticated *apiaries* existing in the country or *zone*;
- b) the presence of *Tropilaelaps* spp. is notifiable in the whole country or *zone*, and any clinical cases suggestive of *Tropilaelaps* spp. infestation are subjected to field and *laboratory* investigations;
- c) for the three years following the last report of the presence of *Tropilaelaps* spp., an annual survey supervised by the *Veterinary Authority* or other *Competent Authority*, with no positive results, have been carried out on a representative sample of *apiaries* in the country or *zone* to provide a confidence level of at least 95% of detecting *Tropilaelaps* spp. if at least 1% of the *apiaries* were infested at a within-apiary prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with a higher likelihood of infestation;
- d) to maintain free status, an annual survey supervised by the *Veterinary Authority* or other *Competent Authority*, with no positive results, is carried out on a representative sample of *apiaries* in the country or *zone* to indicate that there has been no new cases; such surveys may be targeted towards areas with a higher likelihood of infestation;
- e) either there is no wild or self-sustaining feral population of species of the genus *Apis* in the country or *zone*, or there is an ongoing *surveillance* programme of the wild or self-sustaining feral population of species of the genus *Apis* which demonstrates no evidence of the presence of the mite in the country or *zone*;
- f) the importation of the *commodities* listed in this chapter into the country or *zone* is carried out, in conformity with the recommendations of this chapter.

Article 9.5.5.

**Recommendations for the importation of live queen honey bees, worker honey bees, drone honey bees, larvae of honey bees, pupae of honey bees, and brood combs**

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

- 1) the *commodities* come from *apiaries* situated in a country or *zone* free from *Tropilaelaps* spp.;

OR

- 2) the shipment comprises only queen honey bees with attendant worker honey bees without associated brood combs and the honey bees:
  - a) come from an artificial broodless swarm with the caged queen;
  - b) caged queen and swarm have been treated with an effective veterinary medicinal product and kept isolated for 21 days from brood prior to the shipment;
- 3) the honey bee queens were inspected by a representative of the *Veterinary Services* prior to the shipment and showed no evidence of the presence of the mites.

Article 9.5.6.

**Recommendations for the importation of used apicultural equipment**

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

- 1) comes from *apiaries* situated in a country or *zone* free from *Tropilaelaps* spp.; or

- 2) contains no live honey bees or bee brood and has been held in a bee-proof environment for at least 21 days prior to shipment; or
- 3) has been treated to ensure the destruction of *Tropilaelaps* spp., in conformity with one of the following procedures:
  - a) heating to 50°C core temperature and holding at that temperature for 20 minutes; or
  - b) freezing at core temperature of -12°C or less for at least 24 hours; or
  - c) fumigation with methyl bromide at a rate of 48 g per cubic metre at atmospheric pressure and at a temperature of 10-15°C for a period of 2 hours; or
  - d) irradiation with 350 Gy; or
  - e) by any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing and exporting countries*.

Article 9.5.7.

**Recommendations for the importation of honey**

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

- 1) comes from *apiaries* situated in a country or *zone* free from *Tropilaelaps* spp.; or
- 2) has been strained through a filter of pore size no greater than 0.42 mm; or
- 3) has been treated to ensure the destruction of *Tropilaelaps* spp., in conformity with one of the following procedures:
  - a) heating to 50°C core temperature and holding at that temperature for 20 minutes; or
  - b) freezing at core temperature of -12°C or less for at least 24 hours; or
  - c) irradiation with 350 Gy; or
  - d) by any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing and exporting countries*.

Article 9.5.8.

**Recommendations for the importation of bee-collected pollen**

*Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that the bee-collected pollen:

- 1) comes from *apiaries* situated in a country or *zone* free from *Tropilaelaps* spp.; or
- 2) has been treated to ensure the destruction of *Tropilaelaps* spp., in conformity with one of the following procedures:
- 3) has been treated to ensure the destruction of *Tropilaelaps* spp., in conformity with one of the following procedures:
  - a) freezing at core temperature of -12°C or less for at least 24 hours; or
  - b) irradiation with 350 Gy; or
  - c) desiccation by freeze drying or equivalent; or
  - d) by any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing and exporting countries*.

Article 9.5.9.

**Recommendations for the importation of beeswax and propolis**

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

- 1) come from *apiaries* situated in a country or *zone* free from *Tropilaelaps* spp.; or
- 2) are processed beeswax or processed propolis; or
- 3) have been treated to ensure the destruction of *Tropilaelaps* spp., in conformity with one of the following procedures:
  - a) freezing at core temperature of -12°C or less for at least 24 hours; or
  - b) fumigation with methyl bromide at a rate of 48 g per cubic metre at atmospheric pressure and at a temperature of 10-15°C for a period of 2 hours; or

- c) irradiation with 350 Gy; or
  - d) desiccation by freeze drying or equivalent; or
  - e) by any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing and exporting countries*.
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## CHAPTER 9.6.

# INFESTATION OF HONEY BEES WITH *Varroa* SPP. (VARROOSIS)

### Article 9.6.1.

#### General provisions

For the purposes of the *Terrestrial Code*, varroosis is a *disease* of honey bees (species of the genus *Apis*) caused by mites in the genus *Varroa*, primarily *Varroa destructor*. The mite is an ectoparasite of adults and brood of honey bees and spreads by direct contact from adult honey bee to adult honey bee, and by the movement of infested honey bees, bee brood, bee products and used apicultural equipment.

The number of mites steadily increases with increasing brood production and the growth of the honey bee population, especially late in the season when clinical signs of *infestation* can first be recognised. The lifespan of an individual mite depends on temperature and humidity but, in practice, it can be said to last from some days to a few months.

Honey bee colonies are often carriers of viruses. The mite acts as a *vector* for viruses (particularly deformed wing virus) facilitating their penetration and the *infection* of the honey bees. Most of the symptoms of varroosis are therefore the results of the combined action of *Varroa* spp. mites and viruses. The viral load within the colony increases with the mite *infestation*. Insufficient or late treatments lead to the killing of mites but the virus load remains high for several weeks with deleterious effects on the honey bee population. The control of the varroosis is mainly performed by the control of *Varroa* spp. and the diagnosis of varroosis is also performed by measuring the parasitic load.

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.6.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the varroosis status of the honey bee population of the *exporting country or zone*.

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

### Article 9.6.2.

#### Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any *Varroa* spp. related conditions, regardless of the *Varroa* spp. status of the honey bee population of the *exporting country or zone*:

- 1) honey bee semen;
- 2) honey bee venom;
- 3) honey bee eggs;
- 4) royal jelly.

### Article 9.6.3.

#### Determination of *Varroa* spp. status of a country or zone

The *Varroa* spp. status of a country or *zone* can only be determined after considering the following criteria:

- 1) a *risk assessment* has been conducted, identifying all potential factors for *Varroa* spp. occurrence and their historic perspective;
- 2) the presence of *Varroa* spp. should be notifiable in the whole country or *zone* and all clinical signs suggestive of varroosis should be subjected to field and *laboratory* investigations;
- 3) an ongoing awareness programme should be in place to encourage reporting of all cases suggestive of varroosis;

- 4) the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the country.

Article 9.6.4.

**Country or zone free from *Varroa* spp.**

1) Historically free status

A country or zone may be considered free from *Varroa* spp. after conducting a *risk assessment* as referred to in Article 9.6.3. but without formally applying a specific *surveillance* programme (historical freedom) if the country or zone complies with the provisions of Chapter 11.4.

2) Free status as a result of an eradication programme

A country or zone which does not meet the conditions of point 1 above may be considered free from *Varroa* spp. after conducting a *risk assessment* as referred to in Article 9.6.3. and when:

- a) the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees has current knowledge of, and authority over, all domesticated *apiaries* existing in the country or zone;
- b) the presence of *Varroa* spp. is notifiable in the whole country or zone, and any clinical cases suggestive of varroosis are subjected to field and *laboratory* investigations;
- c) for the three years following the last report of the presence of *Varroa* spp., an annual survey supervised by the *Veterinary Authority* or other *Competent Authority*, with no positive results, have been carried out on a representative sample of *apiaries* in the country or zone to provide a confidence level of at least 95% of detecting *Varroa* spp. if at least 1% of the *apiaries* were infested at a within-*apiary* prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with a higher likelihood of *infestation*;
- d) to maintain free status, an annual survey supervised by the *Veterinary Authority* or other *Competent Authority*, with no positive results, is carried out on a representative sample of *apiaries* in the country or zone to indicate there has been no new cases; such surveys may be targeted towards areas with a higher likelihood of *infestation*;
- e) either there is no wild or self-sustaining feral population of species of the genus *Apis* in the country or zone, or there is an ongoing *surveillance* programme of the wild or self-sustaining feral population of species of the genus *Apis* which demonstrates no evidence of the presence of the mite in the country or zone;
- f) the importation of the *commodities* listed in this chapter into the country or zone is carried out in conformity with the recommendations of this chapter.

Article 9.6.5.

**Recommendations for the importation of live queen honey bees, worker honey bees, drone honey bees, larvae of honey bees, pupae of honey bees and brood combs**

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

- 1) the *commodities* come from *apiaries* situated in a country or zone free from *Varroa* spp.; or
- 2) the shipment comprises only queen honey bees with attendant worker honey bees without associated brood combs and the honey bees:
  - a) come from an artificial broodless swarm with the caged queen;
  - b) caged queen and swarm have been treated with an effective *veterinary medicinal product*;
  - c) were inspected by a representative of the *Veterinary Services* prior to the shipment and showed no evidence of the presence of the mites;
  - d) the queen honey bees were inspected by the *Veterinary Services* of the *importing country* based on a visual inspection described in the relevant chapter of the *Terrestrial Manual* and the attendant worker honey bees were killed.

Article 9.6.6.

**Recommendations for the importation of used apicultural equipment**

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

- 1) comes from *apiaries* situated in a country or *zone* free from *Varroa* spp.; or
- 2) contains no live honey bees or bee brood and has been held in a bee-proof environment for at least 21 days prior to shipment; or
- 3) has been treated to ensure the destruction of *Varroa* spp., in conformity with one of the following procedures:
  - a) heating to 50°C core temperature and holding at that temperature for 20 minutes; or
  - b) freezing at core temperature of -12°C or less for at least 24 hours; or
  - c) fumigation with methyl bromide at a rate of 48 g per cubic metre at atmospheric pressure and at a temperature of 10-15°C for a period of 2 hours; or
  - d) irradiation with 350 Gy; or
  - e) by any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing* and *exporting countries*.

Article 9.6.7.

**Recommendations for the importation of honey**

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

- 1) comes from *apiaries* situated in a country or *zone* free from *Varroa* spp.; or
- 2) has been strained through a filter of pore size no greater than 0.42 mm; or
- 3) has been treated to ensure the destruction of *Varroa* spp. in conformity with one of the following procedures:
  - a) heating to 50°C core temperature and holding at that temperature for 20 minutes; or
  - b) freezing at core temperature of -12°C or less for at least 24 hours; or
  - c) irradiation with 350 Gy; or
  - d) by any procedure of equivalent efficacy recognised by the *Veterinary Authorities* of the *importing* and *exporting countries*.

Article 9.6.8.

**Recommendations for the importation of bee-collected pollen**

*Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that the bee-collected pollen:

- 1) comes from *apiaries* situated in a country or *zone* free from *Varroa* spp.; or
- 2) has been treated to ensure the destruction of *Varroa* spp., in conformity with one of the following procedures:
  - a) freezing at core temperature of -12°C or less for at least 24 hours; or
  - b) irradiation with 350 Gy; or
  - c) desiccation by freeze drying or equivalent; or
  - d) by any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing* and *exporting countries*.

Article 9.6.9.

**Recommendations for the importation of beeswax and propolis**

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

- 1) come from *apiaries* situated in a country or *zone* free from *Varroa* spp.; or

- 2) are processed beeswax or processed propolis; or
  - 3) have been treated to ensure the destruction of *Varroa* spp., in conformity with one of the following procedures:
    - a) freezing at core temperature of -12°C or less for at least 24 hours; or
    - b) fumigation with methyl bromide at a rate of 48 g per cubic metre at atmospheric pressure and at a temperature of 10-15°C for a period of 2 hours; or
    - c) irradiation with 350 Gy; or
    - d) desiccation by freeze drying or equivalent; or
    - e) by any procedure of equivalent efficacy recognised by the *Veterinary Authority* of the *importing and exporting countries*.
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## SECTION 10.

### AVES

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#### CHAPTER 10.1.

### AVIAN CHLAMYDIOSIS

Article 10.1.1.

#### **General provisions**

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

Article 10.1.2.

#### **Trade in commodities**

*Veterinary Authorities* of countries free from avian chlamydiosis may prohibit importation or transit through their territory, from countries considered infected with avian chlamydiosis, of birds of the *Psittacidae* family.

Article 10.1.3.

#### **Recommendations for the importation of birds of the *Psittacidae* family**

*Veterinary Authorities of importing countries* should require 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.
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## CHAPTER 10.2.

# AVIAN INFECTIOUS BRONCHITIS

### Article 10.2.1.

#### General provisions

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 10.2.2.

#### Recommendations for the importation of chickens

*Veterinary Authorities of importing countries* should require 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* should also be stated in the *certificate*).

### Article 10.2.3.

#### Recommendations for the importation of day-old birds

*Veterinary Authorities of importing countries* should require 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 Chapter 6.4.;
- 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/or 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 10.2.4.

#### Recommendations for the importation of hatching eggs of chickens

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

- 1) have been disinfected in conformity with the standards referred to in Chapter 6.4.;

- 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 Chapter 6.4.;
  - 3) were shipped in clean and unused packages.
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## CHAPTER 10.3.

# AVIAN INFECTIOUS LARYNGOTRACHEITIS

### Article 10.3.1.

#### General provisions

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 10.3.2.

#### Recommendations for the importation of chickens

*Veterinary Authorities of importing countries* should require 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* should also be stated in the *certificate*).

### Article 10.3.3.

#### Recommendations for the importation of day-old birds

*Veterinary Authorities of importing countries* should require 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 Chapter 6.4.;
- 2) have not been vaccinated against ILT; or
- 3) were vaccinated against ILT (the nature of the vaccine used and the date of *vaccination* should 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 10.3.4.

#### Recommendations for the importation of hatching eggs of chickens

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

- 1) have been disinfected in conformity with the standards referred to in Chapter 6.4.;
- 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 Chapter 6.4.;

- 3) were shipped in clean and unused packages.
-

## CHAPTER 10.4.

# INFECTION WITH AVIAN INFLUENZA VIRUSES

### Article 10.4.1.

#### General provisions

- 1) For the purposes of the *Terrestrial Code*, avian influenza is defined as an *infection* of *poultry* caused by any influenza A virus of the H5 or H7 subtypes or by any influenza A virus with an intravenous pathogenicity index (IVPI) greater than 1.2 (or as an alternative at least 75 percent mortality) as described below. These viruses are divided into high pathogenicity avian influenza viruses and low pathogenicity avian influenza viruses:
  - a) High pathogenicity avian influenza viruses have an IVPI in six-week-old chickens greater than 1.2 or, as an alternative, cause at least 75 percent mortality in four-to eight-week-old chickens infected intravenously. H5 and H7 viruses which do not have an IVPI of greater than 1.2 or cause less than 75 percent mortality in an intravenous lethality test should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0); if the amino acid motif is similar to that observed for other high pathogenicity avian influenza isolates, the isolate being tested should be considered as high pathogenicity avian influenza virus;
  - b) low pathogenicity avian influenza viruses are all influenza A viruses of H5 and H7 subtypes that are not high pathogenicity avian influenza viruses.
- 2) The following defines the occurrence of *infection* with an avian influenza virus: the virus has been isolated and identified as such or specific viral ribonucleic acid (RNA) has been detected in *poultry* or a product derived from *poultry*.
- 3) *Poultry* is defined as 'all domesticated birds, including backyard *poultry*, used for the production of *meat* or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds, as well as fighting cocks used for any purpose'.

Birds that are kept in captivity for any reason other than those reasons referred to in the preceding paragraph, including those that are kept for shows, races, exhibitions, competitions or for breeding or selling these categories of birds as well as pet birds, are not considered to be *poultry*.
- 4) For the purposes of the *Terrestrial Code*, the *incubation period* for avian influenza shall be 21 days.
- 5) This chapter deals not only with the occurrence of clinical signs caused by avian influenza, but also with the presence of *infection* with avian influenza viruses in the absence of clinical signs.
- 6) Antibodies to H5 or H7 subtype, which have been detected in *poultry* and are not a consequence of *vaccination*, should be immediately investigated. In the case of isolated serological positive results, *infection* with avian influenza viruses may be ruled out on the basis of a thorough epidemiological and *laboratory* investigation that does not demonstrate further evidence of such an *infection*.
- 7) For the purposes of the *Terrestrial Code*, 'avian influenza free establishment' means an *establishment* in which the *poultry* have shown no evidence of *infection* with avian influenza viruses, based on *surveillance* in accordance with Articles 10.4.27. to 10.4.33.
- 8) *Infection* with influenza A viruses of high pathogenicity in birds other than *poultry*, including wild birds, should be notified according to Article 1.1.3. However, a Member Country should not impose bans on the trade in *poultry commodities* in response to such a *notification*, or other information on the presence of any influenza A virus in birds other than *poultry*, including wild birds.
- 9) Standards for diagnostic tests, including pathogenicity testing, are described in the *Terrestrial Manual*. Any vaccine used should comply with the standards described in the *Terrestrial Manual*.

### Article 10.4.2.

#### Determination of the avian influenza status of a country, zone or compartment

The avian influenza status of a country, a *zone* or a *compartment* can be determined on the basis of the following criteria:

- 1) avian influenza is notifiable in the whole country, an ongoing avian influenza awareness programme is in place, and all notified suspect occurrences of avian influenza are subjected to field and, where applicable, *laboratory* investigations;

- 2) appropriate *surveillance* is in place to demonstrate the presence of *infection* in the absence of clinical signs in *poultry*, and the *risk* posed by birds other than *poultry*; this may be achieved through an avian influenza *surveillance* programme in accordance with Articles 10.4.27. to 10.4.33.;
- 3) consideration of all epidemiological factors for avian influenza occurrence and their historical perspective.

Article 10.4.3.

**Country, zone or compartment free from avian influenza**

A country, *zone* or *compartment* may be considered free from avian influenza when it has been shown that *infection* with avian influenza viruses in *poultry* has not been present in the country, *zone* or *compartment* for the past 12 months, based on *surveillance* in accordance with Articles 10.4.27. to 10.4.33.

If *infection* has occurred in *poultry* in a previously free country, *zone* or *compartment*, avian influenza free status can be regained:

- 1) In the case of *infections* with high pathogenicity avian influenza viruses, three months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that *surveillance* in accordance with Articles 10.4.27. to 10.4.33. has been carried out during that three-month period.
- 2) In the case of *infections* with low pathogenicity avian influenza viruses, *poultry* may be kept for *slaughter* for human consumption subject to conditions specified in Article 10.4.19. or a *stamping-out policy* may be applied; in either case, three months after the *disinfection* of all affected *establishments*, providing that *surveillance* in accordance with Articles 10.4.27. to 10.4.33. has been carried out during that three-month period.

Article 10.4.4.

**Country, zone or compartment free from infection with high pathogenicity avian influenza viruses in poultry**

A country, *zone* or *compartment* may be considered free from *infection* with high pathogenicity avian influenza viruses in *poultry* when:

- 1) it has been shown that *infection* with high pathogenicity avian influenza viruses in *poultry* has not been present in the country, *zone* or *compartment* for the past 12 months, although its status with respect to low pathogenicity avian influenza viruses may be unknown; or
- 2) when, based on *surveillance* in accordance with Articles 10.4.27. to 10.4.33., it does not meet the criteria for freedom from avian influenza but any virus detected has not been identified as high pathogenicity avian influenza virus.

The *surveillance* may need to be adapted to parts of the country or existing *zones* or *compartments* depending on historical or geographical factors, industry structure, population data, or proximity to recent *outbreaks*.

If *infection* has occurred in *poultry* in a previously free country, *zone* or *compartment*, the free status can be regained three months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that *surveillance* in accordance with Articles 10.4.27. to 10.4.33. has been carried out during that three-month period.

Article 10.4.5.

**Recommendations for importation from a country, zone or compartment free from avian influenza**

For live poultry (other than day-old poultry)

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

- 1) the *poultry* showed no clinical sign of avian influenza on the day of shipment;
- 2) the *poultry* were kept in an avian influenza free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;
- 3) the *poultry* are transported in new or appropriately sanitized *containers*.

If the *poultry* have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* have been attached to the *certificate*.

Article 10.4.6.

**Recommendations for the importation of live birds other than poultry**

Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) on the day of shipment, the birds showed no clinical sign of *infection* with a virus which would be considered avian influenza in *poultry*;
- 2) the birds were kept in isolation approved by the *Veterinary Services* since they were hatched or for at least the 21 days prior to shipment and showed no clinical sign of *infection* with a virus which would be considered avian influenza in *poultry* during the isolation period;
- 3) a statistically valid sample of the birds, selected in accordance with the provisions of Article 10.4.29., was subjected to a diagnostic test within 14 days prior to shipment to demonstrate freedom from *infection* with a virus which would be considered avian influenza in *poultry*;
- 4) the birds are transported in new or appropriately sanitized *containers*.

If the birds have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* have been attached to the *certificate*.

Article 10.4.7.

**Recommendations for importation from a country, zone or compartment free from avian influenza**

For day-old live poultry

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

- 1) the *poultry* were kept in an avian influenza free country, *zone* or *compartment* since they were hatched;
- 2) the *poultry* were derived from parent *flocks* which had been kept in an avian influenza free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;
- 3) the *poultry* are transported in new or appropriately sanitized *containers*.

If the *poultry* or the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* have been attached to the *certificate*.

Article 10.4.8.

**Recommendations for importation from a country, zone or compartment free from infection with high pathogenicity avian influenza viruses in poultry**

For day-old live poultry

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

- 1) the *poultry* were kept in a country, *zone* or *compartment* free from infection with high pathogenicity avian influenza viruses in *poultry* since they were hatched;
- 2) the *poultry* were derived from parent *flocks* which had been kept in an avian influenza free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;
- 3) the *poultry* are transported in new or appropriately sanitized *containers*.

If the *poultry* or the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* have been attached to the *certificate*.



Article 10.4.9.

**Recommendations for the importation of day-old live birds other than poultry**

Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) on the day of shipment, the birds showed no clinical sign of *infection* with a virus which would be considered avian influenza in *poultry*;
- 2) the birds were hatched and kept in isolation approved by the *Veterinary Services*;
- 3) the parent *flock* birds were subjected to a diagnostic test at the time of the collection of the eggs to demonstrate freedom from *infection* with a virus which would be considered avian influenza in *poultry*;
- 4) the birds are transported in new or appropriately sanitized *containers*.

If the birds or parent flocks have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* have been attached to the *certificate*.

Article 10.4.10.

**Recommendations for importation from a country, zone or compartment free from avian influenza**

For hatching eggs of poultry

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

- 1) the eggs came from an avian influenza free country, *zone* or *compartment*;
- 2) the eggs were derived from parent *flocks* which had been kept in an avian influenza free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;
- 3) the eggs are transported in new or appropriately sanitized packaging materials.

If the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* have been attached to the *certificate*.

Article 10.4.11.

**Recommendations for importation from a country, zone or compartment free from infection with high pathogenicity avian influenza viruses in poultry**

For hatching eggs of poultry

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

- 1) the eggs came from a country, *zone* or *compartment* free from infection with high pathogenicity avian influenza viruses in *poultry*;
- 2) the eggs were derived from parent *flocks* which had been kept in an avian influenza free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;
- 3) the eggs have had their surfaces sanitized (in accordance with Chapter 6.4.);
- 4) the eggs are transported in new or appropriately sanitized packaging materials.

If the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* have been attached to the *certificate*.

Article 10.4.12.

**Recommendations for the importation of hatching eggs from birds other than poultry**

Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the parent *flock* birds were subjected to a diagnostic test seven days prior to and at the time of the collection of the eggs to demonstrate freedom from *infection* with a virus which would be considered avian influenza in *poultry*;
- 2) the eggs have had their surfaces sanitized (in accordance with Chapter 6.4.);

- 3) the eggs are transported in new or appropriately sanitized packaging materials.

If the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* have been attached to the *certificate*.

Article 10.4.13.

**Recommendations for importation from a country, zone or compartment free from avian influenza**

For eggs for human consumption

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

- 1) the eggs were produced and packed in an avian influenza free country, *zone* or *compartment*;
- 2) the eggs are transported in new or appropriately sanitized packaging materials.

Article 10.4.14.

**Recommendations for importation from a free country, zone or compartment free from infection with high pathogenicity avian influenza viruses in poultry**

For eggs for human consumption

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

- 1) the eggs were produced and packed in a country, *zone* or *compartment* free from infection with high pathogenicity avian influenza viruses in *poultry*;
- 2) the eggs have had their surfaces sanitized (in accordance with Chapter 6.4.);
- 3) the eggs are transported in new or appropriately sanitized packaging materials.

Article 10.4.15.

**Recommendations for importation of egg products of poultry**

Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the *commodity* is derived from eggs which meet the requirements of Articles 10.4.13. or 10.4.14.; or
- 2) the *commodity* has been processed to ensure the destruction of avian influenza virus in accordance with Article 10.4.25.;

AND

- 3) the necessary precautions were taken to avoid contact of the *commodity* with any source of avian influenza virus.

Article 10.4.16.

**Recommendations for importation from a country, zone or compartment free from avian influenza**

For poultry semen

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

- 1) showed no clinical sign of avian influenza on the day of semen collection;
- 2) were kept in an avian influenza free country, *zone* or *compartment* for at least the 21 days prior to and at the time of semen collection.

Article 10.4.17.

**Recommendations for the importation from a country, zone or compartment free from infection with high pathogenicity avian influenza viruses in poultry**

For poultry semen

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

- 1) showed no clinical sign of *infection* with high pathogenicity avian influenza viruses in *poultry* on the day of semen collection;
- 2) were kept in a country, *zone* or *compartment* free from *infection* with high pathogenicity avian influenza viruses in *poultry* for at least the 21 days prior to and at the time of semen collection.

Article 10.4.18.

**Recommendations for the importation of semen of birds other than poultry**

Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the donor birds:

- 1) were kept in isolation approved by the *Veterinary Services* for at least the 21 days prior to semen collection;
- 2) showed no clinical sign of *infection* with a virus which would be considered avian influenza in *poultry* during the isolation period;
- 3) were tested within 14 days prior to semen collection and shown to be free from *infection* with a virus which would be considered avian influenza in *poultry*.

Article 10.4.19.

**Recommendations for importation from a country, zone or compartment free from avian influenza or free from infection with high pathogenicity avian influenza viruses in poultry**

For fresh meat of poultry

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

- 1) which have been kept in a country, *zone* or *compartment* free from *infection* with high pathogenicity avian influenza viruses in *poultry* since they were hatched or for at least the past 21 days;
- 2) which have been slaughtered in an approved *abattoir* in a country, *zone* or *compartment* free from *infection* with high pathogenicity avian influenza viruses in *poultry* and have been subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. and have been found free of any signs suggestive of avian influenza.

Article 10.4.20.

**Recommendations for the importation of meat products of poultry**

Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the *commodity* is derived from *fresh meat* which meet the requirements of Article 10.4.19.; or
- 2) the *commodity* has been processed to ensure the destruction of avian influenza virus in accordance with Article 10.4.26.;

AND

- 3) the necessary precautions were taken to avoid contact of the *commodity* with any source of avian influenza virus.

Article 10.4.21.

**Recommendations for the importation of products of poultry origin, other than feather meal and poultry meal, intended for use in animal feeding, or for agricultural or industrial use**

Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) these *commodities* were processed in an avian influenza free country, *zone* or *compartment* from *poultry* which were kept in an avian influenza free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*; or
- 2) these *commodities* have been processed to ensure the destruction of avian influenza virus (under study);

AND

- 3) the necessary precautions were taken to avoid contact of the *commodity* with any source of avian influenza virus.

Article 10.4.22.

**Recommendations for the importation of feathers and down of poultry**

Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) these *commodities* originated from *poultry* as described in Article 10.4.19. and were processed in an avian influenza free country, *zone* or *compartment*; or
- 2) these *commodities* have been processed to ensure the destruction of avian influenza virus (under study);

AND

- 3) the necessary precautions were taken to avoid contact of the *commodity* with any source of avian influenza virus.

Article 10.4.23.

**Recommendations for the importation of feathers and down of birds other than poultry**

Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) these *commodities* have been processed to ensure the destruction of any virus which would be considered avian influenza in *poultry* (under study); and
- 2) the necessary precautions were taken to avoid contact of the *commodity* with any source of viruses which would be considered avian influenza in *poultry*.

Article 10.4.24.

**Recommendations for the importation of feather meal and poultry meal**

Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) these *commodities* were processed in an avian influenza free country, *zone* or *compartment* from *poultry* which were kept in an avian influenza free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*; or
- 2) these *commodities* have been processed either:
  - a) with moist heat at a minimum temperature of 118°C for minimum of 40 minutes; or
  - b) with a continuous hydrolysing process under at least 3.79 bar of pressure with steam at a minimum temperature of 122°C for a minimum of 15 minutes; or
  - c) with an alternative rendering process that ensures that the internal temperature throughout the product reaches at least 74°C;

AND

- 3) the necessary precautions were taken to avoid contact of the *commodity* with any source of avian influenza viruses.

Article 10.4.25.

#### Procedures for the inactivation of the avian influenza viruses in eggs and egg products

The following times for industry standard temperatures are suitable for the inactivation of avian influenza viruses present in eggs and egg products:

	Core temperature (°C)	Time
Whole egg	60	188 seconds
Whole egg blends	60	188 seconds
Whole egg blends	61.1	94 seconds
Liquid egg white	55.6	870 seconds
Liquid egg white	56.7	232 seconds
10% salted yolk	62.2	138 seconds
Dried egg white	67	20 hours
Dried egg white	54.4	513 hours

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

Article 10.4.26.

#### Procedures for the inactivation of the avian influenza viruses in meat

The following times for industry standard temperatures are suitable for the inactivation of avian influenza viruses present in *meat*.

	Core temperature (°C)	Time
Poultry meat	60.0	507 seconds
	65.0	42 seconds
	70.0	3.5 seconds
	73.9	0.51 second

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

Article 10.4.27.

**Surveillance: introduction**

Articles 10.4.27. to 10.4.33. define the principles and provide a guide on the *surveillance* for avian influenza complementary to Chapter 1.4., applicable to Member Countries seeking to determine their avian influenza status. This may be for the entire country, *zone* or *compartment*. Guidance for Member Countries seeking free status following an *outbreak* and for the maintenance of avian influenza status is also provided.

The presence of influenza A viruses in wild birds creates a particular problem. In essence, no Member Country can declare itself free from influenza A in wild birds. However, the definition of avian influenza in this chapter refers to the *infection* in *poultry* only, and Articles 10.4.27. to 10.4.33. were developed under this definition.

The impact and epidemiology of avian influenza differ widely in different regions of the world and therefore it is impossible to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from avian influenza at an acceptable level of confidence will need to be adapted to the local situation. Variables such as the frequency of contacts of *poultry* with wild birds, different biosecurity levels and production systems and the commingling of different susceptible species including domestic waterfowl require specific *surveillance* strategies to address each specific situation. It is incumbent upon the Member Country to provide scientific data that explains the epidemiology of avian influenza in the region concerned and also demonstrates how all the risk factors are managed. There is therefore considerable latitude available to Member Countries to provide a well-reasoned argument to prove that absence of *infection* with avian influenza viruses *infection* is assured at an acceptable level of confidence.

*Surveillance* for avian influenza should be in the form of a continuing programme designed to establish that the country, *zone* or *compartment*, for which application is made, is free from *infection* with avian influenza viruses.

Article 10.4.28.

**Surveillance: general conditions and methods**

- 1) A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. In particular:
  - a) a formal and ongoing system for detecting and investigating *outbreaks* of *disease* or *infection* with avian influenza viruses should be in place;
  - b) a procedure should be in place for the rapid collection and transport of samples from suspect cases of avian influenza to a *laboratory* for avian influenza diagnosis;
  - c) a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.
- 2) The avian influenza *surveillance* programme should:
  - a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers, who have day-to-day contact with *poultry*, as well as diagnosticians, should report promptly any suspicion of avian influenza to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All suspected cases of avian influenza should be investigated immediately. As suspicion cannot always be resolved by epidemiological and clinical investigation alone, samples should be taken and submitted to a *laboratory* for appropriate tests. This requires that sampling kits and other equipment are available for those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in avian influenza diagnosis and control. In cases where potential public health implications are suspected, notification to the appropriate public health authorities is essential;
  - b) implement, when relevant, regular and frequent clinical inspection, serological and virological testing of high-risk groups of *animals*, such as those adjacent to an avian influenza infected country, *zone* or *compartment*, places where birds and *poultry* of different origins are mixed, such as live bird markets, *poultry* in close proximity to waterfowl or other potential sources of influenza A viruses.

An effective *surveillance* system will periodically identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is influenza A viruses. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Documentation for freedom from *infection* with avian influenza viruses should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of *laboratory* testing and the control measures to which the *animals* concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

## Article 10.4.29.

**Surveillance strategies**1. Introduction

The target population for *surveillance* aimed at identification of *disease* and *infection* should cover all the susceptible *poultry* species within the country, *zone* or *compartment*. Active and passive *surveillance* for avian influenza should be ongoing. The frequency of active *surveillance* should be at least every six months. *Surveillance* should be composed of random and targeted approaches using molecular, virological, serological and clinical methods.

The strategy employed may be based on randomised sampling requiring *surveillance* consistent with demonstrating the absence of *infection* with avian influenza viruses at an acceptable level of confidence. Random *surveillance* is conducted using serological tests. Positive serological results should be followed up with molecular or virological methods.

Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. Virological and serological methods should be used concurrently to define the avian influenza status of high risk populations.

A Member Country should justify the *surveillance* strategy chosen as adequate to detect the presence of *infection* with avian influenza viruses in accordance with Chapter 1.4. and the prevailing epidemiological situation, including cases of high pathogenicity influenza A detected in any birds. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clear clinical signs (e.g. chickens). Similarly, virological and serological testing could be targeted to species that may not show clinical signs (e.g. ducks).

If a Member Country wishes to declare freedom from *infection* with avian influenza viruses in a specific *zone* or *compartment*, the design of the survey and the basis for the sampling process would need to be aimed at the population within the *zone* or *compartment*.

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

Irrespective of the survey approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the *vaccination* and *infection* history and the different species in the target population.

Irrespective of the testing system employed, *surveillance* system design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as *flocks* which may be epidemiologically linked to it.

The principles involved in *surveillance* for *disease* and *infection* are technically well defined. The design of *surveillance* programmes to prove the absence of *infection* with, or circulation of, avian influenza viruses needs to be carefully followed to avoid producing results that are either insufficiently reliable, or excessively costly and logistically complicated. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.

2. Clinical surveillance

Clinical *surveillance* aims at the detection of clinical signs of avian influenza at the *flock* level. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection should not be underrated. Monitoring of production parameters, such as increased mortality, reduced feed and water consumption, presence of clinical signs of a respiratory *disease* or a drop in egg production, is important for the early detection of *infection* with avian influenza viruses. In some cases, the only indication of *infection* with low pathogenicity avian influenza virus may be a drop in feed consumption or egg production.

Clinical *surveillance* and *laboratory* testing should always be applied in series to clarify the status of avian influenza suspects detected by either of these complementary diagnostic approaches. *Laboratory* testing may confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive serology. Any sampling unit

within which suspicious *animals* are detected should have restrictions imposed upon it until avian influenza *infection* is ruled out.

Identification of suspect *flocks* is vital to the identification of sources of avian influenza viruses and to enable the molecular, antigenic and other biological characteristics of the virus to be determined. It is essential that avian influenza virus isolates are sent regularly to the regional Reference Laboratory for genetic and antigenic characterization.

3. Virological surveillance

Virological *surveillance* should be conducted:

- a) to monitor at risk populations;
- b) to confirm clinically suspect cases;
- c) to follow up positive serological results;
- d) to test 'normal' daily mortality, to ensure early detection of *infection* in the face of *vaccination* or in *establishments* epidemiologically linked to an *outbreak*.

4. Serological surveillance

Serological *surveillance* aims at the detection of antibodies against avian influenza virus. Positive avian influenza viruses antibody test results can have four possible causes:

- a) natural *infection* with avian influenza viruses;
- b) *vaccination* against avian influenza;
- c) maternal antibodies derived from a vaccinated or infected parent *flock* are usually found in the yolk and can persist in progeny for up to four weeks;
- d) false positive results due to the lack of specificity of the test.

It may be possible to use serum collected for other survey purposes for avian influenza *surveillance*. However, the principles of survey design described in these recommendations and the requirement for a statistically valid survey for the presence of avian influenza viruses should not be compromised.

The discovery of clusters of seropositive *flocks* may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or *infection*. As clustering may signal *infection*, the investigation of all instances should be incorporated in the survey design. Clustering of positive *flocks* is always epidemiologically significant and therefore should be investigated.

If *vaccination* cannot be excluded as the cause of positive serological reactions, diagnostic methods to differentiate antibodies due to *infection* or *vaccination* should be employed.

The results of random or targeted serological surveys are important in providing reliable evidence that no *infection* with avian influenza viruses is present in a country, *zone* or *compartment*. It is therefore essential that the survey be thoroughly documented.

5. Virological and serological surveillance in vaccinated populations

The *surveillance* strategy is dependent on the type of vaccine used. The protection against influenza A virus is haemagglutinin subtype specific. Therefore, two broad *vaccination* strategies exist: 1) inactivated whole viruses, and 2) haemagglutinin expression-based vaccines.

In the case of vaccinated populations, the *surveillance* strategy should be based on virological or serological methods and clinical *surveillance*. It may be appropriate to use sentinel birds for this purpose. These birds should be unvaccinated, virus antibody free birds and clearly and permanently identified. Sentinel birds should be used only if no appropriate *laboratory* procedures are available. The interpretation of serological results in the presence of *vaccination* is described in Article 10.4.33.

Article 10.4.30.

**Documentation of freedom from avian influenza or freedom from infection with high pathogenicity avian influenza viruses in poultry**

1. Additional surveillance procedures for Member Countries declaring freedom of the country, zone or compartment from avian influenza or from infection with high pathogenicity avian influenza viruses in poultry

In addition to the general conditions described in above mentioned articles, a Member Country declaring freedom of the entire country, or a *zone* or a *compartment* from avian influenza or from *infection* with high pathogenicity avian influenza viruses in *poultry* should provide evidence for the existence of an effective *surveillance* programme.



The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and should be planned and implemented according to general conditions and methods described in this chapter, to demonstrate absence of *infection* with avian influenza viruses or with high pathogenicity avian influenza viruses, during the preceding 12 months in susceptible *poultry* populations (vaccinated and non-vaccinated). This requires the support of a *laboratory* able to undertake identification of *infection* with avian influenza viruses through virus detection and antibody tests. This *surveillance* may be targeted to *poultry* population at specific risks linked to the types of production, possible direct or indirect contact with wild birds, multi-age *flocks*, local trade patterns including live bird markets, use of possibly contaminated surface water, and the presence of more than one species on the holding and poor biosecurity measures in place.

## 2. Additional requirements for countries, zones or compartments that practise vaccination

*Vaccination* to prevent the transmission of high pathogenicity avian influenza virus may be part of a *disease* control programme. The level of *flock* immunity required to prevent transmission will depend on the *flock* size, composition (e.g. species) and density of the susceptible *poultry* population. It is therefore impossible to be prescriptive. Based on the epidemiology of avian influenza in the country, *zone* or *compartment*, it may be that a decision is reached to vaccinate only certain species or other *poultry* subpopulations.

In all vaccinated *flocks* there is a need to perform virological and serological tests to ensure the absence of virus circulation. The use of sentinel *poultry* may provide further confidence of the absence of virus circulation. The tests have to be repeated at least every six months or at shorter intervals according to the risk in the country, *zone* or *compartment*.

Evidence to show the effectiveness of the *vaccination* programme should also be provided.

### Article 10.4.31.

#### **Additional surveillance procedures for countries, zones or compartments declaring that they have regained freedom from avian influenza or from infection with high pathogenicity avian influenza viruses in poultry following an outbreak**

In addition to the general conditions described in the above-mentioned articles, a Member Country declaring that it has regained country, *zone* or *compartment* freedom from avian influenza or from infection with high pathogenicity avian influenza viruses in *poultry* should show evidence of an active *surveillance* programme depending on the epidemiological circumstances of the *outbreak* to demonstrate the absence of the *infection*. This will require *surveillance* incorporating virus detection and antibody tests. The use of sentinel birds may facilitate the interpretation of *surveillance* results.

A Member Country declaring freedom of country, *zone* or *compartment* after an *outbreak* of avian influenza should report the results of an active *surveillance* programme in which the susceptible *poultry* population undergoes regular clinical examination and active *surveillance* planned and implemented according to the general conditions and methods described in these recommendations. The *surveillance* should at least give the confidence that can be given by a randomized representative sample of the populations at risk.

### Article 10.4.32.

#### **Additional surveillance procedures for avian influenza free establishments**

The declaration of avian influenza free *establishments* requires the demonstration of absence of *infection* with avian influenza viruses. Birds in these *establishments* should be randomly tested using virus detection or isolation tests, and serological methods, following the general conditions of these recommendations. The frequency of testing should be based on the risk of *infection* and at a maximum interval of 21 days.

### Article 10.4.33.

#### **The use and interpretation of serological and virus detection tests**

*Poultry* infected with avian influenza virus produce antibodies to haemagglutinin (HA), neuraminidase (NA), nonstructural proteins (NSPs), nucleoprotein/matrix (NP/M) and the polymerase complex proteins. Detection of antibodies against the polymerase complex proteins will not be covered in this chapter. Tests for NP/M antibodies include direct and blocking ELISA, and agar gel immunodiffusion (AGID) tests. Tests for antibodies against NA include the neuraminidase inhibition (NI), indirect fluorescent antibody and direct and blocking ELISA tests. For the HA,

antibodies are detected in haemagglutination inhibition (HI), ELISA and neutralization (SN) tests. The HI test is reliable in avian species but not in mammals. The SN test can be used to detect subtype specific antibodies to the haemagglutinin and is the preferred test for mammals and some avian species. The AGID test is reliable for detection of NP/M antibodies in chickens and turkeys, but not in other avian species. As an alternative, blocking ELISA tests have been developed to detect NP/M antibodies in all avian species.

The HI and NI tests can be used to subtype influenza A viruses into 16 haemagglutinin and 9 neuraminidase subtypes. Such information is helpful for epidemiological investigations and in categorization of influenza A viruses.

*Poultry* can be vaccinated with a variety of influenza A vaccines including inactivated whole virus vaccines, and haemagglutinin expression-based vaccines. Antibodies to the haemagglutinin confer subtype specific protection. Various strategies can be used to differentiate vaccinated from infected birds including serosurveillance in unvaccinated sentinel birds or specific serological tests in the vaccinated birds.

Influenza A virus *infection* of unvaccinated birds including sentinels is detected by antibodies to the NP/M, subtype specific HA or NA proteins, or NSP. *Poultry* vaccinated with inactivated whole virus vaccines containing a virus of the same H sub-type but with a different neuraminidase may be tested for field exposure by applying serological tests directed to the detection of antibodies to the NA of the field virus. For example, birds vaccinated with H7N3 in the face of a H7N1 epidemic may be differentiated from infected birds (DIVA) by detection of subtype specific NA antibodies of the N1 protein of the field virus. Alternatively, in the absence of DIVA, inactivated vaccines may induce low titres of antibodies to NSP and the titre in infected birds would be markedly higher. Encouraging results have been obtained experimentally with this system, but it has not yet been validated in the field. In *poultry* vaccinated with haemagglutinin expression-based vaccines, antibodies are detected to the specific HA, but not any of the other viral proteins. *Infection* is evident by antibodies to the NP/M or NSP, or the specific NA protein of the field virus.

All *flocks* with seropositive results should be investigated. Epidemiological and supplementary *laboratory* investigation results should document the status of avian influenza *infection* for each positive *flock*.

A confirmatory test should have a higher specificity than the screening test and sensitivity at least equivalent than that of the screening test.

Information should be provided on the performance characteristics and validation of tests used.

1. Procedure in case of positive test results if vaccination is used

In case of vaccinated populations, one has to exclude the likelihood that positive test results are indicative of virus circulation. To this end, the following procedure should be followed in the investigation of positive serological test results derived from *surveillance* conducted on vaccinated *poultry*. The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated, and the results should be collated in the final report.

Knowledge of the type of vaccine used is crucial in developing a serological based strategy to differentiate infected from vaccinated *animals*.

- a) Inactivated whole virus vaccines can use either homologous or heterologous neuraminidase subtypes between the vaccine and field strains. If *poultry* in the population have antibodies to NP/M and were vaccinated with inactivated whole virus vaccine, the following strategies should be applied:
  - i) sentinel birds should remain NP/M antibody negative. If positive for NP/M antibodies, indicating influenza A virus *infection*, specific HI tests should be performed to identify H5 or H7 virus *infection*;
  - ii) if vaccinated with inactivated whole virus vaccine containing homologous NA to field virus, the presence of antibodies to NSP could be indicative of *infection*. Sampling should be initiated to exclude the presence of avian influenza virus by either virus isolation or detection of virus specific genomic material or proteins;
  - iii) if vaccinated with inactivated whole virus vaccine containing heterologous NA to field virus, presence of antibodies to the field virus NA or NSP would be indicative of *infection*. Sampling should be initiated to exclude the presence of avian influenza virus by either virus isolation or detection of virus specific genomic material or proteins.
- b) Haemagglutinin expression-based vaccines contain the HA protein or gene homologous to the HA of the field virus. Sentinel birds as described above can be used to detect avian influenza *infection*. In vaccinated or sentinel birds, the presence of antibodies against NP/M, NSP or field virus NA is indicative of *infection*. Sampling should be initiated to exclude the presence of avian influenza virus by either virus isolation or detection of virus specific genomic material or proteins.

2. Procedure in case of test results indicative of infection with avian influenza viruses

The detection of antibodies indicative of an *infection* with avian influenza virus in unvaccinated *poultry* should result in the initiation of epidemiological and virological investigations to determine if the *infections* are due to low and high pathogenicity viruses.

Virological testing should be initiated in all antibody-positive and at risk populations. The samples should be evaluated for the presence of avian influenza virus, by virus isolation and identification, or detection of influenza A specific proteins or nucleic acids (Figure 2). Virus isolation is the gold standard for detecting *infection* by avian influenza virus. All influenza A virus isolates should be tested to determine HA and NA subtypes, and *in vivo* tested in chickens or sequencing of HA proteolytic cleavage site of H5 and H7 subtypes for determination of classification as high or low pathogenicity avian influenza viruses or other influenza A viruses. As an alternative, nucleic acid detection tests have been developed and validated; these tests have the sensitivity of virus isolation, but with the advantage of providing results within a few hours. Samples with detection of H5 and H7 HA subtypes by nucleic acid detection methods should either be submitted for virus isolation, identification, and *in vivo* testing in chickens, or sequencing of nucleic acids for determination of proteolytic cleavage site as high or low pathogenicity avian influenza viruses. The use of antigen detection systems, because of low sensitivity, should be limited to screening clinical field *cases* for *infection* by influenza A virus looking for NP/M proteins. NP/M positive samples should be submitted for virus isolation, identification and pathogenicity determination.

*Laboratory* results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral circulation includes but is not limited to:

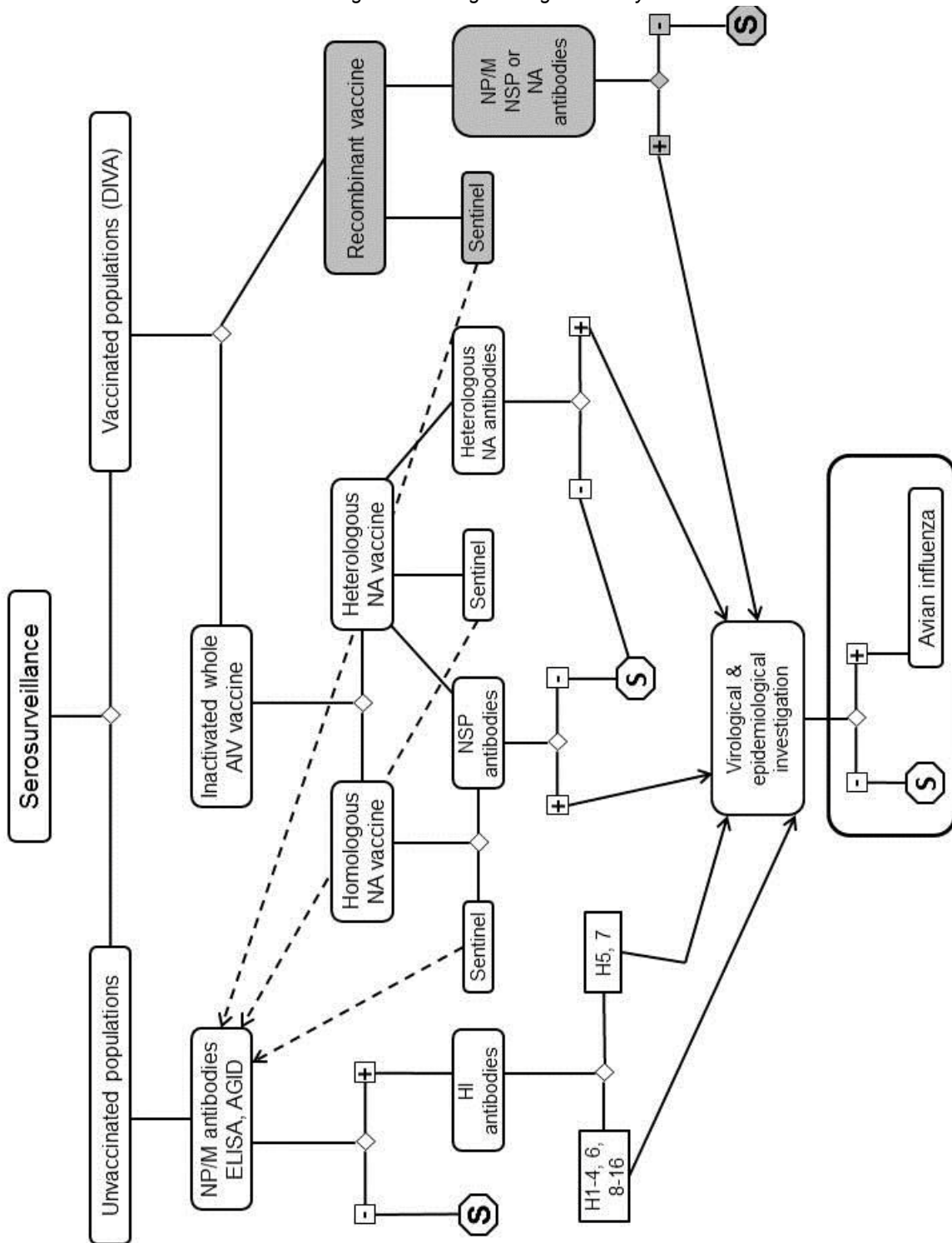
- a) characterization of the existing production systems;
- b) results of clinical *surveillance* of the suspects and their cohorts;
- c) quantification of *vaccinations* performed on the affected sites;
- d) sanitary protocol and history of the affected *establishments*;
- e) control of *animal identification* and movements;
- f) other parameters of regional significance in historic avian influenza virus transmission.

The entire investigative process should be documented as standard operating procedure within the epidemiological *surveillance* programme.

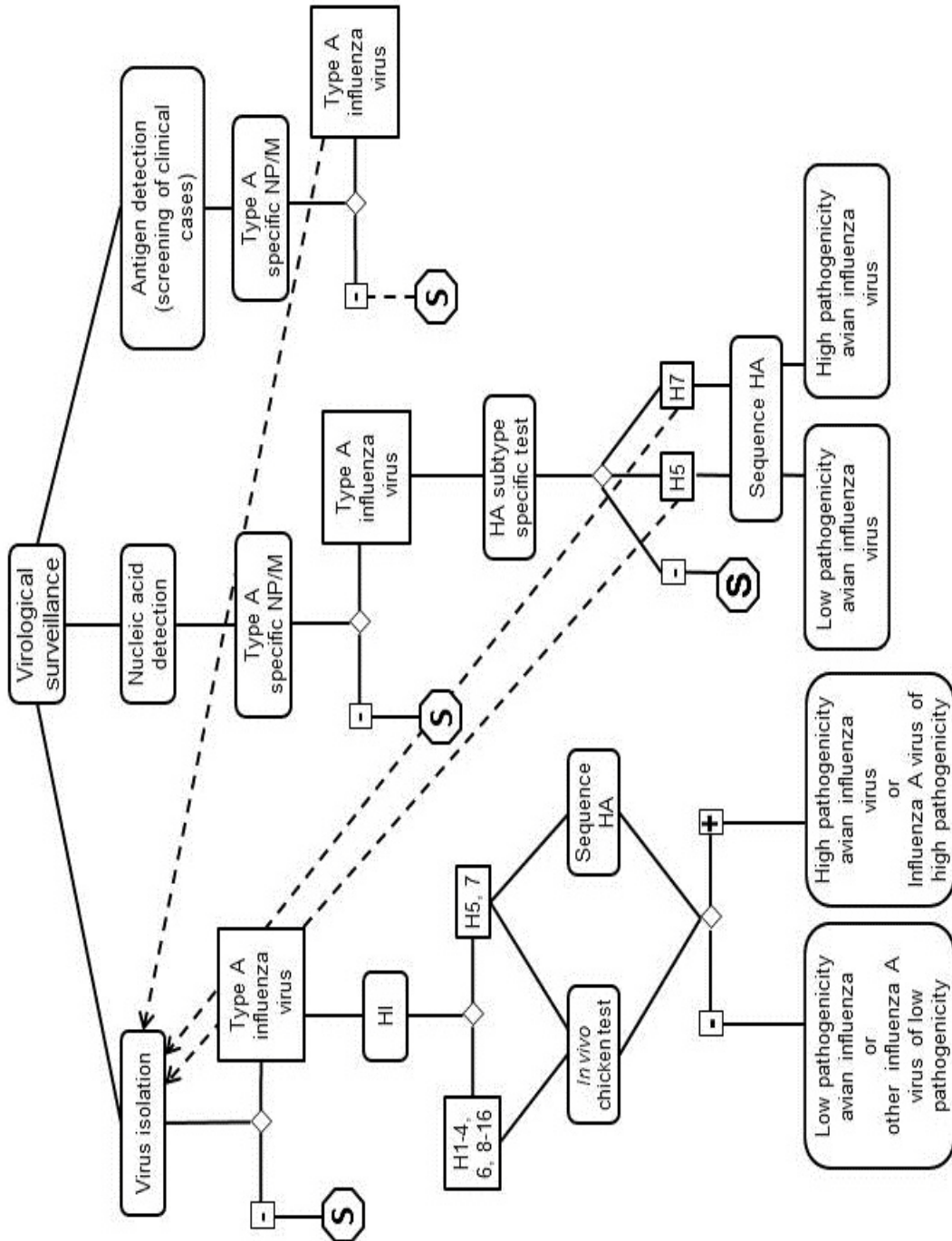
Figures 1 and 2 indicate the tests which are recommended for use in the investigation of *poultry flocks*.

Key:	
AGID	Agar gel immunodiffusion
DIVA	Differentiating infected from vaccinated animals
ELISA	Enzyme-linked immunosorbant assay
HA	Haemagglutinin
HI	Haemagglutination inhibition
NA	Neuraminidase
NP/M	Nucleoprotein and matrix protein
NSP	Nonstructural protein
S	No evidence of avian influenza virus

**Fig. 1.** Schematic representation of laboratory tests for determining evidence of avian influenza infection through or following serological surveys



**Fig. 2.** Schematic representation of laboratory tests for determining evidence of avian influenza infection using virological methods



## CHAPTER 10.5.

# AVIAN MYCOPLASMOSIS (*Mycoplasma gallisepticum*)

### Article 10.5.1.

#### General provisions

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

### Article 10.5.2.

#### Establishment free from avian mycoplasmosis

To qualify as free from avian mycoplasmosis, an *establishment* should 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 percent 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 10.5.3.

#### Recommendations for the importation of chickens and turkeys

*Veterinary Authorities of importing countries* should require 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 10.5.4.

#### Recommendations for the importation of day-old birds

*Veterinary Authorities of importing countries* should require 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 Chapter 6.4.;
- 2) were shipped in clean and unused packages.

### Article 10.5.5.

#### Recommendations for the importation of hatching eggs of chickens and turkeys

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

- 1) have been disinfected in conformity with the standards referred to in Chapter 6.4.;

- 2) come from *establishments* free from avian mycoplasmosis and from hatcheries which comply with the standards referred to in Chapter 6.4.;
  - 3) were shipped in clean and unused packages.
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## CHAPTER 10.6.

# DUCK VIRUS HEPATITIS

### Article 10.6.1.

#### General provisions

For the purposes of the *Terrestrial Code*, the *incubation period* for duck virus hepatitis (DVH) shall be seven days.

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

### Article 10.6.2.

#### Recommendations for the importation of ducks

*Veterinary Authorities of importing countries* should require 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* should also be stated in the *certificate*).

### Article 10.6.3.

#### Recommendations for the importation of day-old ducks

*Veterinary Authorities of importing countries* should require 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 Chapter 6.4.;
- 2) have not been vaccinated against DVH; or
- 3) were vaccinated against DVH (the nature of the vaccine used and the date of *vaccination* should 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 10.6.4.

#### Recommendations for the importation of hatching eggs of ducks

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

- 1) have been disinfected in conformity with the standards referred to in Chapter 6.4.;
- 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 Chapter 6.4.;



- 3) were shipped in clean and unused packages.
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## CHAPTER 10.7.

# FOWL TYPHOID AND PULLORUM DISEASE

### Article 10.7.1.

#### General provisions

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

### Article 10.7.2.

#### Recommendations for the importation of domestic birds

*Veterinary Authorities of importing countries* should require 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 10.7.3.

#### Recommendations for the importation of day-old birds

*Veterinary Authorities of importing countries* should require 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 Chapter 6.4.;
- 2) were shipped in clean and unused packages.

### Article 10.7.4.

#### Recommendations for the importation of hatching eggs of domestic birds

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

- 1) have been disinfected in conformity with the standards referred to in Chapter 6.4.;
- 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 Chapter 6.4.;
- 3) were shipped in clean and unused packages.

CHAPTER 10.8.  
**INFECTIOUS BURSAL DISEASE  
(GUMBORO DISEASE)**

Article 10.8.1.

**General provisions**

For the purposes of the *Terrestrial Code*, the *incubation period* for infectious bursal disease shall be seven days.

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

Article 10.8.2.

**Recommendations for the importation of domestic birds**

*Veterinary Authorities of importing countries* should require 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* should also be stated in the *certificate*).

Article 10.8.3.

**Recommendations for importation from countries considered infected with infectious bursal disease**

For day-old birds

*Veterinary Authorities of importing countries* should require 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 Chapter 6.4.;
- 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* should 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 10.8.4.

**Recommendations for the importation of hatching eggs of domestic birds**

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

- 1) have been disinfected in conformity with the standards referred to in Chapter 6.4.;

- 2) come from *establishments* which are regularly inspected by the *Veterinary Authority* and from hatcheries which comply with the standards referred to in Chapter 6.4.;
  - 3) were shipped in clean and unused packages.
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## CHAPTER 10.9.

# NEWCASTLE DISEASE

### Article 10.9.1.

#### General provisions

- 1) For the purposes of the *Terrestrial Code*, Newcastle disease (ND) is defined as an *infection of poultry* caused by a virus (NDV) of avian paramyxovirus serotype 1 (APMV-1) that meets one of the following criteria for virulence:
  - a) the virus has an intracerebral pathogenicity index (ICPI) in day-old chicks (*Gallus gallus*) of 0.7 or greater; or
  - b) multiple basic amino acids have been demonstrated in the virus (either directly or by deduction) at the C-terminus of the F2 protein and phenylalanine at residue 117, which is the N-terminus of the F1 protein. The term 'multiple basic amino acids' refers to at least three arginine or lysine residues between residues 113 and 116. Failure to demonstrate the characteristic pattern of amino acid residues as described above would require characterisation of the isolated virus by an ICPI test.

In this definition, amino acid residues are numbered from the N-terminus of the amino acid sequence deduced from the nucleotide sequence of the F0 gene, 113–116 corresponds to residues –4 to –1 from the cleavage site.'

- 2) *Poultry* is defined as 'all domesticated birds, including backyard *poultry*, used for the production of *meat* or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds, as well as fighting cocks used for any purpose'.

Birds that are kept in captivity for any reason other than those reasons referred to in the preceding paragraph, including those that are kept for shows, races, exhibitions, competitions, or for breeding or selling these categories of birds as well as pet birds, are not considered to be *poultry*.

- 3) For the purposes of the *Terrestrial Code*, the *incubation period* for ND shall be 21 days.
- 4) This chapter deals with NDV *infection of poultry* as defined in Point 2 above, in the presence or absence of clinical signs.
- 5) The occurrence of *infection* with NDV is defined as the isolation and identification of NDV as such or the detection of viral RNA specific for NDV.
- 6) Standards for diagnostic tests, including pathogenicity testing, are described in the *Terrestrial Manual*. When the use of ND vaccines is appropriate, those vaccines should comply with the standards described in the *Terrestrial Manual*.
- 7) A Member Country should not impose bans on the trade in *poultry commodities* in response to information on the presence of any APMV-1 in birds other than *poultry*, including wild birds.

### Article 10.9.2.

#### Determination of the Newcastle disease status of a country, zone or compartment

The ND status of a country, a *zone* or a *compartment* can be determined on the basis of the following criteria:

- 1) ND is notifiable in the whole country, an on-going ND awareness programme is in place, and all notified suspect occurrences of ND are subjected to field and, where applicable, *laboratory* investigations;
- 2) appropriate *surveillance* is in place to demonstrate the presence of NDV *infection* in the absence of clinical signs in *poultry*, this may be achieved through an ND *surveillance* programme in accordance with Articles 10.9.22. to 10.9.26.;
- 3) consideration of all epidemiological factors for ND occurrence and their historical perspective.

Article 10.9.3.

**Newcastle disease free country, zone or compartment**

A country, *zone* or *compartment* may be considered free from ND when it has been shown that NDV *infection* in *poultry* has not been present in the country, *zone* or *compartment* for the past 12 months, based on *surveillance* in accordance with Articles 10.9.22. to 10.9.26.

If *infection* has occurred in *poultry* in a previously free country, *zone* or *compartment*, ND free status can be regained three months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that *surveillance* in accordance with Articles 10.9.22. to 10.9.26. has been carried out during that three-month period.

Article 10.9.4.

**Recommendations for importation from an Newcastle disease free country, zone or compartment as defined in Article 10.9.3.**

For live poultry (other than day-old poultry)

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

- 1) the *poultry* showed no clinical sign suggestive of ND on the day of shipment;
- 2) the *poultry* were kept in an ND free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;
- 3) the *poultry* are transported in new or appropriately sanitized *containers*.

If the *poultry* have been vaccinated against ND, the nature of the vaccine used and the date of *vaccination* have been attached to the *certificate*.

Article 10.9.5.

**Recommendations for the importation of live birds other than poultry**

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the birds showed no clinical sign suggestive of *infection* by NDV on the day of shipment;
- 2) the birds were kept in isolation approved by the *Veterinary Services* since they were hatched or for at least the 21 days prior to shipment and showed no clinical sign of *infection* during the isolation period;
- 3) a statistically valid sample of the birds, selected in accordance with the provisions of Article 10.9.24., was subjected to a diagnostic test within 14 days prior to shipment to demonstrate freedom from *infection* with NDV;
- 4) the birds are transported in new or appropriately sanitized *containers*.

If the birds have been vaccinated against ND, the nature of the vaccine used and the date of *vaccination* have been attached to the *certificate*.

Article 10.9.6.

**Recommendations for importation from an Newcastle disease free country, zone or compartment**

For day-old live poultry

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

- 1) the *poultry* were hatched and kept in an ND free country, *zone* or *compartment* since they were hatched;
- 2) the *poultry* were derived from parent *flocks* which had been kept in an ND free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;
- 3) the *poultry* are transported in new or appropriately sanitized *containers*.

If the *poultry* or parent *flocks* have been vaccinated against ND, the nature of the vaccine used and the date of *vaccination* have been attached to the *certificate*.

## Article 10.9.7.

**Recommendations for the importation of day-old live birds other than poultry**

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the birds showed no clinical sign suggestive of *infection* by NDV on the day of shipment;
- 2) the birds were hatched and kept in isolation approved by the *Veterinary Services*;
- 3) the parent *flock* birds were subjected to a diagnostic test at the time of the collection of the eggs to demonstrate freedom from *infection* with NDV;
- 4) the birds are transported in new or appropriately sanitized *containers*.

If the birds or parent *flocks* have been vaccinated against ND, the nature of the vaccine used and the date of *vaccination* have been attached to the *certificate*.

## Article 10.9.8.

**Recommendations for importation from an Newcastle disease free country, zone or compartment**For hatching eggs of poultry

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

- 1) the eggs came from an ND free country, *zone* or *compartment*;
- 2) the eggs were derived from parent *flocks* which had been kept in an ND free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;
- 3) the eggs are transported in new or appropriately sanitized packaging materials.

If the parent *flocks* have been vaccinated against ND, the nature of the vaccine used and the date of *vaccination* have been attached to the *certificate*.

## Article 10.9.9.

**Recommendations for the importation of hatching eggs from birds other than poultry**

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the parent *flock* birds were subjected to a diagnostic test seven days prior to and at the time of the collection of the eggs to demonstrate freedom from *infection* with NDV;
- 2) the eggs have had their surfaces sanitized (in accordance with Chapter 6.4.);
- 3) the eggs are transported in new or appropriately sanitized packaging materials.

If the parent *flocks* have been vaccinated against ND, the nature of the vaccine used and the date of *vaccination* have been attached to the *certificate*.

## Article 10.9.10.

**Recommendations for importation from an Newcastle disease free country, zone or compartment**For eggs for human consumption

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

- 1) the eggs were produced and packed in an ND free country, *zone* or *compartment*;
- 2) the eggs are transported in new or appropriately sanitized packaging materials.

Article 10.9.11.

**Recommendations for importation of egg products of poultry**

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the *commodity* is derived from eggs which meet the requirements of Article 10.9.10.; or
- 2) the *commodity* has been processed to ensure the destruction of NDV in accordance with Article 10.9.20.;

AND

- 3) the necessary precautions were taken to avoid contact of the egg products with any source of NDV.

Article 10.9.12.

**Recommendations for importation from an Newcastle disease free country, zone or compartment**

For poultry semen

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

- 1) showed no clinical sign suggestive of ND on the day of semen collection;
- 2) were kept in an ND free country, *zone* or *compartment* for at least the 21 days prior to and at the time of semen collection.

Article 10.9.13.

**Recommendations for the importation of semen of birds other than poultry**

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the donor birds:

- 1) were kept in isolation approved by the *Veterinary Services* for at least the 21 days prior to and on the day of semen collection;
- 2) showed no clinical sign suggestive of *infection* with NDV during the isolation period and on the day of semen collection;
- 3) were subjected to a diagnostic test within 14 days prior to semen collection to demonstrate freedom from *infection* with NDV.

Article 10.9.14.

**Recommendations for importation from an Newcastle disease free country, zone or compartment**

For fresh meat of poultry

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

- 1) which have been kept in an ND free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;
- 2) which have been slaughtered in an approved *abattoir* in an ND free country, *zone* or *compartment* and have been subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. and have been found free of any sign suggestive of ND.

Article 10.9.15.

**Recommendations for importation of meat products of poultry**

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

- 1) the *commodity* is derived from *fresh meat* which meet the requirements of Article 10.9.14.; or



- 2) the *commodity* has been processed to ensure the destruction of NDV in accordance with Article 10.9.21.;

AND

- 3) the necessary precautions were taken to avoid contact of the *commodity* with any source of NDV.

Article 10.9.16.

**Recommendations for the importation of products of poultry origin, other than feather meal and poultry meal, intended for use in animal feeding, or for agricultural or industrial use**

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) these *commodities* were processed in a ND free country, *zone* or *compartment* from *poultry* which were kept in a ND free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*; or
- 2) these *commodities* have been processed to ensure the destruction of NDV (under study);

AND

- 3) the necessary precautions were taken to avoid contact of the *commodity* with any source of NDV.

Article 10.9.17.

**Recommendations for the importation of feathers and down of poultry**

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) these *commodities* originated from *poultry* as described in Article 10.9.14. and were processed in a ND free country, *zone* or *compartment*; or
- 2) these *commodities* have been processed to ensure the destruction of NDV (under study);

AND

- 3) the necessary precautions were taken to avoid contact of the *commodity* with any source of NDV.

Article 10.9.18.

**Recommendations for the importation of feathers and down of birds other than poultry**

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) these *commodities* have been processed to ensure the destruction of NDV (under study); and
- 2) the necessary precautions were taken to avoid contact of the *commodity* with any source of NDV.

Article 10.9.19.

**Recommendations for the importation of feather meal and poultry meal**

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) these *commodities* were processed in a ND free country, *zone* or *compartment* from *poultry* which were kept in a ND free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*; or
- 2) these *commodities* have been processed either:
  - a) with moist heat at a minimum temperature of 118°C for minimum of 40 minutes; or
  - b) with a continuous hydrolysing process under at least 3.79 bar of pressure with steam at a minimum temperature of 122°C for a minimum of 15 minutes; or

- c) with an alternative rendering process that ensures that the internal temperature throughout the product reaches at least 74°C for a minimum of 280 seconds;

AND

- 3) the necessary precautions were taken to avoid contact of the *commodity* with any source of ND virus.

Article 10.9.20.

#### Procedures for the inactivation of the Newcastle disease virus in eggs and egg products

The following times and temperatures are suitable for the inactivation of ND virus present in eggs and egg products:

	Core temperature (°C)	Time
Whole egg	55	2,521 seconds
Whole egg	57	1,596 seconds
Whole egg	59	674 seconds
Liquid egg white	55	2,278 seconds
Liquid egg white	57	986 seconds
Liquid egg white	59	301 seconds
10% salted yolk	55	176 seconds
Dried egg white	57	50.4 hours

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

Article 10.9.21.

#### Procedures for the inactivation of the Newcastle disease virus in meat

The following times for industry standard temperatures are suitable for the inactivation of ND virus present in *meat*.

	Core temperature (°C)	Time
Poultry meat	65.0	39.8 seconds
	70.0	3.6 seconds
	74.0	0.5 second
	80.0	0.03 second

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

## Article 10.9.22.

**Surveillance: introduction**

Articles 10.9.22. to 10.9.26. define the principles and provide a guide on the *surveillance* for ND as defined in Article 10.9.1. and is complementary to Chapter 1.4. It is applicable to Member Countries seeking to determine their ND status. This may be for the entire country, *zone* or *compartment*. Guidance for Member Countries seeking free status following an *outbreak* and for the maintenance of ND status is also provided.

*Surveillance* for ND is complicated by the known occurrence of avian paramyxovirus serotype 1 (APMV-1) *infections* in many bird species, both domestic and wild, and the widespread utilization of ND vaccines in domestic *poultry*.

The impact and epidemiology of ND differ widely in different regions of the world and therefore it is not possible to provide specific recommendations for all situations. Therefore, *surveillance* strategies employed for demonstrating freedom from ND at an acceptable level of confidence will need to be adapted to the local situation. Variables such as the frequency of contacts of *poultry* with wild birds, different biosecurity levels, production systems and the commingling of different susceptible species require specific *surveillance* strategies to address each specific situation. It is incumbent upon the Member Country to provide scientific data that explains the epidemiology of ND in the region concerned and also demonstrates how all the risk factors are managed. There is, therefore, considerable latitude available to Member Countries to provide a well-reasoned argument to prove freedom from NDV *infection*.

*Surveillance* for ND should be in the form of a continuing programme designed to establish that the country, *zone* or *compartment*, for which application is made, is free from NDV *infection*.

## Article 10.9.23.

**Surveillance: general conditions and methods**

- 1) A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. In particular there should be in place:
  - a) a formal and ongoing system for detecting and investigating *outbreaks* of *disease* or NDV *infection*;
  - b) a procedure for the rapid collection and transport of samples from suspect cases of ND to a *laboratory* for ND diagnosis;
  - c) a system for recording, managing and analysing diagnostic and *surveillance* data.
- 2) The ND *surveillance* programme should:
  - a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers, who have day-to-day contact with *poultry*, as well as diagnosticians, should report promptly any suspicion of ND to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All suspected cases of ND should be investigated immediately. As suspicion cannot be resolved by epidemiological and clinical investigation alone, samples should be taken and submitted to a *laboratory* for appropriate tests. This requires that sampling kits and other equipment are available to those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in ND diagnosis and control;
  - b) implement, when relevant, regular and frequent clinical, virological and serological *surveillance* of high risk groups of *poultry* within the target population (e.g. those adjacent to an ND infected country, *zone*, *compartment*, places where birds and *poultry* of different origins are mixed, or other sources of NDV).

An effective *surveillance* system may identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is due to NDV *infection*. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from NDV *infection* should provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of *laboratory* testing and the control measures to which the *animals* concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

## Surveillance strategies

### 1. Introduction

Any *surveillance* programme requires inputs from professionals competent and experienced in this field and should be thoroughly documented. The design of *surveillance* programmes to prove the absence of NDV *infection* / circulation needs to be carefully followed to avoid producing results that are either unreliable, or excessively costly and logistically complicated.

If a Member Country wishes to declare freedom from NDV *infection* in a country, *zone* or *compartment*, the subpopulation used for the *surveillance* for the *disease* / *infection* should be representative of all *poultry* within the country, *zone* or *compartment*. Multiple *surveillance* methods should be used concurrently to accurately define the true ND status of *poultry* populations. Active and passive *surveillance* for ND should be ongoing with the frequency of active *surveillance* being appropriate to the disease situation in the country. *Surveillance* should be composed of random and/or targeted approaches, dependent on the local epidemiological situation and using clinical, virological and serological methods. If alternative tests are used they should have been validated as fit-for-purpose in accordance with OIE standards. A Member Country should justify the *surveillance* strategy chosen as adequate to detect the presence of NDV *infection* in accordance with Chapter 1.4. and the prevailing epidemiological situation.

In surveys, the sample size selected for testing should be statistically justified to detect *infection* at a predetermined target prevalence. The sample size and expected prevalence determine the level of confidence in the results of the survey. The survey design and frequency of sampling should be dependent on the historical and current local epidemiological situation. The Member Country should justify the choice of survey design and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4.

Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in a population) may be an appropriate strategy.

It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clear clinical signs (e.g. unvaccinated chickens). Similarly, virological and serological testing could target species that may not show clinical signs (Article 10.9.2.) of ND and are not routinely vaccinated (e.g. ducks). *Surveillance* may also target *poultry* populations at specific risk, for example direct or indirect contact with wild birds, multi-age *flocks*, local trade patterns including live *poultry* markets, the presence of more than one species on the holding and poor biosecurity measures in place. In situations where wild birds have been shown to play a role in the local epidemiology of ND, *surveillance* of wild birds may be of value in alerting *Veterinary Services* to the possible exposure of *poultry* and, in particular, of free ranging *poultry*.

The sensitivity and specificity of the diagnostic tests are key factors in the choice of survey design, which should anticipate the occurrence of false positive and false negative reactions. Ideally, the sensitivity and specificity of the tests used should be validated for the *vaccination* / *infection* history and for the different species in the target population. If the characteristics of the testing system are known, the rate at which these false reactions are likely to occur can be calculated in advance. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as *flocks* which may be epidemiologically linked to it.

The results of active and passive *surveillance* are important in providing reliable evidence that no NDV *infection* is present in a country, *zone* or *compartment*.

### 2. Clinical surveillance

Clinical *surveillance* aims to detect clinical signs suggestive of ND at the *flock* level and should not be underestimated as an early indication of *infection*. Monitoring of production parameters (e.g. a drop in feed or water consumption or egg production) is important for the early detection of NDV *infection* in some populations, as there may be no, or mild clinical signs, particularly if they are vaccinated. Any sampling unit within which suspicious *animals* are detected should be considered as infected until evidence to the contrary is produced. Identification of infected *flocks* is vital to the identification of sources of NDV.

A presumptive diagnosis of clinical ND in suspect infected populations should always be confirmed by virological testing in a *laboratory*. This will enable the molecular, antigenic and other biological characteristics of the virus to be determined.

It is desirable that NDV isolates are sent promptly to an OIE Reference Laboratory for archiving and further characterization if required.

### 3. Virological surveillance

Virological *surveillance* should be conducted to:

- a) monitor at risk populations;
- b) confirm suspect clinical cases;
- c) follow up positive serological results in unvaccinated populations or sentinel birds;
- d) test 'normal' daily mortalities (if warranted by an increased risk e.g. *infection* in the face of *vaccination* or in establishments epidemiologically linked to an *outbreak*).

### 4. Serological surveillance

Where *vaccination* is carried out, serological *surveillance* is of limited value. Serological *surveillance* cannot be used to discriminate between NDV and other APMV-1. Positive NDV antibody test results can have five possible causes:

- a) natural *infection* with APMV-1;
- b) *vaccination* against ND;
- c) exposure to vaccine virus;
- d) maternal antibodies derived from a vaccinated or infected parent *flock* are usually found in the yolk and can persist in progeny for up to four weeks;
- e) non-specific test reactions.

It may be possible to use serum collected for other survey purposes for ND *surveillance*. However, the principles of survey design described in these recommendations and the requirement for a statistically valid survey for the presence of NDV should not be compromised.

Discovery of seropositive, unvaccinated *flocks* should be investigated further by conducting a thorough epidemiological investigation. Since seropositive results are not necessarily indicative of *infection*, virological methods should be used to confirm the presence of NDV in such populations. Until validated strategies and tools to differentiate vaccinated *animals* from those infected with field APMV-1 are available, serological tools should not be used to identify NDV *infection* in vaccinated populations.

### 5. Use of sentinel poultry

There are various applications of the use of sentinel *poultry* as a *surveillance* tool to detect virus circulation. They may be used to monitor vaccinated populations or species which are less susceptible to the development of clinical *disease* for the circulation of virus. Sentinel *poultry* should be immunologically naïve and may be used in vaccinated *flocks*. In case of the use of sentinel *poultry*, the structure and organisation of the *poultry* sector, the type of vaccine used and local epidemiological factors will determine the type of production systems where sentinels should be placed, the frequency of placement and monitoring of the sentinels.

Sentinel *poultry* should be in close contact with, but should be identified to be clearly differentiated from, the target population. Sentinel *poultry* should be observed regularly for evidence of clinical *disease* and any disease incidents investigated by prompt *laboratory* testing. The species to be used as sentinels should be proven to be highly susceptible to *infection* and ideally develop clear signs of clinical *disease*. Where the sentinel *poultry* do not necessarily develop overt clinical *disease* a programme of regular active testing by virological and serological tests should be used (the development of clinical *disease* may be dependent on the sentinel species used or use of live vaccine in the target population that may infect the sentinel *poultry*). The testing regime and the interpretation of the results will depend on the type of vaccine used in the target population. Sentinel birds should be used only if no appropriate *laboratory* procedures are available.

Article 10.9.25.

## **Documentation of Newcastle disease free status: additional surveillance procedures**

The requirements for a country, *zone* or *compartment* to declare freedom from ND are given in Article 10.9.3.

A Member Country declaring freedom of a country, *zone* or *compartment* (with or without *vaccination*) should report the results of a *surveillance* programme in which the ND susceptible *poultry* population undergoes regular *surveillance* planned and implemented according to the general conditions and methods described in these recommendations.

### 1. Member Countries declaring freedom from Newcastle disease for the country, zone or compartment

In addition to the general conditions described in the *Terrestrial Code*, a Member Country declaring freedom from ND for the entire country, or a *zone* or a *compartment* should provide evidence for the existence of an effective

*surveillance* programme. The *surveillance* programme should be planned and implemented according to general conditions and methods described in this chapter to demonstrate absence of NDV *infection* in *poultry* during the preceding 12 months.

2. Additional requirements for countries, zones or compartments that practice vaccination

*Vaccination* against ND may be used as a component of a disease prevention and control programme.

In vaccinated populations there is a need to perform *surveillance* to ensure the absence of NDV circulation. The use of sentinel *poultry* may provide further confidence of the absence of virus circulation. The *surveillance* should be repeated at least every six months or at shorter intervals according to the risk in the country, *zone* or *compartment*, or evidence to show the effectiveness of the *vaccination* programme is regularly provided.

Article 10.9.26.

**Countries, zones or compartments regaining freedom from Newcastle disease following an outbreak: additional surveillance procedures**

A Member Country regaining country, *zone* or *compartment* freedom from ND should show evidence of an active *surveillance* programme depending on the epidemiological circumstances of the *outbreak* to demonstrate the absence of the *infection*.

A Member Country declaring freedom of a country, *zone* or *compartment* after an *outbreak* of ND (with or without *vaccination*) should report the results of a *surveillance* programme in which the ND susceptible *poultry* population undergoes regular *surveillance* planned and implemented according to the general conditions and methods described in these recommendations.

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## SECTION 11.

### BOVIDAE

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#### CHAPTER 11.1.

### BOVINE ANAPLASMOSIS

Article 11.1.1.

#### General provisions

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

Article 11.1.2.

#### Recommendations for importation from countries considered infected with bovine anaplasmosis

##### For cattle

*Veterinary Authorities* of free countries should require 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 two 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 five 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 repellent against biting insects prior to shipment and were completely free of ticks.
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CHAPTER 11.2.  
**BOVINE BABESIOSIS**

Article 11.2.1.

**General provisions**

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

Article 11.2.2.

**Recommendations for importation from countries considered infected with bovine babesiosis**

For cattle

*Veterinary Authorities* of free countries should require 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 two 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.
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## CHAPTER 11.3.

# BOVINE BRUCELLOSIS

### Article 11.3.1.

#### General provisions

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

### Article 11.3.2.

#### 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 percent 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 three 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 five years, the system for further control may be decided by the country concerned.

### Article 11.3.3.

#### 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 three years;
- 3) it only contains *animals* which have not showed evidence of bovine brucellosis *infection* during the past six months, all suspect cases (such as *animals* which have prematurely calved) having been subjected to the necessary laboratory investigations;
- 4) all cattle over the age of one year (except castrated males) were subjected to serological tests with negative results on two occasions, at an interval of 12 months between each test; this requirement is maintained even if the entire *herd* is normally tested every year or testing is conducted in conformity with other requirements established by the *Veterinary Authority* of the country concerned;
- 5) additions to the *herd* shall only come from *herds* officially free from bovine brucellosis. This condition may be waived for *animals* which have not been vaccinated, come from a *herd* free from bovine brucellosis, provided that negative results were shown following a buffered *Brucella* antigen test and the complement fixation test during the 30 days prior to entry into the *herd*. Any recently calved or calving *animal* should be retested after 14 days, as tests are not considered valid in female *animals* which have calved during the past 14 days.

Article 11.3.4.

**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* should be carried out between three and six months of age, in which case these female cattle should be identified with a permanent mark;
- 4) all cattle over the age of one year are controlled as provided in point 4 of the definition of a *herd* of cattle officially free from bovine brucellosis; however, cattle under 30 months of age which have been vaccinated using a live vaccine before reaching six 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 11.3.5.

**Recommendations for the importation of cattle for breeding or rearing (except castrated males)**

*Veterinary Authorities* of *importing countries* should require 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 six months prior to shipment;
- 3) were kept in a country or *zone* free from bovine brucellosis, or were from a *herd* officially free from bovine brucellosis and were subjected to a serological test for bovine brucellosis with negative results during the 30 days prior to shipment; or
- 4) were kept in a *herd* free from bovine brucellosis and were subjected to buffered *Brucella* antigen and complement fixation tests with negative results during the 30 days prior to shipment;

if the cattle come from a *herd* other than those mentioned above:

- 5) were isolated prior to shipment and were subjected to a serological test for bovine brucellosis with negative results on two occasions, with an interval of not less than 30 days between each test, the second test being performed during the 15 days prior to shipment. These tests are not considered valid in female *animals* which have calved during the past 14 days.

Article 11.3.6.

**Recommendations for the importation of cattle for slaughter (except castrated males)**

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

- 1) showed no clinical sign of bovine brucellosis on the day of shipment;
- 2) are not being eliminated as part of an eradication programme against bovine brucellosis;
- 3) were kept in a country or *zone* free from bovine brucellosis; or
- 4) were kept in a *herd* officially free from bovine brucellosis; or
- 5) were kept in a *herd* free from bovine brucellosis; or
- 6) were subjected to a serological test for bovine brucellosis with negative results during the 30 days prior to shipment.

Article 11.3.7.

**Recommendations for the importation of bovine semen**

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

- 1) when the semen is from an *artificial insemination centre*, the testing programme includes the buffered *Brucella* antigen and complement fixation tests;
- 2) when the semen is not from an *artificial insemination centre*, the donor *animals*:
  - a) were kept in a country or *zone* free from bovine brucellosis; or
  - b) were kept in a *herd* officially free from bovine brucellosis, showed no clinical sign of bovine brucellosis on the day of collection of the semen and were subjected to a buffered *Brucella* antigen test with negative results during the 30 days prior to collection; or
  - c) were kept in a *herd* free from bovine brucellosis, showed no clinical sign of bovine brucellosis on the day of collection and were subjected to the buffered *Brucella* antigen and complement fixation tests with negative results during the 30 days prior to collection;
- 3) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 11.3.8.

**Recommendations for the importation of *in vivo* embryos/ova**

*Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 11.3.9.

**Recommendations for the importation of *in vitro* produced embryos/ova**

*Veterinary Authorities of importing countries* should require 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 Chapter 1.3.;
  - 2) the oocytes were fertilised with semen meeting the conditions referred to in Chapters 4.5. and 4.6.;
  - 3) the embryos/oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.8. and 4.9., as relevant.
-

## CHAPTER 11.4.

# BOVINE GENITAL CAMPYLOBACTERIOSIS

### Article 11.4.1.

#### General provisions

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

### Article 11.4.2.

#### Recommendations for the importation of female bovines for breeding

*Veterinary Authorities of importing countries* should require 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 11.4.3.

#### Recommendations for the importation of bulls for breeding

*Veterinary Authorities of importing countries* should require 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 11.4.4.

#### Recommendations for the importation of bovine semen

*Veterinary Authorities of importing countries* should require 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 11.5.

# BOVINE SPONGIFORM ENCEPHALOPATHY

### Article 11.5.1.

#### General provisions and safe commodities

The recommendations in this chapter are intended to manage the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agent in cattle (*Bos taurus* and *B. indicus*) only.

- 1) When authorising import or transit of the following *commodities* and any products made from these *commodities* and containing no other tissues from cattle, *Veterinary Authorities* should not require any BSE related conditions, regardless of the BSE risk status of the cattle population of the *exporting country, zone or compartment*:
  - a) *milk and milk products*;
  - b) semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;
  - c) hides and skins;
  - d) gelatine and collagen prepared exclusively from hides and skins;
  - e) tallow with maximum level of insoluble impurities of 0.15 percent in weight and derivatives made from this tallow;
  - f) dicalcium phosphate (with no trace of protein or fat);
  - g) deboned skeletal muscle meat (excluding mechanically separated meat) from cattle which were not subjected to a stunning process prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity or to a pithing process, and which passed ante- and post-mortem inspections and which has been prepared in a manner to avoid contamination with tissues listed in Article 11.5.14.;
  - h) blood and blood by-products, from cattle which were not subjected to a stunning process, prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process.
- 2) When authorising import or transit of other *commodities* listed in this chapter, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the BSE risk status of the cattle population of the *exporting country, zone or compartment*.
- 3) When authorising import of *commodities* according to the conditions prescribed in this chapter, the risk status of an *importing country* is not affected by the BSE risk status of the *exporting country, zone or compartment*.

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

### Article 11.5.2.

#### The BSE risk status of the cattle population of a country, zone or compartment

The BSE risk status of the cattle population of a country, *zone or compartment* should be determined on the basis of the following criteria:

- 1) the outcome of a *risk assessment*, based on the provisions of the *Terrestrial Code*, identifying all potential factors for BSE occurrence and their historic perspective. Member Countries should review the *risk assessment* annually to determine whether the situation has changed.
  - a) Entry assessment

Entry assessment consists of assessing, through consideration of the following, the likelihood that the BSE agent has either been introduced into the country, *zone or compartment* via *commodities* potentially contaminated with it, or is already present in the country, *zone or compartment*:

    - i) the presence or absence of the BSE agent in the indigenous ruminant population of the country, *zone or compartment* and, if present, evidence regarding its prevalence;
    - ii) production of *meat-and-bone meal* or *greaves* from the indigenous ruminant population;
    - iii) imported *meat-and-bone meal* or *greaves*;

- iv) imported cattle, sheep and goats;
- v) imported animal feed and feed ingredients;
- vi) imported products of ruminant origin for human consumption, which may have contained tissues listed in Article 11.5.14. and may have been fed to cattle;
- vii) imported products of ruminant origin intended for *in vivo* use in cattle.

The results of *surveillance* and other epidemiological investigations into the disposition of the *commodities* identified above should be taken into account in carrying out the assessment.

b) Exposure assessment

If the entry assessment identifies a *risk* factor, an exposure assessment should be conducted, consisting of assessing the likelihood of cattle being exposed to the BSE agent, through a consideration of the following:

- i) recycling and amplification of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;
  - ii) the use of ruminant carcasses (including from fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;
  - iii) the feeding or not of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants, including measures to prevent cross-contamination of animal feed;
  - iv) the level of *surveillance* for BSE conducted on the cattle population up to that time and the results of that *surveillance*;
- 2) on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and *slaughter* of cattle to encourage reporting of all *cases* showing clinical signs consistent with BSE in target sub-populations as defined in Articles 11.5.20. to 11.5.22.;
  - 3) the compulsory notification and investigation of all cattle showing clinical signs consistent with BSE;
  - 4) the examination carried out in accordance with the *Terrestrial Manual* in a *laboratory* of brain or other tissues collected within the framework of the aforementioned *surveillance* and monitoring system.

When the *risk assessment* demonstrates negligible risk, the Member Country should conduct Type B *surveillance* in accordance with Articles 11.5.20. to 11.5.22.

When the *risk assessment* fails to demonstrate negligible risk, the Member Country should conduct Type A *surveillance* in accordance with Articles 11.5.20. to 11.5.22.

Article 11.5.3.

**Negligible BSE risk**

*Commodities* from the cattle population of a country, *zone* or *compartment* pose a negligible risk of transmitting the BSE agent if the following conditions are met:

- 1) a *risk assessment*, as described in point 1 of Article 11.5.2., has been conducted in order to identify the historical and existing risk factors, and the Member Country has demonstrated that appropriate specific measures have been taken for the relevant period of time defined below to manage each identified risk;
  - 2) the Member Country has demonstrated that Type B *surveillance* in accordance with Articles 11.5.20. to 11.5.22. is in place and the relevant points target, in accordance with Table 1, has been met;
  - 3) EITHER:
    - a) there has been no *case* of BSE or, if there has been a *case*, every *case* of BSE has been demonstrated to have been imported and has been completely destroyed, and
      - i) the criteria in points 2 to 4 of Article 11.5.2. have been complied with for at least seven years; and
      - ii) it has been demonstrated through an appropriate level of control and audit, including that of cross contamination, that for at least eight years neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants;
- OR
- b) if there has been an indigenous *case*, every indigenous *case* was born more than 11 years ago; and
    - i) the criteria in points 2 to 4 of Article 11.5.2. have been complied with for at least seven years; and
    - ii) it has been demonstrated through an appropriate level of control and audit, including that of cross contamination, that for at least eight years neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants;

- iii) all BSE cases, as well as:
- all cattle which, during their first year of life, were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or
  - if the results of the investigation are inconclusive, all cattle born in the same *herd* as, and within 12 months of the birth of, the BSE cases,
- if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.

The Member Country or *zone* will be included in the list of negligible risk only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information for the previous 12 months on *surveillance* results and feed controls be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

#### Article 11.5.4.

#### Controlled BSE risk

*Commodities* from the cattle population of a country, *zone* or *compartment* pose a controlled risk of transmitting the BSE agent if the following conditions are met:

- 1) a *risk assessment*, as described in point 1 of Article 11.5.2., has been conducted in order to identify the historical and existing risk factors, and the Member Country has demonstrated that appropriate measures are being taken to manage all identified risks, but these measures have not been taken for the relevant period of time;
- 2) the Member Country has demonstrated that Type A *surveillance* in accordance with Articles 11.5.20. to 11.5.22. has been carried out and the relevant points target, in accordance with Table 1, has been met; Type B *surveillance* may replace Type A *surveillance* once the relevant points target is met;
- 3) EITHER:
  - a) there has been no *case* of BSE or, if there has been a *case*, every *case* of BSE has been demonstrated to have been imported and has been completely destroyed, the criteria in points 2 to 4 of Article 11.5.2. are complied with, and it can be demonstrated through an appropriate level of control and audit, including that of cross contamination, that neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants, but at least one of the following two conditions applies:
    - i) the criteria in points 2 to 4 of Article 11.5.2. have not been complied with for seven years;
    - ii) it cannot be demonstrated that controls over the feeding of *meat-and-bone meal* or *greaves* derived from ruminants to ruminants have been in place for eight years;

OR

- b) there has been an indigenous *case* of BSE, the criteria in points 2 to 4 of Article 11.5.2. are complied with, and it can be demonstrated through an appropriate level of control and audit, including that of cross contamination, that neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants;

and all BSE cases, as well as:

- all cattle which, during their first year of life, were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or
- if the results of the investigation are inconclusive, all cattle born in the same *herd* as, and within 12 months of the birth of, the BSE cases,

if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.

The Member Country or *zone* will be included in the list of controlled risk only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information for the previous 12 months on *surveillance* results and feed controls be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

Article 11.5.5.

**Undetermined BSE risk**

The cattle population of a country, *zone* or *compartment* poses an undetermined BSE risk if it cannot be demonstrated that it meets the requirements of another category.

Article 11.5.6.

**Recommendations for the importation of bovine commodities from a country, zone or compartment posing a negligible BSE risk**

For all commodities from cattle not listed in point 1 of Article 11.5.1.

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the country, *zone* or *compartment* complies with the conditions in Article 11.5.3.

Article 11.5.7.

**Recommendations for the importation of cattle from a country, zone or compartment posing a negligible BSE risk but where there has been an indigenous case**

For cattle selected for export

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

- 1) are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as described in point 3b)iii) of Article 11.5.3.;
- 2) were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants had been effectively enforced.

Article 11.5.8.

**Recommendations for the importation of cattle from a country, zone or compartment posing a controlled BSE risk**

For cattle

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

- 1) the country, *zone* or *compartment* complies with the conditions referred to in Article 11.5.4.;
- 2) cattle selected for export are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as described in point 3b) of Article 11.5.4.;
- 3) cattle selected for export were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants was effectively enforced.

Article 11.5.9.

**Recommendations for the importation of cattle from a country, zone or compartment posing an undetermined BSE risk**

For cattle

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

- 1) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;
- 2) all BSE cases, as well as:
  - a) all cattle which, during their first year of life, were reared with the BSE cases during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, or



- b) if the results of the investigation are inconclusive, all cattle born in the same *herd* as, and within 12 months of the birth of, the BSE cases,  
if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed;
- 3) cattle selected for export:
  - a) are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as demonstrated in point 2 above;
  - b) were born at least two 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 11.5.10.

**Recommendations for the importation of meat and meat products from a country, zone or compartment posing a negligible BSE risk**

For fresh meat and meat products from cattle (other than those listed in point 1 of Article 11.5.1.)

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

- 1) the country, *zone* or *compartment* complies with the conditions in Article 11.5.3.;
- 2) the cattle from which the *fresh meat* and *meat products* were derived passed ante- and post-mortem inspections;
- 3) in countries with negligible BSE risk where there have been indigenous *cases*, the cattle from which the *fresh meat* and *meat products* were derived were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants had been effectively enforced.

Article 11.5.11.

**Recommendations for the importation of meat and meat products from a country, zone or compartment posing a controlled BSE risk**

For fresh meat and meat products from cattle (other than those listed in point 1 of Article 11.5.1.)

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

- 1) the country, *zone* or *compartment* complies with the conditions referred to in Article 11.5.4.;
- 2) the cattle from which the *fresh meat* and *meat products* were derived passed ante- and post-mortem inspections;
- 3) cattle from which the *fresh meat* and *meat products* destined for export were derived were not subjected to a stunning process, prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;
- 4) the *fresh meat* and *meat products* were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:
  - a) the tissues listed in points 1 and 2 of Article 11.5.14.,
  - b) mechanically separated meat from the skull and vertebral column from cattle over 30 months of age.

Article 11.5.12.

**Recommendations for the importation of meat and meat products from a country, zone or compartment posing an undetermined BSE risk**

For fresh meat and meat products from cattle (other than those listed in point 1 of Article 11.5.1.)

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

- 1) the cattle from which the *fresh meat* and *meat products* originate:
  - a) have not been fed *meat-and-bone meal* or *greaves* derived from ruminants;
  - b) passed ante- and post-mortem inspections;
  - c) were not subjected to a stunning process, prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;

- 2) the *fresh meat* and *meat products* were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:
  - a) the tissues listed in points 1 and 3 of Article 11.5.14.,
  - b) nervous and lymphatic tissues exposed during the deboning process,
  - c) mechanically separated meat from the skull and vertebral column from cattle over 12 months of age.

Article 11.5.13.

**Recommendations on ruminant-derived meat-and-bone meal or greaves**

- 1) Ruminant-derived *meat-and-bone meal* or *greaves*, or any commodities containing such products, which originate from a country, *zone* or *compartment* defined in Article 11.5.3., but where there has been an indigenous case of BSE, should not be traded if such products were derived from cattle born before the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants had been effectively enforced.
- 2) Ruminant-derived *meat-and-bone meal* or *greaves*, or any commodities containing such products, which originate from a country, *zone* or *compartment* defined in Articles 11.5.4. and 11.5.5. should not be traded between countries.

Article 11.5.14.

**Recommendations on commodities that should not be traded**

- 1) From cattle of any age originating from a country, *zone* or *compartment* defined in Articles 11.5.4. and 11.5.5., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: tonsils and distal ileum. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this chapter) should also not be traded.
- 2) From cattle that were at the time of *slaughter* over 30 months of age originating from a country, *zone* or *compartment* defined in Article 11.5.4., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull and vertebral column. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this chapter) should also not be traded.
- 3) From cattle that were at the time of *slaughter* over 12 months of age originating from a country, *zone* or *compartment* defined in Article 11.5.5., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull and vertebral column. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this chapter) should also not be traded.

Article 11.5.15.

**Recommendations for the importation of gelatine and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices**

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

- 1) the *commodities* came from a country, *zone* or *compartment* posing a negligible BSE risk;
- OR
- 2) they originate from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk and are derived from cattle which have passed ante- and post-mortem inspections; and that
    - a) vertebral columns from cattle over 30 months of age at the time of *slaughter* and skulls have been excluded;
    - b) the bones have been subjected to a process which includes all of the following steps:
      - i) degreasing,

- ii) acid demineralisation,
- iii) acid or alkaline treatment,
- iv) filtration,
- v) sterilisation at  $\geq 138^{\circ}\text{C}$  for a minimum of 4 seconds,  
or to an equivalent or better process in terms of infectivity reduction (such as high pressure heating).

Article 11.5.16.

**Recommendations for the importation of tallow (other than as defined in Article 11.5.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices**

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

- 1) the tallow came from a country, *zone* or *compartment* posing a negligible BSE risk; or
- 2) it originates from a country, *zone* or *compartment* posing a controlled BSE risk, is derived from cattle which have passed ante- and post-mortem inspections, and has not been prepared using the tissues listed in points 1 and 2 of Article 11.5.14.

Article 11.5.17.

**Recommendations for the importation of dicalcium phosphate (other than as defined in Article 11.5.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices**

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

- 1) the dicalcium phosphate came from a country, *zone* or *compartment* posing a negligible BSE risk; or
- 2) it originates from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk and is a by-product of bone gelatine produced according to Article 11.5.15.

Article 11.5.18.

**Recommendations for the importation of tallow derivatives (other than those made from tallow as defined in Article 11.5.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices**

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

- 1) the tallow derivatives originate from a country, *zone* or *compartment* posing a negligible BSE risk; or
- 2) they are derived from tallow meeting the conditions referred to in Article 11.5.16.; or
- 3) they have been produced by hydrolysis, saponification or transesterification using high temperature and pressure.

Article 11.5.19.

**Procedures for the reduction of BSE infectivity in meat-and-bone meal**

The following procedure should be used to reduce the infectivity of any transmissible spongiform encephalopathy agents which may be present during the production of *meat-and-bone meal* containing ruminant proteins.

- 1) The raw material should be reduced to a maximum particle size of 50 mm before heating.
- 2) The raw material should be heated under saturated steam conditions to a temperature of not less than  $133^{\circ}\text{C}$  for a minimum of 20 minutes at an absolute pressure of 3 bar.

Article 11.5.20.

**Surveillance: introduction**

- 1) Depending on the risk category of a country, *zone* or *compartment* with regard to bovine spongiform encephalopathy (BSE), *surveillance* for BSE may have one or more goals:
  - a) detecting BSE, to a pre-determined design prevalence, in a country, *zone* or *compartment*;
  - b) monitoring the evolution of BSE in a country, *zone* or *compartment*;
  - c) monitoring the effectiveness of a feed ban and/or other risk mitigation measures, in conjunction with auditing;
  - d) supporting a claimed BSE status;
  - e) gaining or regaining a higher BSE status.
- 2) When the BSE agent is present in a country or *zone*, the cattle population will comprise the following sectors, in order of decreasing size:
  - a) cattle not exposed to the infective agent;
  - b) cattle exposed but not infected;
  - c) infected cattle, which may lie within one of three stages in the progress of BSE:
    - i) the majority will die or be killed before reaching a stage at which BSE is detectable by current methods;
    - ii) some will progress to a stage at which BSE is detectable by testing before clinical signs appear;
    - iii) the smallest number will show clinical signs.
- 3) The BSE status of a country, *zone* or *compartment* cannot be determined only on the basis of a *surveillance* programme but should be determined in accordance with all the factors listed in Article 11.5.2. The *surveillance* programme should take into account the diagnostic limitations associated with the above sectors and the relative distributions of infected cattle among them.
- 4) With respect to the distribution and expression of the BSE agent within the sectors described above, the following four subpopulations of cattle have been identified for *surveillance* purposes:
  - a) cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects);
  - b) cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency *slaughter* or condemned at ante-mortem inspection (casualty or emergency *slaughter* or downer cattle);
  - c) cattle over 30 months of age which are found dead or killed on farm, during transport or at an *abattoir* (fallen stock);
  - d) cattle over 36 months of age at routine *slaughter*.
- 5) A gradient is used to describe the relative value of *surveillance* applied to each subpopulation. *Surveillance* should focus on the first subpopulation, but investigation of other subpopulations will help to provide an accurate assessment of the BSE situation in the country, *zone* or *compartment*. This approach is consistent with Articles 11.5.20. to 11.5.22.
- 6) When establishing a *surveillance* strategy, authorities need to take into account the inherent difficulties of obtaining samples on farm, and overcome them. These difficulties include higher cost, the necessity to educate and motivate owners, and counteracting potentially negative socio-economic implications.

Article 11.5.21.

**Surveillance: description of cattle subpopulations**

1. Cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects)

Cattle affected by illnesses that are refractory to treatment, and displaying progressive behavioural changes such as excitability, persistent kicking when milked, changes in *herd* hierarchical status, hesitation at doors, gates and barriers, as well as those displaying progressive neurological signs without signs of infectious illness are candidates for examination. These behavioural changes, being very subtle, are best identified by those who handle *animals* on a daily basis. Since BSE causes no pathognomonic clinical signs, all Member Countries with cattle populations will observe individual *animals* displaying clinical signs consistent with BSE. It should be recognised that *cases* may display only some of these signs, which may also vary in severity, and such *animals* should still be investigated as potential BSE affected *animals*. The rate at which such suspicious cases are likely to occur will differ among epidemiological situations and cannot therefore be predicted reliably.

This subpopulation is the one exhibiting the highest prevalence. The accurate recognition, reporting and classification of such *animals* will depend on the ongoing owner/veterinarian awareness programme. This and the

quality of the investigation and *laboratory* examination systems (Article 11.5.2.), implemented by the *Veterinary Services*, are essential for the credibility of the *surveillance* system.

2. Cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency slaughter or condemned at ante-mortem inspection (casualty or emergency slaughter, or downer cattle)

These cattle may have exhibited some of the clinical signs listed above which were not recognised as being consistent with BSE. Experience in Member Countries where BSE has been identified indicates that this subpopulation is the one demonstrating the second highest prevalence. For that reason, it is the second most appropriate population to target in order to detect BSE.

3. Cattle over 30 months of age which are found dead or killed on farm, during transport or at an abattoir (fallen stock)

These cattle may have exhibited some of the clinical signs listed above prior to death, but were not recognised as being consistent with BSE. Experience in Member Countries where BSE has been identified indicates that this subpopulation is the one demonstrating the third highest prevalence.

4. Cattle over 36 months of age at routine slaughter

Experience in Member Countries where BSE has been identified indicates that this subpopulation is the one demonstrating the lowest prevalence. For that reason, it is the least appropriate population to target in order to detect BSE. However, sampling in this subpopulation may be an aide in monitoring the progress of the epizootic and the efficacy of control measures applied, because it offers continuous access to a cattle population of known class, age structure and geographical origin. Testing of routine slaughter cattle 36 months of age or less is of relatively very little value (Table 2).

#### Article 11.5.22.

#### Surveillance activities

In order to implement efficiently a *surveillance* strategy for BSE, a Member Country should use documented records or reliable estimates of the age distribution of the adult cattle population and the number of cattle tested for BSE stratified by age and by subpopulation within the country, *zone* or *compartment*.

The approach assigns 'point values' to each sample, based on the subpopulation from which it was collected and the likelihood of detecting infected cattle in that subpopulation. The number of points a sample is assigned is determined by the subpopulation from which the sample is collected and the age of the animal sampled. The total points accumulation is then periodically compared to the target number of points for a country, *zone* or *compartment*.

A *surveillance* strategy should be designed to ensure that samples are representative of the *herd* of the country, *zone* or *compartment*, and include consideration of demographic factors such as production type and geographic location, and the potential influence of culturally unique husbandry practices. The approach used and the assumptions made should be fully documented, and the documentation retained for seven years.

The points targets and *surveillance* point values in this chapter were obtained by applying the following factors to a statistical model:

- 1) the design prevalence for Type A or Type B *surveillance*;
- 2) a confidence level of 95 percent;
- 3) the pathogenesis, and pathological and clinical expression of BSE:
  - a) sensitivity of diagnostic methods used;
  - b) relative frequency of expression by age;
  - c) relative frequency of expression within each subpopulation;
  - d) interval between pathological change and clinical expression;
- 4) demographics of the cattle population, including age distribution and population size;
- 5) influence of BSE on culling or attrition of *animals* from the cattle population via the four subpopulations;
- 6) percentage of infected *animals* in the cattle population which are not detected.

Although the procedure accepts very basic information about a cattle population, and can be used with estimates and less precise data, careful collection and documentation of the data significantly enhance their value. Since samples from clinical suspect *animals* provide many times more information than samples from healthy or dead-of-unknown-cause

*animals*, careful attention to the input data can substantially decrease the procedure's cost and the number of samples needed. The essential input data are:

- 7) cattle population numbers stratified by age;
- 8) the number of cattle tested for BSE stratified by age and by subpopulation.

This chapter utilises Tables 1 and 2 to determine a desired *surveillance* points target and the point values of *surveillance* samples collected.

Within each of the subpopulations above in a country, *zone* or *compartment*, a Member Country may wish to target cattle identifiable as imported from countries or *zones* not free from BSE and cattle which have consumed potentially contaminated feedstuffs from countries or *zones* not free from BSE.

All clinical suspects should be investigated, regardless of the number of points accumulated. In addition, *animals* from the other subpopulations should be tested.

#### 1. Type A surveillance

The application of Type A *surveillance* will allow the detection of BSE around a design prevalence of at least one case per 100,000 in the adult cattle population in the country, *zone* or *compartment* of concern, at a confidence level of 95 percent.

#### 2. Type B surveillance

The application of Type B *surveillance* will allow the detection of BSE around a design prevalence of at least one case per 50,000 in the adult cattle population in the country, *zone* or *compartment* of concern, at a confidence level of 95 percent.

Type B *surveillance* may be carried out by countries, *zones* or *compartments* of negligible BSE risk status (Article 11.5.3.) to confirm the conclusions of the *risk assessment*, for example by demonstrating the effectiveness of the measures mitigating any risk factors identified, through *surveillance* targeted to maximise the likelihood of identifying failures of such measures.

Type B *surveillance* may also be carried out by countries, *zones* or *compartments* of controlled BSE risk status (Article 11.5.4.), following the achievement of the relevant points target using Type A *surveillance*, to maintain confidence in the knowledge gained through Type A *surveillance*.

#### 3. Selecting the points target

The *surveillance* points target should be selected from Table 1, which shows target points for adult cattle populations of different sizes. The size of the adult cattle population of a country, *zone* or *compartment* may be

estimated or may be set at one million because, for statistical reasons, one million is the point beyond which sample size does not further increase with population size.

**Table 1. Points targets for different adult cattle population sizes in a country, zone or compartment.**

Points targets for country, zone or compartment		
Adult cattle population size (24 months and older)	Type A surveillance	Type B surveillance
>1,000,000	300,000	150,000
1,000,000	238,400	119,200
900,001-1,000,000	214,600	107,300
800,001-900,000	190,700	95,350
700,001-800,000	166,900	83,450
600,001-700,000	143,000	71,500
500,001-600,000	119,200	59,600
400,001-500,000	95,400	47,700
300,001-400,000	71,500	35,750
200,001-300,000	47,700	23,850
100,001-200,000	22,100	11,500
90,001-100,000	19,900	9,950
80,001-90,000	17,700	8,850
70,001-80,000	15,500	7,750
60,001-70,000	13,000	6,650
50,001-60,000	11,000	5,500
40,001-50,000	8,800	4,400
30,001-40,000	6,600	3,300
20,001-30,000	4,400	2,200
10,001-20,000	2,100	1,050
9,001-10,000	1,900	950
8,001-9,000	1,600	800
7,001-8,000	1,400	700
6,001-7,000	1,200	600
5,001-6,000	1,000	500
4,001-5,000	800	400
3,001-4,000	600	300
2,001-3,000	400	200
1,001-2,000	200	100

#### 4. Determining the point values of samples collected

Table 2 can be used to determine the point values of the *surveillance* samples collected. The approach assigns point values to each sample according to the likelihood of detecting *infection* based on the subpopulation from which the sample was collected and the age of the animal sampled. This approach takes into account the general principles of *surveillance* described in Chapter 1.4. and the epidemiology of BSE.

Because precise aging of the *animals* that are sampled may not be possible, Table 2 combines point values into five age categories. The point estimates for each category were determined as an average for the age range

comprising the group. The age groups were selected on their relative likelihoods of expressing BSE according to scientific knowledge of the incubation of the *disease* and the world BSE experience. Samples may be collected from any combination of subpopulations and ages but should reflect the demographics of the cattle *herd* of the country, *zone* or *compartment*. In addition, Member Countries should sample at least three of the four subpopulations.

**Table 2. Surveillance point values for samples collected from animals in the given subpopulation and age category.**

Surveillance subpopulation			
Routine slaughter <sup>1</sup>	Fallen stock <sup>2</sup>	Casualty slaughter <sup>3</sup>	Clinical suspect <sup>4</sup>
Age $\geq$ 1 year and $<$ 2 years			
0.01	0.2	0.4	N/A
Age $\geq$ 2 years and $<$ 4 years (young adult)			
0.1	0.2	0.4	260
Age $\geq$ 4 years and $<$ 7 years (middle adult)			
0.2	0.9	1.6	750
Age $\geq$ 7 years and $<$ 9 years (older adult)			
0.1	0.4	0.7	220
Age $\geq$ 9 years			
0.0	0.1	0.2	45

If a country, *zone* or *compartment* determines, based on the demographics and epidemiological characteristics of its cattle population, that precise classification of the subpopulations 'casualty or emergency slaughter, or downer cattle' and 'fallen stock' is not possible, these subpopulations may be combined. In such a case, the *surveillance* point values accorded to the combined subpopulation would be that of 'fallen stock'.

The total points for samples collected may be accumulated over a period of a maximum of seven consecutive years to achieve the target number of points determined in Table 1.

*Surveillance* points remain valid for seven years (the 95th percentile of the incubation period).

Article 11.5.23.

### BSE risk assessment: introduction

The first step in determining the BSE risk status of the cattle population of a country or *zone* is to conduct a *risk assessment* (reviewed annually), based on Section 2. of this *Terrestrial Code*, identifying all potential factors for BSE occurrence and their historic perspective.

#### 1. Entry assessment

Entry assessment consists of assessing the likelihood that a BSE agent has been introduced via the importation of the following *commodities* potentially contaminated with a BSE agent:

- a) *meat-and-bone meal* or *greaves*;
- b) *live animals*;
- c) *animal feed* and *feed ingredients*;
- d) *products of animal origin* for human consumption.

#### 2. Exposure assessment

Exposure assessment consists of assessing the likelihood of exposure of the BSE agent to cattle, through a consideration of the following:

- a) *epidemiological situation* concerning BSE agents in the country or *zone*;



- b) recycling and amplification of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;
- c) the origin and use of ruminant carcasses (including fallen stock), by-products and *slaughterhouse* waste, the parameters of the rendering processes and the methods of animal feed manufacture;
- d) implementation and enforcement of feed bans, including measures to prevent cross-contamination of animal feed; thorough epidemiological investigations of any indigenous case born after the date of the implementation of feed bans should be conducted.

The following recommendations are intended to assist *Veterinary Services* in conducting such a *risk assessment*. They provide guidance on the issues that need to be addressed when conducting a country-based assessment of BSE risk. They apply equally to self-assessment in preparation of dossiers for categorisation of countries. The recommendations are supported by greater detail in the questionnaire used for the submission of data for country assessment.

#### Article 11.5.24.

##### **The potential for the entry of the BSE agent through the importation of meat-and-bone meal or greaves**

This point is irrelevant if the exposure assessment outlined below in Article 11.5.27. indicates that *meat-and-bone meal* or *greaves* has not been fed, either deliberately or accidentally, in the past eight years. Nevertheless, documentation should be provided on the control systems (including relevant legislation) in place to ensure that *meat-and-bone meal* or *greaves* has not been fed to ruminants.

*Assumption:* That *meat-and-bone meal* or *greaves* of ruminant origin plays the only significant role in BSE transmission.

*Question to be answered:* Has *meat-and-bone meal*, *greaves*, or feedstuffs containing either been imported within the past eight years? If so, where from and in what quantities?

*Rationale:* Knowledge of the origin of *meat-and-bone meal*, *greaves* or feedstuffs containing either *meat-and-bone meal* or *greaves*, is necessary to assess the likelihood of entry of BSE agent. *Meat-and-bone meal* and *greaves* originating in countries of high BSE risk pose a higher likelihood of entry than that from low risk countries. *Meat-and-bone meal* and *greaves* originating in countries of unknown BSE risk pose an unknown likelihood of entry.

*Evidence required:*

- Documentation to support claims that *meat-and-bone meal*, *greaves* or feedstuffs containing either *meat-and-bone meal* or *greaves* have not been imported, OR
- Where *meat-and-bone meal*, *greaves* or feedstuffs containing them have been imported, documentation of country of origin and, if different, the country of export.
- Documentation on annual volume, by country of origin, of *meat*, *greaves* or feedstuffs containing them imported during the past eight years.
- Documentation describing the composition (on a species and class of stock basis) of the imported *meat-and-bone meal*, *greaves* or feedstuffs containing them.
- Documentation, from the country of production, supporting why the rendering processes used to produce *meat-and-bone meal*, *greaves* or feedstuffs containing them would have inactivated, or significantly reduced the titre of BSE agent, should it be present.
- Documentation describing the fate of imported *meat-and-bone meal* and *greaves*.

#### Article 11.5.25.

##### **The potential for the entry of the BSE agent through the importation of live animals potentially infected with BSE**

*Assumptions:*

- Countries which have imported ruminants from countries infected with BSEs are more likely to experience BSE.
- Cattle pose the only known risk although other species are under study.
- *Animals* imported for breeding may pose a greater risk than *animals* imported for *slaughter* because of the hypothetical risk of maternal transmission and because they are kept to a greater age than *animals* imported for *slaughter*.
- Risk is influenced by the date at which imports occurred, relative to the BSE status of the country of origin.
- Risk is proportional to volume of imports (Article 2.1.3.).

**Question to be answered:** Have live *animals* been imported within the past seven years?

**Rationale:** The likelihood of entry is dependent on:

- country of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical *disease*, or following active *surveillance*, or assessment of geographical BSE risk;
- feeding and management of the *animals* in the country of origin;
- use to which the *commodity* has been put as apart from representing risk of developing clinical *disease*, the *slaughter*, rendering and recycling in *meat-and-bone meal* of imported *animals* represents a potential route of exposure of indigenous livestock even if *meat-and-bone meal* and *greaves*, or feedstuffs containing them, have not been imported;
- species;
- dairy versus meat breeds, where there are differences in exposure in the country of origin because feeding practices result in greater exposure of one category;
- age at *slaughter*.

**Evidence required:**

- Documentation on the country of origin of imports. This should identify the country of breeding of *animals*, the length of time they lived in that country and of any other country in which they have resided during their lifetime.
- Documentation describing origins, species and volume of imports.
- Documentation describing the fate of imported *animals*, including their age at *slaughter*.
- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Article 11.5.26.

**The potential for the entry of the BSE agent through the importation of products of animal origin potentially infected with BSE**

**Assumptions:**

- Semen, embryos, hides and skins or milk are not considered to play a role in the transmission of BSE.
- Countries which have imported products of animal origin from countries with BSEs are more likely to experience BSE.
- Risk is influenced by the date at which imports occurred, relative to the BSE status of the country of origin.
- Risk is proportional to volume of imports (Article 2.1.3.).

**Question to be answered:** What products of animal origin have been imported within the past seven years?

**Rationale:** The likelihood of entry is dependent on:

- the species of origin of the animal products and whether these products contain tissues known to contain BSE infectivity (Article 11.5.14.);
- country of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical *disease*, or following active *surveillance*, or assessment of geographical BSE risk;
- feeding and management of the *animals* in the country of origin;
- use to which the *commodity* has been put as apart from representing risk of developing clinical *disease*, the *slaughter*, rendering and recycling in *meat-and-bone meal* of imported *animals* represents a potential route of exposure of indigenous livestock even if *meat-and-bone meal* and *greaves*, or feedstuffs containing them, have not been imported;
- species;
- dairy versus meat breeds, where there are differences in exposure in the country of origin because feeding practices result in greater exposure of one category;
- age at *slaughter*.

**Evidence required:**

- Documentation on the country of origin of imports. This should identify the country of breeding of *animals*, the length of time they lived in that country and of any other country in which they have resided during their lifetime.
- Documentation describing origins, species and volume of imports.

- Documentation describing the end use of imported animal products, and the disposal of waste.
- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Article 11.5.27.

**The potential for the exposure of cattle to the BSE agent through consumption of meat-and-bone meal or greaves of ruminant origin**

*Assumptions:*

- That the consumption by bovines of *meat-and-bone meal* or *greaves* of ruminant origin plays the only significant role in BSE transmission.
- That commercially-available products of animal origin used in animal feeds may contain *meat-and-bone meal* or *greaves* of ruminant origin.
- Milk and blood are not considered to play a role in the transmission of BSE.

*Question to be answered:* Has *meat-and-bone meal* or *greaves* of ruminant origin been fed to cattle within the past eight years (see Articles 11.5.3. and 11.5.4.)?

*Rationale:* If cattle have not been fed products of animal origin (other than milk or blood) potentially containing *meat-and-bone meal* or *greaves* of ruminant origin within the past eight years, *meat-and-bone meal* and *greaves* can be dismissed as a risk.

Article 11.5.28.

**The origin of animal waste, the parameters of the rendering processes and the methods of animal feed production**

*Assumptions:*

- BSE has a long *incubation period* and insidious onset of signs, so *cases* may escape detection.
- Pre-clinical BSE infectivity cannot reliably be detected by any method and may enter rendering, in particular if specified risk materials are not removed.
- Tissues most likely to contain high titres of BSE infectivity (brain, spinal cord, eyes) may not be harvested for human consumption and may be rendered.
- BSE may manifest in sudden death, chronic disease, or recumbency, and may be presented as fallen stock or materials condemned as unfit for human consumption.
- BSE agent survival in rendering is affected by the method of processing. Adequate rendering processes are described in Article 11.5.19.
- BSE agent is present at much higher titres in central nervous system and reticulo-endothelial tissues (so-called 'Specified Risk Materials', or SRM).

*Question to be answered:* How has animal waste been processed over the past eight years?

*Rationale:* If potentially infected *animals* or contaminated materials are rendered, there is a risk that the resulting *meat-and-bone meal* could retain BSE infectivity.

Where *meat-and-bone meal* is utilized in the production of any animal feeds, the risk of cross-contamination exists.

*Evidence required:*

- Documentation describing the collection and disposal of fallen stock and materials condemned as unfit for human consumption.

- Documentation describing the definition and disposal of specified risk material, if any.
- Documentation describing the rendering process and parameters used to produce *meat-and-bone meal* and *greaves*.
- Documentation describing methods of animal feed production, including details of ingredients used, the extent of use of *meat-and-bone meal* in any livestock feed, and measures that prevent cross-contamination of cattle feed with ingredients used in monogastric feed.
- Documentation describing monitoring and enforcement of the above.

Article 11.5.29.

#### Conclusions of the risk assessment

The overall risk of BSE in the cattle population of a country or *zone* is proportional to the level of known or potential exposure to BSE infectivity and the potential for recycling and amplification of the infectivity through livestock feeding practices. For the *risk assessment* to conclude that the cattle population of a country or *zone* is free from BSE risk, it should have demonstrated that appropriate measures have been taken to manage any risks identified.

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1 See point 4) of Article 11.5.21.

2 See point 3) of Article 11.5.21.

3 See point 2) of Article 11.5.21.

4 See point 1) of Article 11.5.21.

## CHAPTER 11.6.

# BOVINE TUBERCULOSIS

### Article 11.6.1.

#### General provisions

The recommendations in this chapter are intended to manage the human and animal health risks associated with *Mycobacterium bovis* (*M. bovis*) infection in domestic (permanently captive and owned free-range) bovines including cattle (*Bos taurus*, *B. indicus* and *B. grunniens*), water buffaloes (*Bubalus bubalis*) and wood bison (*Bison bison* and *B. bonasus*).

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

### Article 11.6.2.

#### Country or zone free from bovine tuberculosis

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

- 1) *M. bovis* infection in domestic (permanently captive and owned free-range) bovines including cattle, water buffaloes and wood bison is a *notifiable disease* in the country;
- 2) an on-going awareness programme should be in place to encourage reporting of all cases suggestive of bovine tuberculosis;
- 3) regular and periodic testing of all cattle, water buffalo and wood bison *herds* demonstrated that *M. bovis* infection was not present in at least 99.8 percent of the *herds* and 99.9 percent of the cattle, water buffaloes and wood bison in the country or *zone* for three consecutive years;
- 4) a *surveillance* programme should be in place to detect bovine tuberculosis in the country or *zone* through ante- and post-mortem inspection as described in Chapter 6.2.;
- 5) if the *surveillance* programme described in points 3 and 4 above demonstrated that *M. bovis* infection was not present in at least 99.8 percent of the *herds* and 99.9 percent of the cattle, water buffaloes and wood bison in the country or *zone* for five consecutive years, *surveillance* may be maintained through ante- and post-mortem inspection as described in Chapter 6.2.;
- 6) cattle, water buffaloes and wood bison introduced into a country or *zone* free from bovine tuberculosis should be accompanied by a certificate from an *official veterinarian* attesting that they come from a country, *zone*, *compartment* or *herd* free from bovine tuberculosis or comply with the relevant provisions in Article 11.6.5. or in Article 11.6.6.

### Article 11.6.3.

#### Compartment free from bovine tuberculosis

To qualify as a *compartment* free from bovine tuberculosis, all cattle, water buffaloes or wood bison in a *compartment* should be certified by the *Veterinary Authority* as satisfying the following requirements:

- 1) the cattle, water buffaloes and wood bison:
  - a) showed no sign of bovine tuberculosis or lesions at ante- or post-mortem inspections for at least three consecutive years;
  - b) were over six weeks of age at the time of the first test and have shown a negative result to at least two tuberculin tests carried out at an interval of a minimum of six months, the first test being performed at least six months following the *slaughter* of the last affected *animal*;
  - c) met one of the following conditions:
    - i) showed a negative result to a tuberculin test carried out twice yearly to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is more than one percent of all *herds* in the country or *zone* during the last two years; or

- ii) showed a negative result to an annual tuberculin test to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is more than 0.2 percent but not more than 1 percent of all *herds* in the country or *zone* during the last two years; or
  - iii) showed a negative result to a tuberculin test every three years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.2 percent of all *herds* in the country or *zone* during the last four years; or
  - iv) showed a negative result to a tuberculin test every four years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.1 percent of all *herds* in the country or *zone* during the last six years;
- 2) cattle, water buffaloes and wood bison introduced into the *compartment* come from a *herd* free from bovine tuberculosis. This condition may be waived for *animals* which have been isolated for at least 90 days and which, prior to entry into the *compartment*, were subjected to at least two tuberculin tests carried out at a six-month interval with negative results with the second tuberculin test performed during the 30 days prior to entry into the *compartment*;
  - 3) cattle, water buffaloes and wood bison in a *compartment* free from bovine tuberculosis are protected from contact with *wildlife* reservoirs of bovine tuberculosis and are managed under a common *biosecurity plan* protecting them from contamination with *M. bovis*, and the *compartment* has been approved by the *Veterinary Authority* in accordance with Chapters 4.3. and 4.4.

Article 11.6.4.

**Herd free from bovine tuberculosis**

To qualify as free from bovine tuberculosis, a *herd* of cattle, water buffaloes or wood bison should satisfy the following requirements:

- 1) the *herd* is in a country, *zone* or *compartment* free from bovine tuberculosis and is certified free by the *Veterinary Authority*; or
- 2) cattle, water buffaloes and wood bison in the *herd*:
  - a) showed no sign of bovine tuberculosis or lesions at ante- or post-mortem inspections for at least one year;
  - b) were over six weeks of age at the time of the first test and have shown a negative result to at least two tuberculin tests carried out at a minimal interval of six months; in case of regaining of free status after an *outbreak*, the first test should be performed at least six months following the *slaughter* of the last affected *animal*;
  - c) to maintain the free status, met one of the following conditions:
    - i) showed a negative result to an annual tuberculin test to ensure the continuing absence of bovine tuberculosis; or
    - ii) showed a negative result to a tuberculin test every two years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 1 percent of all *herds* in the country or *zone* during the last two years; or
    - iii) showed a negative result to a tuberculin test every three years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.2 percent of all *herds* in the country or *zone* during the last four years; or
    - iv) showed a negative result to a tuberculin test every four years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.1 percent of all *herds* in the country or *zone* during the last six years;
- 3) cattle, water buffaloes and wood bison introduced into the *herd* come from a *herd* free from bovine tuberculosis. This condition may be waived for *animals* which have been isolated for at least 90 days and which, prior to entry into the *herd*, were subjected to at least two tuberculin tests carried out at a six-month interval with negative results with the second tuberculin test performed during the 30 days prior to entry into the *herd*.

Article 11.6.5.

**Recommendations for the importation of cattle, water buffaloes and wood bison for breeding or rearing**

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

- 1) showed no sign of bovine tuberculosis on the day of shipment;

- 2) originate from a *herd* free from bovine tuberculosis that is in a country, *zone* or *compartment* free from bovine tuberculosis; or
- 3) were subjected to the tuberculin test for bovine tuberculosis with negative results during the 30 days prior to shipment and come from a *herd* free from bovine tuberculosis; or
- 4) have been isolated for at least 90 days prior to entry into the *herd* including protection from contact with *wildlife* reservoirs of bovine tuberculosis and were subjected to at least two tuberculin tests carried out at a six-month interval with negative results with the second tuberculin test performed during the 30 days prior to entry into the *herd*.

Article 11.6.6.

**Recommendations for the importation of cattle, water buffaloes and wood bison for slaughter**

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

- 1) showed no sign of bovine tuberculosis on the day of shipment;
- 2) originated from a *herd* free from bovine tuberculosis or were subjected to a tuberculin test for bovine tuberculosis with negative results during the 30 days prior to shipment;
- 3) were not being eliminated as part of an eradication programme against bovine tuberculosis.

Article 11.6.7.

**Recommendations for the importation of semen of cattle, water buffaloes and wood bison**

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

- 1) the donor *animals* showed no sign of bovine tuberculosis on the day of collection of the semen and either:
  - a) were kept in an *artificial insemination centre* free from bovine tuberculosis in a country, *zone* or *compartment* free from bovine tuberculosis and which only accepts *animals* from free *herds* in a free country, *zone* or *compartment*; or
  - b) showed negative results to tuberculin tests carried out annually and were kept in a *herd* free from bovine tuberculosis;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 11.6.8.

**Recommendations for the importation of embryos/ova of cattle, water buffaloes and wood bison**

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

- 1) the donor females and all other susceptible *animals* in the *herd* of origin showed no sign of bovine tuberculosis during the 24 hours prior to embryo collection; and either
  - a) originated from a *herd* free from bovine tuberculosis in a country, *zone* or *compartment* free from bovine tuberculosis; or
  - b) were kept in a *herd* free from bovine tuberculosis, and were subjected to a tuberculin test for bovine tuberculosis with negative results during an isolation period of 30 days in the *establishment* of origin prior to collection;
- 2) the embryos/ova were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 11.6.9.

**Recommendations for the importation of fresh meat and meat products of cattle, water buffaloes and wood bison**

*Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* comes from *animals* which have been subjected to ante- and post-mortem inspections as described in Chapter 6.2.

Article 11.6.10.

**Recommendations for the importation of milk and milk products of cattle, water buffaloes and wood bison**

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

- 1) has been derived from *animals* in a *herd* free from bovine tuberculosis; or
  - 2) was subjected to pasteurization; or
  - 3) was subjected to a combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.
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## CHAPTER 11.7.

# BOVINE TUBERCULOSIS OF FARMED CERVIDAE

### Article 11.7.1.

#### General provisions

The recommendations in this chapter are intended to manage the human and animal health risks associated with *Mycobacterium bovis* (*M. bovis*) infection in domestic (permanently captive and owned free-range) farmed cervidae (red deer, wapiti, sika, samba, rusa, fallow deer, white-tailed, black-tailed and mule deer [*Cervus elephus*, *C. canadensis*, *C. nippon*, *C. unicolor unicolor*, *C. timorensis*, *Dama dama dama*, *Odocoileus virginianus borealis*, *Odocoileus hemionus columbianus* and *Odocoileus hemionus hemionus*]). The chapter does not address the management of tuberculosis in wild cervid populations.

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

### Article 11.7.2.

#### Country or zone free from bovine tuberculosis of farmed cervidae

To qualify as free from bovine tuberculosis of farmed cervidae, a country or *zone* should satisfy the following requirements:

- 1) *M. bovis* infection in domestic bovines and in farmed cervidae as specified in Article 11.7.1. is a *notifiable disease* in the country;
- 2) an on-going awareness programme should be in place to encourage reporting of all cases suggestive of tuberculosis;
- 3) regular and periodic testing of all *herds* of farmed cervidae has demonstrated that *M. bovis* infection was not present in at least 99.8 percent of the *herds* and 99.9 percent of the farmed cervidae in the country or *zone* for three consecutive years;
- 4) a *surveillance* programme should be in place to detect bovine tuberculosis in the country or *zone* through ante- and post-mortem inspections as described in Chapter 6.2.;
- 5) if the *surveillance* programme described in points 3 and 4 above demonstrated that *M. bovis* infection was not present in at least 99.8 percent of the *herds* and 99.9 percent of the farmed cervidae in the country or *zone* for five consecutive years, *surveillance* may be maintained through ante- and post-mortem inspections as described in Chapter 6.2.;
- 6) farmed cervidae introduced into a country or *zone* free from bovine tuberculosis should be accompanied by a certificate from an *official veterinarian* attesting that they come from a country, *zone*, *compartment* or *herd* free from bovine tuberculosis or comply with the relevant provisions in Article 11.7.5. or in Article 11.7.6.

### Article 11.7.3.

#### Compartment free from bovine tuberculosis of farmed cervidae

To qualify as a *compartment* free from bovine tuberculosis of farmed cervidae, the *Veterinary Authority* should be able to certify that the following requirements are satisfied:

- 1) all farmed cervidae:
  - a) showed no sign of bovine tuberculosis or lesions at ante- or post-mortem inspection for at least three consecutive years;
  - b) were over six weeks of age at the time of the first test and have shown a negative result to at least two tuberculin tests carried out at an interval of a minimum of six months, the first test being performed at least six months following the *slaughter* of the last affected *animal*;

- c) met one of the following conditions:
  - i) showed a negative result to a twice yearly tuberculin test to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is more than 1 percent of all *herds* in the country or *zone* during the last two years; or
  - ii) showed a negative result to an annual tuberculin test to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is more than 0.2 percent but not more than 1 percent of all *herds* in the country or *zone* during the last two years; or
  - iii) showed a negative result to a tuberculin test every three years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.2 percent of all *herds* in the country or *zone* during the last four years; or
  - iv) showed a negative result to a tuberculin test every four years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.1 percent of all *herds* in the country or *zone* during the last six years;
- 2) farmed cervidae introduced into the *compartment* come from a *herd* free from bovine tuberculosis. This condition may be waived for *animals* which have been isolated for at least 90 days and which, prior to entry into the *compartment*, were subjected to at least two tuberculin tests carried out at a six-month interval with negative results with the second tuberculin test performed during the 30 days prior to entry into the *compartment*;
- 3) farmed cervidae in a *compartment* free from bovine tuberculosis are protected from contact with *wildlife* reservoirs of bovine tuberculosis and are managed under a common *biosecurity plan* protecting them from contamination with *M. bovis*, and the *compartment* has been approved by the *Veterinary Authority* in accordance with Chapters 4.3. and 4.4.

Article 11.7.4.

**Herd free from bovine tuberculosis of farmed cervidae**

To qualify as free from bovine tuberculosis, a *herd* of farmed cervidae should satisfy the following requirements:

- 1) the *herd* is in a country, a *zone* or a *compartment* free from bovine tuberculosis and is certified free by the *Veterinary Authority*; or
- 2) farmed cervidae in the *herd*:
  - a) showed no sign of bovine tuberculosis or lesions at ante- or post-mortem inspection for at least three consecutive years;
  - b) were over six weeks of age at the time of the first test and have shown a negative result to at least two tuberculin tests carried out at a minimum interval of six months; the first test should be performed at least six months following the *slaughter* of the last affected *animal*;
  - c) to maintain the free status, met one of the following conditions:
    - i) showed a negative result to an annual tuberculin test to ensure the continuing absence of bovine tuberculosis; or
    - ii) showed a negative result to a tuberculin test every two years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 1 percent of all *herds* in the country or *zone* during the last two years; or
    - iii) showed a negative result to a tuberculin test every three years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.2 percent of all *herds* in the country or *zone* during the last four years; or
    - iv) showed a negative result to a tuberculin test every four years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.1 percent of all *herds* in the country or *zone* during the last six years;
- 3) farmed cervidae introduced into the *herd* come from a *herd* free from bovine tuberculosis. This condition may be waived for *animals* which have been isolated for at least 90 days and which, prior to entry into the *herd*, were subjected to at least two tuberculin tests carried out at a six-month interval with negative results with the second tuberculin test performed during the 30 days prior to entry into the *herd*.

Article 11.7.5.

**Recommendations for the importation of farmed cervidae for breeding or rearing**

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

- 1) showed no sign of bovine tuberculosis on the day of shipment;
- 2) originate from a *herd* free from bovine tuberculosis of farmed cervidae that is in a country, *zone* or *compartment* free from bovine tuberculosis of farmed cervidae; or
- 3) were subjected to the tuberculin test for bovine tuberculosis with negative results during the 30 days prior to shipment and come from a *herd* free from bovine tuberculosis of farmed cervidae; or
- 4) have been isolated for at least 90 days prior to entry into the *herd* including protection from contact with *wildlife* reservoirs of bovine tuberculosis and were subjected to at least two tuberculin tests carried out at a six-month interval with negative results with the second tuberculin test performed during the 30 days prior to entry into the *herd*.

Article 11.7.6.

**Recommendations for the importation of farmed cervidae for slaughter**

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

- 1) showed no sign of bovine tuberculosis on the day of shipment;
- 2) originated from a *herd* free from bovine tuberculosis of farmed cervidae or were subjected to a tuberculin test for bovine tuberculosis with negative results during the 30 days prior to shipment;
- 3) were not being eliminated as part of an eradication programme against bovine tuberculosis.

Article 11.7.7.

**Recommendations for the importation of semen of farmed cervidae**

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

- 1) the donor *animals* showed no sign of bovine tuberculosis in any species on the day of collection of the semen; and either:
  - a) were kept in a *herd* free from bovine tuberculosis in a country, *zone* or *compartment* free from bovine tuberculosis of farmed cervidae, and which only accepts *animals* from free *herds* in a free country, *zone* or *compartment*; or
  - b) showed negative results to tuberculin tests carried out annually and were kept in a *herd* free from bovine tuberculosis;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 11.7.8.

**Recommendations for the importation of embryos/ova of farmed cervidae**

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

- 1) the donor females and all other susceptible *animals* in the *herd* of origin showed no sign of bovine tuberculosis during the 24 hours prior to embryo collection; and either
  - a) originated from a *herd* free from bovine tuberculosis of farmed cervidae in a country, *zone* or *compartment* free from bovine tuberculosis; or
  - b) were kept in a *herd* free from bovine tuberculosis of farmed cervidae and were subjected to a tuberculin test for bovine tuberculosis with negative results during an isolation period of 30 days in the *establishment* of origin prior to collection;

- 2) the embryos/ova were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 11.7.9.

**Recommendations for the importation of fresh meat and meat products of farmed cervidae**

*Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* comes from *animals* which have been subjected to ante- and post-mortem inspections as described in Chapter 6.2.

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## CHAPTER 11.8.

# INFECTION WITH *MYCOPLASMA MYCOIDES* SUBSP. *MYCOIDES* SC (CONTAGIOUS BOVINE PLEUROPNEUMONIA)

### Article 11.8.1.

#### General provisions

For the purposes of the *Terrestrial Code*, the *incubation period* for contagious bovine pleuropneumonia (CBPP) shall be six months.

For the purpose of this chapter, a *case* of CBPP means an *animal* infected with *Mycoplasma mycoides* subspecies *mycoides* SC (*MmmSC*), and freedom from CBPP means freedom from *MmmSC* infection.

For the purpose of this chapter, susceptible *animals* include cattle (*Bos indicus*, *B. taurus* and *B. grunniens*) and water buffaloes (*Bubalus bubalis*).

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

The following defines the occurrence of *MmmSC* infection:

- 1) *MmmSC* has been isolated and identified as such from an *animal*, embryos, oocytes or semen; or
- 2) antibodies to *MmmSC* antigens which are not the consequence of *vaccination*, or *MmmSC* DNA, have been identified in one or more *animals* showing pathological lesions consistent with *infection* with *MmmSC* with or without clinical signs, and epidemiological links to a confirmed *outbreak* of CBPP in susceptible *animals*.

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

When authorising import or transit of the *commodities* listed in this chapter, with the exception of those listed in Article 11.8.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the CBPP status of the domestic cattle and water buffalo population of the *exporting country, zone or compartment*.

### Article 11.8.2.

#### Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any CBPP related conditions, regardless of the CBPP status of the domestic cattle and water buffalo population of the *exporting country, zone or compartment*:

- 1) *milk* and *milk products*;
- 2) hides and skins;
- 3) *meat* and *meat products* (excluding lung).

### Article 11.8.3.

#### CBPP free country or zone

To qualify for inclusion in the existing list of CBPP free countries and *zones*, a Member 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 CBPP during the past 24 months;
  - b) no evidence of CBPP *infection* has been found during the past 24 months;

- c) no *vaccination* against CBPP has been carried out during the past 24 months, and supply documented evidence that *surveillance* for CBPP in accordance with this chapter is in operation and that regulatory measures for the prevention and control of CBPP have been implemented;
- 3) not have imported since the cessation of *vaccination* any *animals* vaccinated against CBPP.

The country or *zone* will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information in points 2a), 2b), 2c) and 3 above be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

#### Article 11.8.4.

#### **Recovery of free status**

When a CBPP *outbreak* occurs in a CBPP free country or *zone*, one of the following waiting periods is required to regain the status of CBPP free country or *zone*:

- 1) 12 months after the last *case* where a *stamping-out policy* and serological *surveillance* and strict movement control are applied in accordance with this chapter;
- 2) if *vaccination* was used, 12 months after the *slaughter* of the last vaccinated *animal*.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply but Article 11.8.3. applies.

#### Article 11.8.5.

#### **CBPP infected country or zone**

When the requirements for acceptance as a CBPP free country or *zone* are not fulfilled, a country or *zone* shall be considered as infected.

#### Article 11.8.6.

#### **CBPP free compartment**

The bilateral recognition of a CBPP free *compartment* should follow the principles laid down in this chapter and in Chapters 4.3. and 4.4.

#### Article 11.8.7.

#### **Recommendations for importation from CBPP free countries or zones, or from CBPP free compartments**

##### For domestic cattle and water buffaloes

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the *animals* showed no clinical sign of CBPP on the day of shipment.

#### Article 11.8.8.

#### **Recommendations for importation from CBPP infected countries or zones**

##### For domestic cattle and water buffaloes for slaughter

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

- 1) showed no clinical sign of CBPP on the day of shipment;
- 2) originate from an *establishment* where no *case* of CBPP was officially reported for the past six months, and
- 3) are transported directly to the *slaughterhouse* in sealed *vehicles*.

Article 11.8.9.

**Recommendations for importation from CBPP free countries or zones, or from CBPP free compartments**

For bovine semen

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

- 1) the donor *animals*:
  - a) showed no clinical sign of CBPP on the day of collection of the semen;
  - b) were kept in a CBPP free country, *zone* or *compartment* since birth or for at least the past six months;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 11.8.10.

**Recommendations for importation from CBPP infected countries**

For bovine semen

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

- 1) the donor *animals*:
  - a) showed no clinical sign of CBPP on the day of collection of the semen;
  - b) were subjected to the complement fixation test for CBPP with negative results, on two occasions, with an interval of not less than 21 days and not more than 30 days between each test, the second test being performed within 14 days prior to collection;
  - c) were isolated from other domestic bovidae from the day of the first complement fixation test until collection;
  - d) were kept since birth, or for the past six months, in an *establishment* where no *case* of CBPP was reported during that period, and that the *establishment* was not situated in a CBPP *infected zone*;
  - e) AND EITHER:
    - i) have not been vaccinated against CBPP;OR
    - ii) were vaccinated using a vaccine complying with the standards described in the *Terrestrial Manual* not more than four months prior to collection; in this case, the condition laid down in point b) above is not required;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 11.8.11.

**Recommendations for importation from CBPP free countries or zones, or from CBPP free compartments**

For *in vivo* derived or *in vitro* produced embryos or oocytes of bovidae

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

- 1) the donor *animals*:
  - a) showed no clinical sign of CBPP on the day of collection of the embryos or oocytes;
  - b) were kept in a CBPP free country, *zone* or *compartment* since birth or for at least the past six months;
- 2) the oocytes were fertilised with semen meeting the conditions of Article 11.8.9.;
- 3) the embryos or oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 11.8.12.

**Recommendations for importation from CBPP infected countries**

For *in vivo* derived or *in vitro* produced embryos or oocytes of bovidae

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

- 1) the donor *animals*:
  - a) showed no clinical sign of CBPP on the day of collection of the embryos or oocytes;
  - b) were subjected to the complement fixation test for CBPP with negative results, on two occasions, with an interval of not less than 21 days and not more than 30 days between each test, the second test being performed within 14 days prior to collection;
  - c) were isolated from other domestic bovidae from the day of the first complement fixation test until collection;
  - d) were kept since birth, or for the past six months, in an *establishment* where no *case* of CBPP was reported during that period, and that the *establishment* was not situated in a CBPP *infected zone*;
  - e) AND EITHER:
    - i) have not been vaccinated against CBPP;
    - OR
    - ii) were vaccinated using a vaccine complying with the standards described in the *Terrestrial Manual* not more than four months prior to collection; in this case, the condition laid down in point b) above is not required;
- 2) the oocytes were fertilised with semen meeting the conditions of Article 11.8.10.;
- 3) the embryos or oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 11.8.13.

**Surveillance: introduction**

Articles 11.8.13. to 11.8.17. define the principles and provide a guide for the *surveillance* of CBPP in accordance with Chapter 1.4. applicable to Member Countries seeking establishment of freedom from CBPP. Guidance is provided for Member Countries seeking reestablishment of freedom from CBPP for the entire country or for a *zone*, following an *outbreak* and for the maintenance of CBPP free status.

The impact and epidemiology of CBPP differ widely in different regions of the world and therefore it is impossible to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from CBPP at an acceptable level of confidence will need to be adapted to the local situation. It is incumbent upon the applicant Member Country to submit a dossier to the OIE in support of its application that not only explains the epidemiology of CBPP in the region concerned but also demonstrates how all the risk factors are managed. This should include provision of scientifically-based supporting data. There is therefore considerable latitude available to Member Countries to provide a well-reasoned argument to prove that the absence of CBPP *infection* is assured at an acceptable level of confidence.

*Surveillance* for CBPP should be in the form of a continuing programme designed to establish that the whole territory or part of it is free from CBPP *infection*.

Article 11.8.14.

**Surveillance: general conditions and methods**

- 1) A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. A procedure should be in place for the rapid collection and transport of samples from suspect cases of CBPP to a *laboratory* for CBPP diagnoses.
- 2) The CBPP *surveillance* programme should:
  - a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers (such as community animal health workers) who have day-to-day contact with livestock, *meat* inspectors as well as *laboratory* diagnosticians, should report promptly any suspicion of CBPP. They should be integrated directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) into the *surveillance* system. All suspect cases of CBPP should be investigated



immediately. Where suspicion cannot be resolved by epidemiological and clinical investigation, samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment are available for those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in CBPP diagnosis and control;

- b) implement, when relevant, regular and frequent clinical inspection and testing of high-risk groups of *animals*, such as those adjacent to a CBPP infected country or *infected zone* (for example, areas of transhumant production systems);
- c) take into consideration additional factors such as animal movement, different production systems, geographical and socio-economic factors that may influence the risk of *disease* occurrence.

An effective *surveillance* system will periodically identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is CBPP. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from CBPP *infection* should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of laboratory testing and the control measures to which the *animals* concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

#### Article 11.8.15.

### Surveillance strategies

#### 1. Introduction

The target population for *surveillance* aimed at identifying *disease* and *infection* should cover all the susceptible species (*Bos taurus*, *B. indicus* and *Bubalus bubalis*) within the country or *zone*.

Given the limitations of the diagnostic tools available, the interpretation of *surveillance* results should be at the *herd* level rather than at the individual animal level.

Randomised *surveillance* may not be the preferred approach given the epidemiology of the *disease* (usually uneven distribution and potential for occult foci of *infection* in small populations) and the limited sensitivity and specificity of currently available tests. Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in particular localities or species, focusing on *slaughter* findings, and active clinical *surveillance*) may be the most appropriate strategy. The applicant Member Country should justify the *surveillance* strategy chosen as adequate to detect the presence of CBPP *infection* in accordance with Chapter 1.4. and the epidemiological situation.

Targeted *surveillance* may involve testing of the entire target subpopulation or a sample from it. In the latter case the sampling strategy will need to incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect *infection* if it were to occur at a predetermined minimum rate. The sample size and expected disease prevalence determine the level of confidence in the results of the survey. The applicant Member Country should justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated.

Irrespective of the *surveillance* system employed, the design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following-up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve follow-up with supplementary tests, clinical investigation and post-mortem examination in the original sampling unit as well as *herds* which may be epidemiologically linked to it.

#### 2. Clinical surveillance

Clinical *surveillance* aims at detecting clinical signs of CBPP in a *herd* by close physical examination of susceptible *animals*. Clinical inspection will be an important component of CBPP *surveillance* contributing to reach the desired level of confidence of detection of *disease* if a sufficiently large number of clinically susceptible *animals* is examined.

Clinical *surveillance* and laboratory testing should always be applied in series to clarify the status of CBPP suspects detected by either of these complementary diagnostic approaches. Laboratory testing and post-mortem examination may contribute to confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive serology. Any sampling unit within which suspicious *animals* are detected should be classified as infected until contrary evidence is produced.

3. Pathological surveillance

Systematic pathological *surveillance* for CBPP is the most effective approach and should be conducted at *slaughterhouses* and other *slaughter* facilities. Suspect pathological findings should be confirmed by agent identification. Training courses for *slaughter* personnel and *meat* inspectors are recommended.

4. Serological testing

Serological *surveillance* is not the preferred strategy for CBPP. However, in the framework of epidemiologic investigations, serological testing may be used.

The limitations of available serological tests for CBPP will make the interpretation of results difficult and useful only at the *herd* level. Positive findings should be followed-up by clinical and pathological investigations and agent identification.

Clustering of seropositive reactions should be expected in CBPP *infections* and will be usually accompanied by clinical signs. As clustering may signal field strain *infection*, the investigation of all instances should be incorporated in the *surveillance* strategy.

Following the identification of a CBPP infected *herd*, contact *herds* need to be tested serologically. Repeated testing may be necessary to reach an acceptable level of confidence in *herd* classification.

5. Agent surveillance

Agent *surveillance* should be conducted to follow-up and confirm or exclude suspect cases. Isolates should be typed to confirm *MmmSC*.

Article 11.8.16.

**Countries or zones applying for recognition of freedom from CBPP**

In addition to the general conditions described in this chapter, a Member Country applying for recognition of CBPP freedom for the country or a *zone* should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and will be planned and implemented according to general conditions and methods in this chapter, to demonstrate absence of CBPP *infection*, during the preceding 24 months in susceptible populations. This requires the support of a national or other *laboratory* able to undertake identification of CBPP *infection*.

Article 11.8.17.

**Countries or zones re-applying for recognition of freedom from CBPP following an outbreak**

In addition to the general conditions described in this chapter, a Member Country re-applying for recognition of country or *zone* freedom from CBPP should show evidence of an active *surveillance* programme for CBPP, following the recommendations of this chapter.

Two strategies are recognised by the OIE in a programme to eradicate CBPP *infection* following an *outbreak*:

- 1) *slaughter* of all clinically affected and in-contact susceptible *animals*;
- 2) *vaccination* used without subsequent *slaughter* of vaccinated *animals*.

The time periods before which an application can be made for re-instatement of freedom from CBPP depends on which of these alternatives is followed. The time periods are prescribed in Article 11.8.4.

## CHAPTER 11.9.

# ENZOOTIC BOVINE LEUKOSIS

### Article 11.9.1.

#### General provisions

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

For the purpose of this chapter, susceptible *animals* include cattle (*Bos indicus* and *B. taurus*).

### Article 11.9.2.

#### EBL free country or zone

##### 1. Qualification

To qualify as free from enzootic bovine leukosis (EBL), a country or *zone* should satisfy the following requirements for at least three 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 cattle 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 percent 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 should be carried out annually on a random sample of the cattle population of the country or *zone* sufficient to provide a 99 percent level of confidence of detecting EBL if it is present at a prevalence rate exceeding 0.2 percent of the *herds*;
- b) all imported cattle (except for *slaughter*) comply with the provisions of Article 11.9.5.;
- c) all imported bovine semen and embryos/ova fulfil the requirements referred to in Article 11.9.6. and in Article 11.9.7., respectively.

### Article 11.9.3.

#### EBL free compartment

##### 1. Qualification

To qualify as free from EBL, a *compartment* should satisfy the following requirements:

All *herds* in the *compartment* have satisfied the requirements of Article 11.9.4., and;

- a) all cattle introduced into the *compartment* come from a free *herd*;
- b) all bovine semen and embryos/ova introduced into the *compartment* after the first test have fulfilled the conditions referred to in Article 11.9.6. and in Article 11.9.7., respectively;
- c) the *compartment* is managed under a common *biosecurity plan* complying with Article 4.3.3. and Article 4.4.3., which protects the cattle from contact with EBL virus, which might occur from introduction of infected cattle, cattle products or material and through practices such as *vaccinations* and other injections, collection of blood and other biological samples, dehorning, ear-tagging, pregnancy diagnosis, etc.;
- d) the *compartment* has been approved by the *Veterinary Authority* in accordance with Chapters 4.3. and 4.4.

2. Maintenance of free status

For a *compartment* to maintain its EBL free status, all *herds* in the *compartment* should remain free according to Article 11.9.4. and specific *surveillance* implemented according to Article 4.4.5. has not detected the agent.

3. Revocation and re-approval of free status

If in an EBL free *compartment* any cattle react positively to a diagnostic test for EBL as described in the *Terrestrial Manual*, the status of the *compartment* shall be revoked until all *herds* have recovered their free status according to Article 11.9.4. and the *compartment* has been re-approved according to Chapters 4.3. and 4.4.

Article 11.9.4.

**EBL free herd**

1. Qualification

To qualify as free from EBL, a *herd* should 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 two years;
- b) all cattle over 24 months of age have been subjected to a diagnostic test for EBL on two occasions with negative results, at an interval of not less than 4 months during the preceding 12 months;
- c) cattle introduced into the *herd* after the first test have fulfilled the conditions of Article 11.9.5.;
- d) all bovine semen and embryos/ova introduced into the *herd* after the first test have fulfilled the conditions referred to in Article 11.9.6. and in Article 11.9.7., respectively.

2. Maintenance of free status

For a *herd* to maintain its EBL free status, the cattle in the *herd* over 24 months of age on the day of sampling should be subjected to a diagnostic test for EBL with negative results at intervals of no more than 36 months and the conditions referred to in points 1a), 1c) and 1d) above continue to be fulfilled.

3. Suspension and restoration of free status

If in an EBL free *herd* any cattle react positively to a diagnostic test for EBL as described in the *Terrestrial Manual*, the status of the *herd* shall be suspended until the following measures have been taken:

- a) the cattle which have reacted positively, and their progeny since the last negative test, should be removed from the *herd* immediately; however, any cattle 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 cattle should have been subjected to a diagnostic test for EBL carried out as described in point 1b) above with negative results at least four months after removal of the positive cattle and their progeny.

Article 11.9.5.

**Recommendations for the importation of cattle for breeding or rearing**

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

- 1) come from a country, *zone* or *compartment* free from EBL; or
- 2) come from an EBL free *herd*; or
- 3) meet the following three conditions:
  - a) the cattle 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 two years;
    - ii) all cattle 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 cattle were subjected to a diagnostic test for EBL within 30 days prior to shipment with negative results;

- c) if less than two years of age, the cattle 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 11.9.6.

**Recommendations for the importation of bovine semen**

*Veterinary Authorities of importing countries* should require 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 two 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 Chapters 4.5. and 4.6.

Article 11.9.7.

**Recommendations for the importation of bovine embryos/ova**

*Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that the embryos/ova have been collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

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## CHAPTER 11.10.

# HAEMORRHAGIC SEPTICAEMIA (*Pasteurella multocida* SEROTYPES 6:B AND 6:E)

Article 11.10.1.

### General provisions

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 11.10.2.

### HS free country

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 three years.

This period shall be six months after the *slaughter* of the last affected *animal* for countries in which a *stamping-out policy* is practised with or without *vaccination* against HS.

Article 11.10.3.

### HS free zone

A *zone* may be considered free from the *disease* if it can be established that HS has not been present for at least the past three 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 11.10.6. or 11.10.7.

Article 11.10.4.

### HS infected zone

A *zone* shall be considered as infected with HS until at least six months have elapsed after the confirmation of the last *case* and the completion of a *stamping-out policy* and *disinfection* procedures.

Article 11.10.5.

### Trade in commodities

*Veterinary Authorities* of HS free countries may prohibit importation or transit through their territory, from countries considered infected with HS, of cattle and buffaloes.

Article 11.10.6.

**Recommendations for importation from HS free countries or zones**

For cattle and buffaloes

*Veterinary Authorities* should require 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 six months.

Article 11.10.7.

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

For cattle and buffaloes

*Veterinary Authorities* should require 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 three 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.
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## CHAPTER 11.11.

# INFECTIOUS BOVINE RHINOTRACHEITIS/ INFECTIOUS PUSTULAR VULVOVAGINITIS

### Article 11.11.1.

#### General provisions

For the purposes of the *Terrestrial Code*, the *incubation period* for infectious bovine rhinotracheitis/infectious pustular vulvovaginitis (IBR/IPV) shall be 21 days.

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

### Article 11.11.2.

#### Country or zone free from IBR/IPV

##### 1. Qualification

To qualify as free from IBR/IPV, a country or *zone* should 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 three years;
- c) at least 99.8 percent 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 percent level of confidence of detecting IBR/IPV if it is present at a prevalence rate exceeding 0.2 percent of the *herds*;
- b) all imported bovines comply with the provisions of Article 11.11.4.;
- c) all imported bovine semen and embryos/ova fulfil the requirements referred to in Articles 11.11.6. or 11.11.7., and in Article 11.11.8., respectively.

### Article 11.11.3.

#### Herd free from IBR/IPV

##### 1. Qualification

To qualify as free from IBR/IPV, a *herd* of cattle should 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 two months with negative results;
- c) *animals* introduced into the *herd* after the first tests referred to in point a) or point b) as relevant have been:
  - i) kept in an IBR/IPV free *herd*; or
  - ii) placed in isolation for a period of 30 days, and during this period have been subjected to a diagnostic test for IBR/IPV on a blood sample on two occasions with negative results, at an interval of not less than 21 days;



- d) all bovine semen and embryos/ova introduced into the *herd* after the first tests referred to in point a) or point b) as relevant have fulfilled the conditions provided in Articles 11.11.6. or 11.11.7. and in Article 11.11.8., respectively.

## 2. Maintenance of free status

For a *herd* to maintain its status free from IBR/IPV, it should 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 six months; *Veterinary Authorities* applying an IBR/IPV eradication programme may extend these intervals (under study) if more than 98 percent of *herds* have been free from the *disease* for at least three 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 three months of gestation.

*Animals* introduced into the *herd* should satisfy the conditions provided in point 1c) above, and semen and embryos/ova used in the *herd* should satisfy the conditions provided in Articles 11.11.6. or 11.11.7. and in Article 11.11.8., respectively.

### Article 11.11.4.

#### **Recommendations for the importation of cattle destined for herds free from IBR/IPV**

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

- 1) showed no clinical sign of IBR/IPV on the day of shipment;
- 2) come from an IBR/IPV free *herd*; or
- 3) were kept in a *quarantine station* for the 30 days prior to shipment and were subjected to a diagnostic test for IBR/IPV on a blood sample on two occasions with negative results, at an interval of not less than 21 days.

### Article 11.11.5.

#### **Recommendations for the importation of cattle intended for herds not qualified as free from IBR/IPV**

*Veterinary Authorities of importing countries* should require 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 six months prior to shipment.

### Article 11.11.6.

#### **Recommendations for the importation of fresh semen**

*Veterinary Authorities of importing countries* should require 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 Chapters 4.5. and 4.6.

Article 11.11.7.

**Recommendations for the importation of frozen semen**

*Veterinary Authorities of importing countries* should require 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 or PCR, performed in accordance with the *Terrestrial Manual*, with negative results; and
- 4) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 11.11.8.

**Recommendations for the importation of embryos/ova**

*Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that the embryos/ova were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

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## CHAPTER 11.12.

# LUMPY SKIN DISEASE (CAUSED BY GROUP III VIRUS, TYPE NEETHLING)

### Article 11.12.1.

#### General provisions

For the purposes of the *Terrestrial Code*, the *incubation period* for lumpy skin disease (LSD) shall be 28 days.

For the purpose of this chapter, susceptible *animals* include cattle (*Bos indicus* and *B. taurus*) and water buffalo (*Bubalus bubalis*).

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

When authorising import or transit of the *commodities* covered in the chapter, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the LSD status of the cattle population of the *exporting country*.

### Article 11.12.2.

#### LSD free country

A country may be considered free from LSD when:

- 1) LSD is notifiable in the country;
- 2) no *case* of LSD has been confirmed for at least the past three years;
- 3) no *vaccination* against LSD has been performed for at least three years;
- 4) *commodities* are imported in accordance with this chapter.

### Article 11.12.3.

#### Recommendations for importation from LSD free countries

##### For domestic cattle and water buffaloes

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

- 1) showed no clinical sign of LSD on the day of shipment;
- 2) come from an LSD free country.

### Article 11.12.4.

#### Recommendations for importation from LSD free countries

##### For wild cattle

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

- 1) showed no clinical sign of LSD on the day of shipment;
- 2) come from an LSD free country;

if the country of origin has a common border with a country considered infected with LSD:

- 3) were kept in a *quarantine station* for the 28 days prior to shipment.

Article 11.12.5.

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

For domestic cattle and water buffaloes

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

- 1) showed no clinical sign of LSD on the day of shipment;
- 2) either:
  - a) were not vaccinated against LSD and were tested negative using tests according to the *Terrestrial Manual* within 14 days prior to shipment; or
  - b) were vaccinated against LSD between 30 days and 90 days prior to shipment;

OR

- 3) either:
  - a) were kept since birth, or for the past 28 days, in an *establishment* where no case of LSD was officially reported during that period; or
  - b) were kept in a *quarantine station* for the 28 days prior to shipment.

Article 11.12.6.

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

For wild cattle

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

- 1) showed no clinical sign of LSD on the day of shipment;
- 2) were kept in a *quarantine station* for the 28 days prior to shipment.

Article 11.12.7.

**Recommendations for importation from LSD free countries**

For semen of cattle and water buffaloes

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

- 1) the donor *animals*:
  - a) showed no clinical sign of LSD on the day of collection of the semen;
  - b) were kept for at least 28 days prior to collection in an LSD free country;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 11.12.8.

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

For semen of cattle and water buffaloes

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

- 1) the donor *animals*:
  - a) showed no clinical sign of LSD on the day of collection of the semen and for the following 28 days;
  - b) were kept in the *exporting country* for the 28 days prior to collection, in an *establishment* or *artificial insemination centre* where no case of LSD was officially reported during that period, and that the *establishment* or *artificial insemination centre* was not situated in an LSD *infected zone*;
  - c) and either:
    - i) were vaccinated against LSD between 28 days and 90 days before the collection of the semen and thereafter vaccinated annually; or

- ii) were tested with negative results using a serum neutralisation test (SNT) or an indirect enzyme-linked immunosorbent assay (ELISA) for LSD on the day of the first collection of the semen or up to 90 days after last collection; or
  - iii) showed stable seropositivity (not more than a two-fold rise in titre) on paired samples (tested side by side) to indirect ELISA or SNT carried out in quarantine, 28–60 days apart, with the first sample taken on the day of the first collection of the semen;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 11.12.9.

**Recommendations for importation from LSD free countries**

For embryos/oocytes of cattle and water buffaloes

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

- 1) the donor *animals* showed no clinical sign of LSD on the day of collection of the embryos/oocytes; and
- 2) the embryos/oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 11.12.10.

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

For embryos/oocytes of cattle and water buffaloes

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

- 1) the donor *animals*:
  - a) were kept in an *establishment* where no case of LSD has been reported during the 28 days prior to collection; and
  - b) showed no clinical sign of LSD on the day of collection;
  - c) and either:
    - i) were vaccinated against LSD between 28 days and 90 days before the first collection of embryos/oocytes and thereafter vaccinated annually; or
    - ii) were tested with negative results using a serum neutralisation test (SNT) or an indirect enzyme-linked immunosorbent assay (ELISA) for LSD on the day of embryo/oocyte collection or up to 90 days after last collection; or
    - iii) showed stable seropositivity (not more than a two-fold rise in titre) on paired samples tested side by side to indirect ELISA or SNT carried out in quarantine, 28–60 days apart with one of the samples taken on the day of the collection of the embryos/oocytes;
- 2) the embryos/oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 11.12.11.

**Recommendations for importation from LSD free countries**

For products of animal origin (from cattle) intended for agricultural or industrial use

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that these products come from *animals* which have been kept in an LSD free country since birth or for at least the past 28 days.

Article 11.12.12.

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

For products of animal origin (from cattle and water buffaloes) intended for agricultural or industrial use

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

Article 11.12.13.

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

For raw hides of cattle and water buffaloes

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that these products were stored for at least 40 days before shipment.

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## CHAPTER 11.13.

# THEILERIOSIS

### Article 11.13.1.

#### General provisions

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 11.13.2.

#### Recommendations for importation from countries considered infected with theileriosis

##### For cattle

*Veterinary Authorities* of free countries should require 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 two 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 11.14.  
**TRICHOMONOSIS**

Article 11.14.1.

**General provisions**

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

Article 11.14.2.

**Recommendations for the importation of cattle for breeding**

*Veterinary Authorities of importing countries* should require 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 11.14.3.

**Recommendations for the importation of bulls for breeding (natural service or artificial insemination)**

*Veterinary Authorities of importing countries* should require 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 11.14.4.

**Recommendations for the importation of bovine semen**

*Veterinary Authorities of importing countries* should require 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 Chapters 4.5. and 4.6.



## SECTION 12.

### EQUIDAE

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#### CHAPTER 12.1.

### INFECTION WITH AFRICAN HORSE SICKNESS VIRUS

#### Article 12.1.1.

##### General provisions

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

All countries or *zones* adjacent to a country or *zone* not having free status should determine their AHSV status from an ongoing *surveillance* programme. Throughout the chapter, *surveillance* is in all cases understood as being conducted as described in Articles 12.1.13. to 12.1.15.

The following defines a *case* of AHS:

- 1) AHSV has been isolated and identified from an equid or a product derived from that equid; or
- 2) viral antigen or viral RNA specific to one or more of the serotypes of AHSV has been identified in samples from one or more equids showing clinical signs consistent with AHS, or epidemiologically linked to a suspected or confirmed *case*; or
- 3) serological evidence of active *infection* with AHSV by detection of seroconversion with production of antibodies to structural or nonstructural proteins of AHSV that are not a consequence of *vaccination* have been identified in one or more equids that either show clinical signs consistent with AHS, or epidemiologically linked to a suspected or confirmed *case*.

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

#### Article 12.1.2.

##### AHSV free country or zone

- 1) A country or *zone* may be considered free from AHSV when AHS is notifiable in the whole country, systematic *vaccination* is prohibited, importation of equids and their semen, oocytes or embryos are carried out in accordance with this chapter, and either:
  - a) historical freedom as described in Chapter 1.4. has demonstrated no evidence of AHSV in the country or *zone*; or
  - b) the country or *zone* has not reported any *case* of AHS for at least two years and is not adjacent to an infected country or *infected zone*; or
  - c) a *surveillance* programme has demonstrated no evidence of AHSV in the country or *zone* for at least 24 months; or
  - d) the country or *zone* has not reported any *case* of AHS for at least 40 days and a *surveillance* programme has demonstrated no evidence of *Culicoides* for at least two years in the country or *zone*.
- 2) An AHS free country or *zone* adjacent to an infected country or *infected zone* should include a *zone* in which *surveillance* is conducted in accordance with Articles 12.1.13. to 12.1.15. *Animals* within this *zone* should be

subjected to continuing *surveillance*. The boundaries of this *zone* should be clearly defined, and should take account of geographical and epidemiological factors that are relevant to AHS transmission.

- 3) An AHSV free country or *zone* will not lose its free status through the importation of vaccinated or seropositive equids and their semen, oocytes or embryos from infected countries or *infected zones*, provided these imports are carried out in accordance with this chapter.
- 4) To qualify for inclusion in the list of AHSV free countries or *zones*, a Member Country should:
  - a) have a record of regular and prompt animal disease reporting;
  - b) send a declaration to the OIE stating:
    - i) the section under point 1 on which the application is based;
    - ii) no routine *vaccination* against AHS has been carried out during the past 12 months in the country or *zone*;
    - iii) equids are imported in accordance with this chapter;
  - c) supply documented evidence that:
    - i) *surveillance* in accordance with Articles 12.1.13. to 12.1.15. is applied;
    - ii) regulatory measures for the early detection, prevention and control of AHS have been implemented.
- 5) The Member Country will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information in points 4b) ii) and iii) and 4c) ii) above be annually re-submitted and changes in the epidemiological situation or other significant events be reported to the OIE according to the requirements in Chapter 1.1., and in particular, formally state that:
  - a) there has been no *outbreak* of AHS during the past 12 months in the country or *zone*;
  - b) no evidence of *infection* with AHSV has been found during the past 12 months in the country or *zone*.

#### Article 12.1.3.

##### **AHSV seasonally free zone**

- 1) An AHSV seasonally free *zone* is a part of an infected country or an *infected zone* in which for part of a year, ongoing *surveillance* and monitoring consistently demonstrated neither evidence of AHSV transmission nor the evidence of the presence of adult *Culicoides*.
- 2) AHS is notifiable in the whole country.
- 3) For the application of Articles 12.1.8., 12.1.10. and 12.1.11., the seasonally free period is:
  - a) taken to commence the day following the last evidence of AHSV transmission and of the cessation of activity of adult *Culicoides* as demonstrated by an ongoing *surveillance* programme, and
  - b) taken to conclude either:
    - i) at least 40 days before the earliest date that historical data show AHSV activity has recommenced; or
    - ii) immediately when current climatic data or data from a *surveillance* and monitoring programme indicate an earlier resurgence of activity of adult *Culicoides* vectors.
- 4) An AHSV seasonally free *zone* will not lose its free status through the importation of vaccinated or seropositive equids and their semen, oocytes or embryos from infected countries or *infected zones*, provided these imports are carried out in accordance with this chapter.

#### Article 12.1.4.

##### **AHSV infected country or zone**

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

#### Article 12.1.5.

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

In the event of limited *outbreaks* within an AHS free country or *zone*, including within a *protection zone*, a single *containment zone*, which includes all cases, and should be large enough to contain any potentially infected vectors, can

be established for the purpose of minimizing the impact on the entire country or *zone*. For this to be achieved, the *Veterinary Authority* should provide documented evidence that:

- 1) the *outbreaks* are limited based on the following factors:
  - a) immediately on suspicion, a rapid response including notification has been made;
  - b) standstill of movements of equids has been imposed, and effective controls on the movement of equids and their products specified in this chapter are in place;
  - c) epidemiological investigation (trace-back, trace-forward) has been completed;
  - d) the *infection* has been confirmed;
  - e) the primary *outbreak* and likely source of the *outbreak* has been identified;
  - f) all cases have been shown to be epidemiologically linked;
  - g) no new cases have been found in the *containment zone* within a minimum of two infectious *infective periods* as defined in Article 12.1.1.;
- 2) the equids within the *containment zone* should be clearly identifiable as belonging to the *containment zone*;
- 3) increased passive and targeted *surveillance* in accordance with Articles 12.1.13. to 12.1.15. in the rest of the country or *zone* has not detected any evidence of *infection*;
- 4) animal health measures that effectively prevent the spread of AHS to the rest of the country or *zone*, taking into consideration the establishment of a *protection zone* within the *containment zone*, the seasonal *vector* conditions and existing physical, geographical and ecological barriers;
- 5) ongoing *surveillance* in accordance with Articles 12.1.13. to 12.1.15. is in place in the *containment zone*.

The free status of the areas outside the *containment zone* is suspended pending the establishment of the *containment zone* in accordance with points 1 to 5 above. The free status of the areas outside the *containment zone* could be reinstated irrespective of the provisions of Article 12.1.6., once the *containment zone* is recognised by the OIE.

The recovery of the AHS free status of the *containment zone* should follow the provisions of Article 12.1.6.

Article 12.1.6.

#### **Recovery of free status**

When an AHS *outbreak* occurs in an AHS free country or *zone*, to regain the free status, the provisions of Article 12.1.2. apply.

Article 12.1.7.

#### **Recommendations for importation from AHSV free countries or zones**

##### For equids

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

- 1) showed no clinical sign of AHS on the day of shipment;
- 2) have not been vaccinated against AHS within the last 40 days;
- 3) were kept in an AHSV free country or *zone* since birth or for at least 40 days prior to shipment;
- 4) either:
  - a) did not transit through an *infected zone* during transportation to the *place of shipment*; or
  - b) were protected from *Culicoides* attacks at all times when transiting through an *infected zone*.

Article 12.1.8.

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

##### For equids

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

- 1) showed no clinical sign of AHS on the day of shipment;
- 2) have not been vaccinated against AHS within the last 40 days;

- 3) and either:
  - a) were kept in an AHSV seasonally free zone during the seasonally free period since birth or for at least 40 days prior to shipment; or
  - b) were held in isolation in a *vector-protected establishment*:
    - i) for a period of at least 28 days and a serological test according to the *Terrestrial Manual* to detect antibodies to the AHSV group, was carried out with a negative result on a blood sample collected at least 28 days after introduction into the *vector-protected establishment*; or
    - ii) for a period of at least 40 days and serological tests according to the *Terrestrial Manual* to detect antibodies against AHSV were carried out with no significant increase in antibody titre on blood samples collected on two occasions, with an interval of not less than 21 days, the first sample being collected at least 7 days after introduction into the *vector-protected establishment*; or
    - iii) for a period of at least 14 days and an agent identification test according to the *Terrestrial Manual* was carried out with a negative result on a blood sample collected not less than 14 days after introduction into the *vector-protected establishment*;
- 4) were protected from *Culicoides* attacks at all times when transiting through an *infected zone*.

Article 12.1.9.

**Recommendations for importation from AHSV infected countries or zones**

For equids

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

- 1) showed no clinical sign of AHS on the day of shipment;
- 2) have not been vaccinated against AHS within the last 40 days;
- 3) were held in isolation in a *vector-protected establishment*:
  - a) for a period of at least 28 days and a serological test according to the *Terrestrial Manual* to detect antibodies to the AHSV group, was carried out with a negative result on a blood sample collected at least 28 days after introduction into the *vector-protected establishment*; or
  - b) for a period of at least 40 days and serological tests according to the *Terrestrial Manual* to detect antibodies against AHSV were carried out with no significant increase in antibody titre on blood samples collected on two occasions, with an interval of not less than 21 days, the first sample being collected at least 7 days after introduction into the *vector-protected establishment*; or
  - c) for a period of at least 14 days and an agent identification test according to the *Terrestrial Manual* was carried out with a negative result on a blood sample collected not less than 14 days after introduction into the *vector-protected establishment*; or
  - d) for a period of at least 40 days and were vaccinated, at least 40 days before shipment, in accordance with the *Terrestrial Manual* against all serotypes whose presence in the source population has been demonstrated through a *surveillance* programme in accordance with Articles 12.1.13. to 12.1.15., and were identified in the accompanying certification as having been vaccinated;
- 4) were protected from *Culicoides* attacks at all times during transportation (including transportation to and at the *place of shipment*).

Article 12.1.10.

**Recommendations for the importation of equine semen**

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

- 1) showed no clinical sign of AHS on the day of collection of the semen and for the following 40 days;
- 2) had not been immunised against AHS with a live attenuated vaccine within 40 days prior to the day of collection;
- 3) were either:
  - a) kept in an AHSV free country or free zone or from an AHSV seasonally free zone (during the seasonally free period) for at least 40 days before commencement of, and during collection of the semen, or

- b) kept in an AHSV free *vector*-protected *artificial insemination centre* throughout the collection period, and subjected to either:
  - i) a serological test according to the *Terrestrial Manual* to detect antibody to the AHSV group, carried out with a negative result on a blood sample collected at least 28 days and not more than 90 days after the last collection of semen; or
  - ii) agent identification tests according to the *Terrestrial Manual* carried out with negative results on blood samples collected at commencement and conclusion of, and at least every seven days, during semen collection for this consignment.

Article 12.1.11.

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

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

- 1) the donor *animals*:
  - a) showed no clinical sign of AHS on the day of collection of the embryos or oocytes and for the following 40 days;
  - b) had not been immunised against AHS with a live attenuated vaccine within 40 days prior to the day of collection;
  - c) were either:
    - i) kept in an AHSV free country or free *zone* or from an AHSV seasonally free *zone* (during the seasonally free period) for at least 40 days before commencement of, and during collection of the embryos or oocytes, or
    - ii) kept in an AHSV free *vector*-protected *collection centre* throughout the collection period, and subjected to either:
      - a serological test according to the *Terrestrial Manual* to detect antibody to the AHSV group carried out with a negative result on a blood sample collected at least 28 days and not more than 90 days after the last collection of embryos or oocytes; or
      - agent identification tests according to the *Terrestrial Manual* carried out with negative results on blood samples collected at commencement and conclusion of, and at least every seven days during embryos or oocytes collection for this consignment;
- 2) the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant;
- 3) semen used to fertilize the oocytes complies at least with the requirements in Article 12.1.10.

Article 12.1.12.

**Protecting animals from *Culicoides* attacks**

1. Vector-protected establishment or facility

The *establishment* or facility should be approved by the *Veterinary Authority* and the means of protection should at least comprise the following:

- a) Appropriate physical barriers at entry and exit points, for example double-door entry-exit system;
- b) openings of the building are *vector* screened with mesh of appropriate gauge impregnated regularly with an approved insecticide according to the instructions of the manufacturer;
- c) *vector surveillance* and control within and around the building;
- d) measures to limit breeding sites for *vectors* in vicinity of the *establishment* or facility;
- e) Standard Operating Procedure, including description of back-up and alarm systems, for operation of the *establishment* or facility and transport of horses to the place of *loading*.

## 2. During transportation

When transporting equids through AHSV infected countries or AHSV *infected zones*, *Veterinary Authorities* should require strategies to protect *animals* from *Culicoides* attacks during transport, taking into account the local ecology of the *vector*.

### a) Transport by road

Potential *risk management* strategies include a combination of:

- i) treating *animals* with chemical repellents prior to and during transportation, in sanitized *vehicles* treated with appropriate residual contact insecticide;
- ii) *loading*, transporting and *unloading animals* at times of low *vector* activity (i.e. bright sunshine and low temperature);
- iii) ensuring *vehicles* do not stop en route during dawn or dusk, or overnight, unless the *animals* are held behind insect proof netting;
- iv) darkening the interior of the *vehicle*, for example by covering the roof or sides of *vehicles* with shade cloth;
- v) monitoring for *vectors* at common stopping and offloading points to gain information on seasonal variations;
- vi) using historical, ongoing or AHS modelling information to identify low risk ports and transport routes.

### b) Transport by air

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

Crates, *containers* or jet stalls in which equids are being transported and the cargo hold of the aircraft must be sprayed with an approved insecticide just after the doors to the aircraft are closed and prior to takeoff, or immediately prior to the closing of the aircraft doors after *loading*.

In addition, during any stopover in countries or *zones* not free of AHS, prior to, or immediately after the opening of any aircraft door and until all doors are closed, netting of appropriate gauge impregnated with an approved insecticide must be placed over all crates, *containers* or jetstalls.

## Article 12.1.13.

### **Surveillance: introduction**

Articles 12.1.13. to 12.1.15. define the principles and provide guidance on *surveillance* for AHS, complementary to Chapter 1.4. and, for *vectors*, complementary to Chapter 1.5.

AHS is a *vector-borne infection* transmitted by a limited number of species of *Culicoides* insects. Unlike the related bluetongue virus, AHSV is so far geographically restricted to sub Saharan Africa with periodic excursions into North Africa, southwest Europe, the Middle East and adjacent regions of Asia. An important component of AHSV epidemiology is vectorial capacity which provides a measure of *disease risk* that incorporates *vector* competence, abundance, seasonal incidence, biting rates, survival rates and the extrinsic *incubation period*. However, methods and tools for measuring some of these *vector* factors remain to be developed, particularly in a field context.

According to this chapter, a Member Country demonstrating freedom from *infection* with AHSV for the entire country or a *zone* should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and should be planned and implemented according to general conditions and methods described in this chapter. This requires the support of a *laboratory* able to undertake identification of *infection* with AHSV through the virus detection and antibody tests described in the *Terrestrial Manual*.

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

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

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

Article 12.1.14.

**Surveillance: general conditions and methods**

- 1) A *surveillance* system should be under the responsibility of the *Veterinary Authority*. In particular the following should be in place:
  - a) a formal and ongoing system for detecting and investigating *outbreaks* of *disease*;
  - b) a procedure for the rapid collection and transport of samples from suspect cases of AHS to a *laboratory* for AHS diagnosis as described in the *Terrestrial Manual*;
  - c) a system for recording, managing and analysing diagnostic, epidemiological and *surveillance* data.
- 2) The AHS *surveillance* programme should:
  - a) in a country or *zone*, free or seasonally free, include an early warning system for reporting suspicious cases. Persons who have regular contact with equids, as well as diagnosticians, should report promptly any suspicion of AHS to the *Veterinary Authority*. An effective *surveillance* system will periodically identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is AHS. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. All suspected cases of AHS should be investigated immediately and samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment are available for those responsible for *surveillance*;
  - b) conduct random or targeted serological and virological *surveillance* appropriate to the *infection* status of the country or *zone* in accordance with Chapter 1.4.

Article 12.1.15.

**Surveillance strategies**

The target population for *surveillance* aimed at identification of *disease* or *infection* should cover susceptible equids within the country or *zone*. Active and passive *surveillance* for *infection* with AHSV should be ongoing. *Surveillance* should be composed of random or targeted approaches using virological, serological and clinical methods appropriate for the *infection* status of the country or *zone*.

A Member Country should justify the *surveillance* strategy chosen as appropriate to detect the presence of *infection* with AHSV in accordance with Chapter 1.4. and the prevailing epidemiological situation. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clinical signs (e.g. horses). Similarly, virological and serological testing may be targeted to species that rarely show clinical signs (e.g. donkeys).

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

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

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

Irrespective of the survey approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the *vaccination* or *infection* history and the different species in the target population.

Irrespective of the testing system employed, *surveillance* system design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as those which may be epidemiologically linked to it.

The principles for *surveillance* for *disease/infection* are technically well defined. *Surveillance* programmes to prove the absence of AHSV *infection/circulation*, need to be carefully designed to avoid producing results that are either insufficiently reliable to be accepted by international trading partners, or excessively costly and logistically complicated. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.

1. Clinical surveillance

Clinical *surveillance* aims at the detection of clinical signs of AHS in equids particularly during a newly introduced *infection*. In horses, clinical signs may include pyrexia, oedema, hyperaemia of mucosal membranes and dyspnoea.

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

2. Serological surveillance

Serological *surveillance* of equine populations is an important tool to confirm absence of AHSV transmission in a country or *zone*. The species tested should reflect the local epidemiology of *infection* with AHSV, and the equine species available. Management variables that may reduce the likelihood of *infection*, such as the use of insecticides and animal housing, should be taken into account when selecting equids to be included in the *surveillance* system.

Samples should be examined for antibodies against AHSV using tests prescribed in the *Terrestrial Manual*. Positive AHSV antibody tests results can have four possible causes:

- a) natural *infection* with AHSV;
- b) *vaccination* against AHS;
- c) maternal antibodies;
- d) positive results due to the lack of specificity of the test.

It may be possible to use sera collected for other purposes for AHSV *surveillance*. However, the principles of survey design described in these recommendations and the requirements for a statistically valid survey for the presence of *infection* with AHSV should not be compromised.

The results of random or targeted serological surveys are important in providing reliable evidence that no *infection* with AHSV is present in a country or *zone*. It is, therefore, essential that the survey is thoroughly documented. It is critical to interpret the results in light of the movement history of the *animals* being sampled.

Serological *surveillance* in a free *zone* should target those areas that are at highest risk of AHSV transmission, based on the results of previous *surveillance* and other information. This will usually be towards the boundaries of the free *zone*. In view of the epidemiology of AHSV, either random or targeted sampling is suitable to select *herds* or *animals* for testing.

Serological *surveillance* in a free country or *zone* should be carried out over an appropriate distance from the border with an infected country or *infected zone*, based upon geography, climate, history of *infection* and other relevant factors. The *surveillance* should be carried out over a distance of at least 100 kilometres from the border with that country or *zone*, but a lesser distance could be acceptable if there are relevant ecological or geographical features likely to interrupt the transmission of AHSV. An AHSV free country or *zone* may be protected from an adjacent infected country or *infected zone* by a *protection zone*.

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

3. Virological surveillance

Isolation and genetic analysis of AHSV from a proportion of infected *animals* is beneficial in terms of providing information on serotype and genetic characteristics of the viruses concerned.

Virological *surveillance* using tests described in the *Terrestrial Manual* can be conducted:

- a) to identify virus circulation in at risk populations;
- b) to confirm clinically suspect cases;
- c) to follow up positive serological results;
- d) to better characterize the genotype of circulating virus in a country or *zone*.



#### 4. Sentinel animals

Sentinel *animals* are a form of targeted *surveillance* with a prospective study design. They comprise groups of unexposed equids that are not vaccinated and are managed at fixed locations and observed and sampled regularly to detect new *infections* with AHSV.

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

A sentinel equid programme should use *animals* of known source and history of exposure, control management variables such as use of insecticides and animal housing (depending on the epidemiology of AHSV in the area under consideration), and be flexible in its design in terms of sampling frequency and choice of tests.

Care is necessary in choosing the sites for the sentinel groups. The aim is to maximise the chance of detecting AHSV activity at the geographical location for which the sentinel site acts as a sampling point. The effect of secondary factors that may influence events at each location, such as climate, may also be analysed. To avoid confounding factors sentinel groups should comprise *animals* selected to be of similar age and susceptibility to *infection* with AHSV. The only feature distinguishing groups of sentinels should be their geographical location. Sera from sentinel animal programmes should be stored methodically in a serum bank to allow retrospective studies to be conducted in the event of new serotypes being isolated.

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

Definitive information on AHSV circulating in a country or *zone* is provided by isolation and identification of the viruses. If virus isolation is required sentinels should be sampled at sufficiently frequent intervals to ensure that some samples are collected during the period of viraemia.

#### 5. Vector surveillance

AHSV is transmitted between equine hosts by species of *Culicoides* which vary across the world. It is therefore important to be able to identify potential *vector* species accurately although many such species are closely related and difficult to differentiate with certainty.

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

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

*Vector surveillance* should be based on scientific sampling techniques. The choice of the number and types of traps to be used in *vector surveillance* and the frequency of their use should take into account the size and ecological characteristics of the area to be surveyed.

The operation of *vector surveillance* sites at the same locations as sentinel *animals* is advisable.

The use of a *vector surveillance* system to detect the presence of circulating virus is not recommended as a routine procedure as the typically low *vector infection* rates mean that such detections can be rare. Other *surveillance* strategies are preferred to detect virus circulation.

CHAPTER 12.2.  
**CONTAGIOUS EQUINE METRITIS**

Article 12.2.1.

**General provisions**

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 two 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 12.2.2.

**Recommendations for the importation of stallions and mares considered free from CEM (for countries where an official control organisation is present)**

*Veterinary Authorities of importing countries* should require 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 12.2.3.

**Recommendations for the importation of stallions and mares which have previously shown signs of CEM or which have been in contact with contagious equine metritis (for countries where an official control organisation is present)**

*Veterinary Authorities of importing countries* should require 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 12.3.

### DOURINE

#### Article 12.3.1.

##### **General provisions**

For the purposes of the *Terrestrial Code*, the *incubation period* for dourine shall be six months.

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

#### Article 12.3.2.

##### **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 two years;
- 3) breeding horses have been subjected to a diagnostic test for dourine with negative results performed annually over a two-year period.

#### Article 12.3.3.

##### **Recommendations for importation from dourine free countries for the past six months**

###### For equines

*Veterinary Authorities* should require 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 six months prior to shipment, in a country which has been free from dourine for not less than the past six months.

#### Article 12.3.4.

##### **Recommendations for importation from countries considered infected with dourine**

###### For equines

*Veterinary Authorities* should require 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 six 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 12.3.5.

##### **Recommendations for importation from dourine free countries for the past six months**

###### For semen of equines

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the donor *animals* were kept since birth, or for the six months prior to collection of the semen, in a country which has been free from dourine for not less than the past six months.

Article 12.3.6.

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

For semen of equines

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

- 1) the donor *animals*:
    - a) were kept for the six 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 12.4.  
**EQUINE ENCEPHALOMYELITIS**  
**(EASTERN AND WESTERN)**

Article 12.4.1.

**General provisions**

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

Article 12.4.2.

**Recommendations for the importation of equines**

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

- 1) showed no clinical sign of equine encephalomyelitis on the day of shipment and during the three months prior to shipment;
  - 2) were kept for the three 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 12.5.  
**EQUINE INFECTIOUS ANAEMIA**

Article 12.5.1.

**General provisions**

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

Article 12.5.2.

**Recommendations for the importation of equines**

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

- 1) the *animals* showed no clinical sign of equine infectious anaemia (EIA) on the day of shipment and during the 48 hours prior to shipment; and
  - 2) no *case* of EIA has been associated with any premises where the *animals* were kept during the three months prior to shipment; and
  - 3) if imported on a permanent basis, the *animals* were subjected to a diagnostic test for EIA with negative results on blood samples collected during the 30 days prior to shipment; or
  - 4) if imported on a temporary basis, the *animals* were subjected to a diagnostic test for EIA with negative results on blood samples collected during the 90 days prior to shipment.
-

## CHAPTER 12.6.

# INFECTION WITH EQUINE INFLUENZA VIRUS

### Article 12.6.1.

#### General provisions

For the purposes of the *Terrestrial Code*, equine influenza (EI) is defined as an *infection* of domestic equids.

This chapter deals not only with the occurrence of clinical signs caused by equine influenza virus (EIV), but also with the presence of *infection* with EIV in the absence of clinical signs.

For the purposes of this chapter, isolation is defined as 'the separation of domestic equids from domestic equids of a different EI health status, utilising appropriate biosecurity measures, with the purpose of preventing the transmission of *infection*'.

For the purposes of the *Terrestrial Code*, the *infective period* for EI shall be 21 days.

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

When authorising import or transit of the *commodities* listed in this chapter, with the exception of those listed in Article 12.6.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the EI status of the equine population of the *exporting country, zone or compartment*.

### Article 12.6.2.

#### Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any EIV related conditions, regardless of the EI status of the equine population of the *exporting country, zone or compartment*:

- 1) equine semen;
- 2) *in vivo* derived equine embryos collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant (under study).

### Article 12.6.3.

#### Determination of the EI status of a country, a zone or a compartment

The EI status of a country, a *zone* or a *compartment* can be determined on the basis of the following criteria:

- 1) the outcome of a *risk assessment* identifying all risk factors and their historic relevance;
- 2) whether EI is notifiable in the whole country, an on-going EI awareness programme is in place, and all notified suspect occurrences of EI are subjected to field and, where applicable, *laboratory* investigations;
- 3) appropriate *surveillance* is in place to demonstrate the presence of *infection* in the absence of clinical signs in domestic equids.

### Article 12.6.4.

#### EI free country, zone or compartment

A country, *zone* or *compartment* may be considered free from EI provided the *disease* is notifiable in the whole country and it shows evidence, through an effective *surveillance* programme, planned and implemented according to the general principles in Chapter 1.4., that no case of EI occurred in the past two years. The *surveillance* may need to be adapted to parts of the country, *zone* or *compartment* depending on historical or geographical factors, industry structure,

population data, movements of equids within and into the country, *zone* or *compartment*, wild equine populations or proximity to recent *outbreaks*.

A country, *zone* or *compartment* seeking freedom from EI, in which *vaccination* is practised, should also demonstrate that EIV has not been circulating in the population of domestic, feral and wild equids during the past 12 months, through *surveillance*, in accordance with Chapter 1.4. In a country in which *vaccination* is not practised, *surveillance* may be conducted using serological testing alone. In countries where *vaccination* is practised, the *surveillance* should include agent identification methods described in the *Terrestrial Manual* for evidence of *infection*.

A country, *zone* or *compartment* seeking freedom from EI should apply appropriate movement controls to minimise the risk of introduction of EIV in accordance with this chapter.

If an *outbreak* of clinical EI occurs in a previously free country, *zone* or *compartment*, free status can be regained 12 months after the last clinical case, providing that *surveillance* for evidence of *infection* has been carried out during that twelve-month period in accordance with Chapter 1.4.

Article 12.6.5.

**Recommendations for the importation of domestic equids for immediate slaughter**

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the domestic equids showed no clinical sign of EI on the day of shipment.

Article 12.6.6.

**Recommendations for the importation of domestic equids for unrestricted movement**

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

- 1) came from an EI free country, *zone* or *compartment* in which they had been resident for at least 21 days; in the case of a vaccinated domestic equid, information on its *vaccination* status should be included in the veterinary certificate;

OR

- 2) came from a country, *zone* or *compartment* not known to be free from EI, were subjected to pre-export isolation for 21 days and showed no clinical sign of EI during isolation nor on the day of shipment; and
- 3) were immunised according to the recommendations of the manufacturer with a vaccine complying with the standards described in the *Terrestrial Manual* between 21 and 90 days before shipment either with a primary course or a booster; information on their *vaccination* status should be included in the veterinary certificate or the passport in accordance with Chapter 5.12.

For additional security, countries that are free of EI or undertaking an eradication programme may also request that the domestic equids were tested negative for EIV by an agent identification test for EI described in the *Terrestrial Manual* conducted on samples collected on two occasions at 7 to 14 days and less than 5 days before shipment.

Article 12.6.7.

**Recommendations for the importation of domestic equid which will be kept in isolation (see Article 12.6.1.)**

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

- 1) came from an EI free country, *zone* or *compartment* in which they had been resident for at least 21 days; in the case of a vaccinated domestic equid, information on its *vaccination* status should be included in the veterinary certificate;

OR

- 2) showed no clinical sign of EI in any premises in which the domestic equids had been resident for the 21 days prior to shipment nor on the day of shipment; and



- 3) were immunised according to the recommendations of the manufacturer with a vaccine complying with the standards described in the *Terrestrial Manual*; information on their *vaccination* status should be included in the veterinary certificate or the passport in accordance with Chapter 5.12.

Article 12.6.8.

**Recommendations for the importation of fresh meat of equids**

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the *fresh meat* came from equids which had been subjected to ante- and post-mortem inspections as described in Chapter 6.2.

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## CHAPTER 12.7.

# EQUINE PIROPLASMOSIS

Article 12.7.1.

### General provisions

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

Article 12.7.2.

### Recommendations for the importation of equines

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

- 1) showed no clinical sign of equine piroplasmosis on the day of shipment;
- 2) were subjected to diagnostic tests for equine piroplasmosis (*Theileria equi* and *Babesia caballi*) with negative results during the 30 days prior to shipment;
- 3) were maintained free from ticks, by preventive treatment when necessary, during the 30 days prior to shipment.

Article 12.7.3.

### Recommendations for the importation of competition horses on a temporary basis

*Veterinary Authorities of importing countries* should consider the possibility of importing competition horses on a temporary basis and which are positive to the testing procedure referred to in point 2 of Article 12.7.2. under the following safeguards:

- 1) the horses are accompanied by a passport in conformity with the model contained in Chapter 5.12.;
  - 2) the *Veterinary Authorities of importing countries* require the presentation of an *international veterinary certificate* attesting that the *animals*:
    - a) showed no clinical sign of equine piroplasmosis on the day of shipment;
    - b) were treated against ticks within the seven 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 12.8.  
**EQUINE RHINOPNEUMONITIS**

Article 12.8.1.

**General provisions**

Equine rhinopneumonitis (ER) is a collective term for any one of several highly contagious, clinical disease entities of equids that may occur as a result of *infection* by either of two closely related herpesviruses, equid herpesvirus-1 and -4 (EHV-1 and EHV-4).

*Infection* by either EHV-1 or EHV-4 is characterised by a primary respiratory tract *disease* of varying severity that is related to the age and immunological status of the infected *animal*. *Infections* by EHV-1 in particular are capable of progression beyond the respiratory mucosa to cause the more serious disease manifestations of abortion, perinatal foal death, or neurological dysfunction.

For the purpose of *international trade*, recommendations are provided for EHV-1 (abortigenic and paralytic forms) only.

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

Article 12.8.2.

**Recommendations for the importation of equines**

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

- 1) showed no clinical sign of EHV-1 *infection* (abortigenic and paralytic forms) on the day of shipment and during the 21 days prior to shipment;
  - 2) were kept for the 21 days prior to shipment in an *establishment* where no *case* of EHV-1 *infection* (abortigenic and paralytic forms), was reported during that period.
-

## CHAPTER 12.9.

# INFECTION WITH EQUINE ARTERITIS VIRUS

### Article 12.9.1.

#### General provisions

For the purposes of the *Terrestrial Code*, equine viral arteritis (EVA) is defined as an *infection* of domestic equids with equine arteritis virus (EAV).

This chapter deals not only with the occurrence of clinical signs caused by EAV, but also with the presence of *infection* with EAV in the absence of clinical signs. For the purposes of this chapter, isolation is defined as the separation of domestic equids from those of a different EVA health status, utilising appropriate biosecurity measures, with the objective of preventing the transmission of *infection*.

The *infective period* for EVA shall be 28 days for all categories of equids except sexually mature stallion where the *infective period* may be for the life of the *animal*. Because the *infective period* may be extended in the case of virus shedding in semen, the status of seropositive stallions should be checked to ensure that they do not shed virus in their semen.

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

### Article 12.9.2.

#### Recommendations for the importation of uncastrated male equids

*Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that the *animals* showed no clinical sign of EVA on the day of shipment and during the 28 days prior to shipment and met one of the following requirements:

- 1) were isolated for the 28 days prior to shipment and were subjected to a test for EVA carried out on a single blood sample collected during the 21 days prior to shipment with a negative result; or
- 2) were subjected between six and nine months of age to a test for EVA:  
EITHER:
  - a) with a negative result,OR
  - b) with a positive result, followed at least 14 days later by a second test showing a stable or decreasing titre; and were immediately vaccinated against EVA and regularly revaccinated according to the recommendations of the manufacturer; or
- 3) met the following requirements:
  - a) were isolated; and
  - b) not earlier than seven days of commencing isolation were subjected to a test for EVA on a blood sample with a negative result; and
  - c) were then immediately vaccinated; and
  - d) were kept separated from other equids for 21 days following *vaccination*; and
  - e) were regularly revaccinated according to the recommendations of the manufacturer; or
- 4) have been subjected to a test for EVA carried out on a blood sample with a positive result and then: either
  - a) were subsequently test mated to two mares within six months prior to shipment which were subjected to two tests for EVA with negative results on blood samples collected at the time of test mating and again 28 days after the mating; or
  - b) were subjected to a test for EAV with a negative result, carried out on semen collected during the six months prior to shipment; or

- c) were subjected to a test for EAV with a negative result, carried out on semen collected within six months after the blood sample was tested, then immediately vaccinated, and regularly revaccinated according to the recommendations of the manufacturer.

Article 12.9.3.

**Recommendations for the importation of equids other than uncastrated males**

*Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that the *animals* showed no clinical sign of EVA on the day of shipment; and

EITHER

- 1) were kept in an *establishment* where no *animals* have shown any signs of EVA for the 28 days prior to shipment; and
  - a) were subjected to a test for EVA carried out on blood samples collected either once within 21 days prior to shipment with a negative result, or on two occasions at least 14 days apart within 28 days prior to shipment, which demonstrated stable or declining antibody titres; or
  - b) were regularly vaccinated according to the recommendations of the manufacturer;

OR

- 2) were isolated for the 28 days prior to shipment and during this period the *animals* showed no sign of EVA.

Article 12.9.4.

**Recommendations for the importation of equine semen**

*Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that the donors were kept for the 28 days prior to semen collection in an *establishment* where no equid has shown any clinical sign of EVA during that period and showed no clinical sign of EVA on the day of semen collection; and

- 1) were subjected between six and nine months of age to a test for EVA:
  - EITHER:
    - a) with a negative result,
  - OR
    - b) with a positive result, followed at least 14 days later by a second test showing a stable or decreasing titre; and were immediately vaccinated against EVA and regularly revaccinated according to the recommendations of the manufacturer; or
- 2) were isolated and not earlier than seven days of commencing isolation were subjected to a test for EVA on a blood sample with a negative result, immediately vaccinated for EVA, kept for 21 days following *vaccination* separated from other equids and regularly revaccinated according to the recommendations of the manufacturer; or
- 3) were subjected to a test for EVA on a blood sample with a negative result within 14 days prior to semen collection, and had been separated from other equids not of an equivalent EVA status for 14 days prior to blood sampling until the end of semen collection; or
- 4) have been subjected to a test for EVA carried out on a blood sample with a positive result and then: either
  - a) were subsequently test mated to two mares within six months prior to semen collection, which were subjected to two tests for EVA with negative results on blood samples collected at the time of test mating and again 28 days after the test mating; or
  - b) were subjected to a test for EAV with a negative result, carried out on semen collected within six months prior to collection of the semen to be exported; or
  - c) were subjected to a test for EAV with a negative result, carried out on semen collected within six months after the blood sample was collected, then immediately vaccinated, and regularly revaccinated; or
- 5) for frozen semen, were subjected with negative results either:
  - a) to a test for EVA carried out on a blood sample taken not earlier than 14 days and not later than 12 months after the collection of the semen for export; or
  - b) to a test for EAV carried out on an aliquot of the semen collected immediately prior to processing or on an aliquot of semen collected within 14 to 30 days after the first collection of the semen to be exported.

Article 12.9.5.

**Recommendations for the importation of equine embryos**

*Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that the donor *animals* showed no clinical sign of EVA on the day of embryo collection; and

EITHER

- 1) were kept in an *establishment* where no *animals* have shown any signs of EVA for the 28 days prior to collection; and
  - a) were subjected to a test for EVA carried out on blood samples collected either once within 21 days prior to collection with negative results, or on two occasions at least 14 days apart within 28 days prior to collection, which demonstrated stable or declining antibody titres; or
  - b) were regularly vaccinated according to the recommendations of the manufacturer;

OR

- 2) were isolated for the 28 days prior to collection and during this period the *animals* showed no sign of EVA.
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## CHAPTER 12.10.

### GLANDERS

#### Article 12.10.1.

##### **General provisions**

For the purposes of the *Terrestrial Code*, the *incubation period* for glanders shall be six months.

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

#### Article 12.10.2.

##### **Glanders free country**

A country may be considered free from glanders when:

- 1) glanders is notifiable in the country;
- 2) no case of glanders has been reported during the past three years, or no case has been reported for a period of at least six months and a *surveillance* programme is in place demonstrating the absence of the *disease* in accordance with general recommendations on animal health *surveillance* (Chapter 1.4.).

#### Article 12.10.3.

##### **Recommendations for importation from glanders free countries**

###### For equines

*Veterinary Authorities* should require 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 six months prior to shipment, or since birth if less than six months of age, in the *exporting country*.

#### Article 12.10.4.

##### **Recommendations for importation from countries considered infected with glanders**

###### For equines

*Veterinary Authorities* should require 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 six months prior to shipment in an *establishment* where no case of glanders was reported during that period;
- 3) were subjected to a test as prescribed in the *Terrestrial Manual* for glanders with negative results, during the 30 days prior to shipment.

## CHAPTER 12.11.

# VENEZUELAN EQUINE ENCEPHALOMYELITIS

### Article 12.11.1.

#### General provisions

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 12.11.2.

#### 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 two years;
- 3) no equine *animal* has been imported from any country where VEE has been confirmed during the past two 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 12.11.5.

### Article 12.11.3.

#### Trade in commodities

*Veterinary Authorities* of VEE free countries may prohibit importation or transit through their territory, from countries considered infected with VEE, of domestic and wild equines, and may prohibit the importation into their territory, from countries considered infected with VEE, of semen and embryos/ova of domestic and wild equines.

### Article 12.11.4.

#### Recommendations for importation from VEE free countries

##### For domestic and wild equines

The *Veterinary Authorities* of *importing countries* should require 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 six months, been in any country in which VEE has occurred in the last two years;
- 3) have not been vaccinated against VEE within 60 days prior to shipment.



Article 12.11.5.

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

For domestic and wild equines

The *Veterinary Authorities* of *importing countries* should require 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 three 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 three 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 seven 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.

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SECTION 13.  
**LAGOMORPHA**

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CHAPTER 13.1.  
**MYXOMATOSIS**

Article 13.1.1.

**General provisions**

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

Article 13.1.2.

**Recommendations for the importation of domestic rabbits**

*Veterinary Authorities of importing countries* should require 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 six months prior to shipment, in an *establishment* where no case of myxomatosis was officially reported during that period.

Article 13.1.3.

**Recommendations for the importation of skins and fur of domestic and wild rabbits**

*Veterinary Authorities of importing countries* should require 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.

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## CHAPTER 13.2.

# RABBIT HAEMORRHAGIC DISEASE

### Article 13.2.1.

#### General provisions

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

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

### Article 13.2.2.

#### RHD free country

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

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

### Article 13.2.3.

#### RHD free establishment

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

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

- 1) a *stamping-out policy* has been adopted and carcasses have been disposed of by burning;
- 2) the rabbitry has been thoroughly disinfected and kept empty for at least six weeks;
- 3) the rabbitry is properly fenced to prevent the straying of wild lagomorphs into the rabbitry.

### Article 13.2.4.

#### Trade in commodities

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

### Article 13.2.5.

#### Recommendations for importation from RHD free countries

##### For domestic rabbits destined for breeding

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

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

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

Article 13.2.6.

**Recommendations for importation from RHD free countries**

For day-old rabbits destined for breeding

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

- 1) showed no clinical sign of RHD on the day of shipment;
- 2) were born from female rabbits which had been kept in a country free from RHD for at least the past 60 days.

Article 13.2.7.

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

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

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

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

AND

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

OR

- 3) were kept in an *establishment* where no case of RHD was reported during the 60 days prior to shipment and no clinical case of RHD was found when inspected by an *Official Veterinarian* immediately prior to shipment; and
- 4) were kept in an *establishment* where no *animal* has been vaccinated against RHD; and
- 5) were kept in an *establishment* where breeding rabbits (at least 10 percent of the *animals*) were subjected to the serological test for RHD with negative results during the 60 days prior to shipment; and
- 6) have not been vaccinated against RHD; or
- 7) were vaccinated against RHD immediately before shipment (the nature of the vaccine used and the date of *vaccination* shall also be stated in the certificate).

Article 13.2.8.

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

For day-old rabbits destined for breeding

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

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

OR

- 2) were kept in an *establishment* where no case of RHD was reported during the 30 days prior to shipment and no clinical case of RHD was found when inspected by an *Official Veterinarian* immediately before shipment; and
- 3) have not been vaccinated against RHD; and
- 4) were born from female rabbits which were subjected to the serological test for RHD with negative results during the 60 days prior to shipment.

Article 13.2.9.

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

For domestic rabbits destined for immediate slaughter

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

- 1) showed no clinical sign of RHD on the day of shipment;
- 2) were kept in an *establishment* where no case of RHD was reported during the 60 days prior to shipment.

Article 13.2.10.

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

For semen

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

- 1) showed no clinical sign of RHD on the day of collection of the semen;
- 2) were subjected to the serological test for RHD with negative results during the 30 days prior to collection.

Article 13.2.11.

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

For domestic rabbit meat

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

- 1) were kept in an *establishment* where no case of RHD was reported during the 60 days prior to transport to the approved *abattoir*;
- 2) were subjected to ante-mortem inspections for RHD with favourable results;
- 3) showed no lesions of RHD at post-mortem inspections.

Article 13.2.12.

**Recommendations for importation from RHD free countries**

For non-treated pelts

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

Article 13.2.13.

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

For pelts

*Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that the pelts were subjected to a drying treatment for at least one month and a formalin-based treatment by spraying at a 3 percent concentration, or by fumigation carried out, not more than seven days prior to shipment.

SECTION 14.  
OVIDAE AND CAPRIDAE

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CHAPTER 14.1.  
CAPRINE AND OVINE BRUCELLOSIS  
(EXCLUDING *Brucella ovis*)

Article 14.1.1.

**General provisions**

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

Article 14.1.2.

**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* should satisfy the following requirements:

- a) the occurrence or suspected occurrence of caprine and ovine brucellosis has been notifiable for at least five years; and
- b) all *flocks* of sheep and goats in the country or *zone* are under *official veterinary control*; and either
- c) 99.8 percent 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 five years, and no sheep or goat has been vaccinated against the *disease* for at least three 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 percent level of confidence of detecting caprine and ovine brucellosis if it is present at a prevalence rate exceeding 0.2 percent of the *flocks*.

However, for a country or *zone* qualified as officially free under point 1)d) above, maintenance testing is not required.

Article 14.1.3.

**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* should 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 two years ago;
- d) all sheep and goats over six 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 six months; however, for *flocks* situated in a country or *zone* qualified as officially free under point 1d) of Article 14.1.2., testing is not required;
- e) when qualified, it contains only sheep and goats born therein or introduced in conformity with the provisions of Article 14.1.5.

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* should 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 six months of age;
- b) all the *animals* introduced into the *flock* since the previous test;
- c) 25 percent 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 percent level of confidence of detecting caprine and ovine brucellosis if it is present at a prevalence rate exceeding 0.2 percent.

Control tests should be carried out at up to three-year intervals if the *flock* is situated in a *zone* where 99 percent of *flocks* are officially free from caprine and ovine brucellosis and the remainder are submitted to an eradication programme.

However, for *flocks* situated in a country or *zone* qualified as officially free under point 1d) of Article 14.1.2., maintenance testing is not required.

Whatever the periodicity of control tests and the way the status has been obtained, sheep and goats should only be introduced into the *flocks* in conformity with the provisions of Article 14.1.5.

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 six 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 three months.

Article 14.1.4.

**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* should 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 seven 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 14.1.6.

## 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* should 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 percent 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 percent level of confidence of detecting caprine and ovine brucellosis if it is present at a prevalence rate exceeding 0.2 percent.

Sheep and goats should only be introduced into the *flock* in conformity with the provisions of Article 14.1.6.

## 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 six 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 three months.

## 4. Change of status

For a *flock* free from caprine and ovine brucellosis to qualify as officially free, the *flock* should fulfil the following requirements for at least two 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 14.1.5.;

and at the end of the period, all sheep and goats over six months of age on the day of sampling have been subjected to a diagnostic test for caprine and ovine brucellosis, with negative results.

### Article 14.1.5.

#### **Recommendations for the importation of sheep and goats for breeding or rearing (except castrated males) destined for flocks officially free from caprine and ovine brucellosis**

*Veterinary Authorities of importing countries* should require 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 two 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 six weeks.

Article 14.1.6.

**Recommendations for the importation of sheep and goats for breeding or rearing (except castrated males) destined for flocks not officially free from caprine and ovine brucellosis**

*Veterinary Authorities of importing countries* should require 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 14.1.7.

**Recommendations for the importation of sheep and goats for slaughter (except castrated males)**

*Veterinary Authorities of importing countries* should require 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 14.1.8.

**Recommendations for the importation of semen of sheep and goats**

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

- 1) the donor *animals*:
  - a) showed no clinical sign of 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 Chapters 4.5. and 4.6.

Article 14.1.9.

**Recommendations for the importation of embryos/ova of sheep and goats**

*Veterinary Authorities of importing countries* should require 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 Chapters 4.7., 4.8. and 4.9., as relevant.
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## CHAPTER 14.2.

# CAPRINE ARTHRITIS/ENCEPHALITIS

### Article 14.2.1.

#### **General provisions**

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

### Article 14.2.2.

#### **Recommendations for the importation of goats for breeding**

*Veterinary Authorities of importing countries* should require 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 three years, and also that no sheep or goat from a *flock* of inferior health status was introduced into these *flocks* during that period.
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CHAPTER 14.3.  
**CONTAGIOUS AGALACTIA**

Article 14.3.1.

**Recommendations for the importation of sheep and goats**

*Veterinary Authorities of importing countries* should require 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 six 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 14.4.

# CONTAGIOUS CAPRINE PLEUROPNEUMONIA

### Article 14.4.1.

#### General provisions

For the purposes of the *Terrestrial Code*, contagious caprine pleuropneumonia (CCPP) is defined as a *disease* of goats caused by *Mycoplasma capricolum* subspecies *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 14.4.2.

#### CCPP free country

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 14.4.3.

#### CCPP infected zone

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 14.4.4.

#### Trade in commodities

*Veterinary Authorities* of CCPP free countries may prohibit importation or transit through their territory, from countries considered infected with CCPP, of domestic and wild goats, and may prohibit importation into their territory, from countries considered infected with CCPP, of semen of domestic and wild goats and of embryos/ova of domestic goats.

### Article 14.4.5.

#### Recommendations for importation from CCPP free countries

##### For domestic goats

*Veterinary Authorities* should require 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 three months.

Article 14.4.6.

**Recommendations for importation from CCPP free countries**

For wild goats

*Veterinary Authorities* should require 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 14.4.7.

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

For domestic goats

*Veterinary Authorities* should require 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 four months prior to shipment. In this case, point 2 above is not required (under study).

Article 14.4.8.

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

For goats for immediate slaughter

*Veterinary Authorities* should require 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 14.4.9.

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

For wild goats

*Veterinary Authorities* should require 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 four months prior to shipment (under study).

Article 14.4.10.

**Recommendations for importation from CCPP free countries**

For embryos/oocytes of goats

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

- 1) the donor *animals*:
  - a) showed no clinical sign of CCPP on the day of collection;
  - b) were kept in a CCPP free country;
- 2) the embryos/oocytes were collected in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 14.4.11.

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

For embryos/oocytes of goats

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

- 1) the donor *animals*:
  - a) showed no clinical sign of CCPP on the day of collection; and
  - b) were isolated from other domestic goats from the day of the test until collection;
  - c) were kept since birth, or for at least the 45 days prior to collection, 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*;
- 2) the collection fluids and/or degenerated and unfertilized ova were subjected to a validated culture or PCR test for CCPP with negative results;
- 3) the embryos/oocytes were collected in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 14.4.12.

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

For fresh meat of goats

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh 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 lesions of CCPP at the post-mortem inspection.
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## CHAPTER 14.5.

# INFECTION WITH *CHLAMYDOPHILA ABORTUS* (ENZOOTIC ABORTION OF EWES, OVINE CHLAMYDIOSIS)

### Article 14.5.1.

#### General provisions

For the purposes of the *Terrestrial Code*, enzootic abortion of ewes (EAE), also known as ovine chlamydiosis or ovine enzootic abortion, is an *infection* of domestic sheep and goats by the bacterium *Chlamydomphila abortus*.

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 14.5.2.

#### Recommendations for the importation of sheep or goats for breeding

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

- 1) have remained since birth, or for the previous two years, in *establishments* where no EAE has been diagnosed during the past two 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 14.5.3.

#### Sheep flocks 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 two years;
- 3) a statistically valid number of sheep and goats over six months of age were subjected to a diagnostic test for EAE with negative results within the past six 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 14.5.4.

**Recommendations for the importation of semen of sheep or goats**

*Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that the donor *animals* showed no clinical sign on the day of the semen collection; and

- 1) have been kept in *establishments* or *artificial insemination centres* free from EAE according to Article 14.5.3. for the two years prior to collection, and have not been in contact with *animals* of a lower health status; or
- 2) have remained since birth, or for the two years prior to collection, in *establishments* where no EAE has been diagnosed and were subjected to a diagnostic test for EAE with negative results two to three weeks after collection of the semen.

Article 14.5.5.

**Recommendations for the importation of embryos of sheep or goats**

*Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that the donor *animals* showed no clinical sign on the day of collection; and

- 1) have been kept in *establishments* free from EAE according to Article 14.5.3. for the two years prior to collection, and have not been in contact with *animals* of a lower health status; or
- 2) have remained since birth, or for the two years prior to collection, in *establishments* where no EAE has been diagnosed and were subjected to a diagnostic test for EAE with negative results two to three weeks after collection.

The embryos should be collected, processed and stored in accordance with Chapter 4.7.

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CHAPTER 14.6.  
**MAEDI-VISNA**

Article 14.6.1.

**General provisions**

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

Article 14.6.2.

**Recommendations for the importation of sheep and goats for breeding**

*Veterinary Authorities of importing countries* should require 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 three years, and also that no sheep or goat from a *flock* of inferior health status was introduced into these *flocks* during that period.
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## CHAPTER 14.7.

# OVINE EPIDIDYMITIS (*Brucella ovis*)

### Article 14.7.1.

#### General provisions

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

### Article 14.7.2.

#### Sheep flock free from ovine epididymitis

To qualify as free from ovine epididymitis, a sheep *flock* shall satisfy the following requirements:

- 1) it is under *official veterinary control*;
- 2) all sheep in the *flock* showed no clinical evidence of ovine epididymitis during the past year;
- 3) all sheep in the *flock* are permanently identified.

If some or all the males in the *flock* are vaccinated, the *flock* should still be regarded as free.

### Article 14.7.3.

#### Recommendations for the importation of sheep for breeding or rearing (except castrated males)

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

- 1) the *animals* showed no clinical sign of ovine epididymitis on the day of shipment;
- 2) the *animals* come from a sheep *flock* free from ovine epididymitis;
- 3) for sheep over six months of age, the *animals* were isolated in the *establishment* of origin for the 30 days prior to shipment and were subjected to the diagnostic tests for *Brucella ovis* (*B. 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 *B. 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 14.7.4.

#### Recommendations for the importation of semen of sheep

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

- 1) the donor *animals*:
  - a) showed no clinical sign of 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 *B. ovis* with negative results during the 30 days prior to collection;

- 2) the semen does not contain *B. ovis* or other *Brucella* antibodies.
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## CHAPTER 14.8.

# INFECTION WITH PESTE DES PETITS RUMINANTS VIRUS

### Article 14.8.1.

#### General provisions

Peste des petits ruminants (PPR) susceptible *animals* are primarily domestic sheep and goats although cattle, camels, buffaloes and some wild ruminant species can also be infected and may act as sentinels indicating the spill over of peste des petits ruminants virus (PPRV) from domestic small ruminants. Even if some wild small ruminants can be infective, only domestic sheep and goats play a significant epidemiological role.

For the purpose of the *Terrestrial Code*, PPR is defined as an *infection* of domestic sheep and goats with PPRV.

This chapter deals not only with the occurrence of clinical signs caused by PPRV, but also with the presence of *infection* with PPRV in the absence of clinical signs.

The following defines the occurrence of PPRV *infection*:

- 1) PPRV, excluding vaccine strains, has been isolated and identified as such from a domestic sheep or goat or a product derived from it; or
- 2) viral antigen or viral ribonucleic acid (RNA) specific to PPRV, excluding vaccine strains, has been identified in samples from a domestic sheep or goat showing clinical signs consistent with PPR, or epidemiologically linked to an *outbreak* of PPR, or giving cause for suspicion of association or contact with PPR; or
- 3) antibodies to PPRV antigens which are not the consequence of *vaccination*, have been identified in a domestic sheep or goat with either epidemiological links to a confirmed or suspected *outbreak* of PPR or showing clinical signs consistent with recent *infection* of PPRV.

For the purposes of the *Terrestrial Code*, the *incubation period* for the peste des petits ruminants (PPR) shall be 21 days.

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

### Article 14.8.2.

#### Safe commodities

When authorising import or transit through their territory of the following *commodities*, *Veterinary Authorities* should not require any PPR related conditions regardless of PPR status of the *exporting country or zone*:

- 1) semi-processed hides and skins (limed hides, pickled pelts, and semi-processed leather, e.g. wet blue and crust leather), which have been submitted to the usual chemical and mechanical processes in use in the tanning industry.

### Article 14.8.3.

#### PPR free country or zone

- 1) The PPR status of a country or *zone* can only be determined after considering the following criteria, as applicable:
  - a) PPR should be notifiable in the whole territory, and all clinical signs suggestive of PPR should be subjected to appropriate field or *laboratory* investigations;
  - b) an on-going awareness programme should be in place to encourage reporting of all cases suggestive of PPR;
  - c) the *Veterinary Authority* should have current knowledge of, and authority over, all domestic sheep and goats in the country or *zone*;
  - d) appropriate *surveillance*, capable of detecting the presence of *infection* even in the absence of clinical signs, is in place; this may be achieved through a *surveillance* programme in accordance with Articles 14.8.27. to 14.8.33.

- 2) To qualify for inclusion in the list of PPR free countries or *zones*, a Member Country should either:
- a) declare historical freedom as described in point 1 of Article 1.4.6.; or
  - b) submit to the OIE:
    - i) a record of regular and prompt animal *disease* reporting;
    - ii) a declaration stating that:
      - there has been no *outbreak* of PPR during the past 24 months;
      - no evidence of PPRV *infection* has been found during the past 24 months;
      - no *vaccination* against PPR has been carried out during the past 24 months;
    - iii) supply documented evidence that *surveillance* in accordance with Chapter 1.4. is in operation and that regulatory measures for the prevention and control of PPR have been implemented;
    - iv) evidence that no *animals* vaccinated against PPR have been imported since the cessation of *vaccination*.

The Member Country will be included in the list only after the submitted evidence has been accepted by the OIE. Changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1. Retention on the list requires that the information in points b)i) to b)iv) above be re-submitted annually.

#### Article 14.8.4.

#### PPR free compartment

A PPR free *compartment* can be established in either a PPR free country or *zone* or in an infected country or *infected zone*. In defining such a *compartment* the principles of Chapters 4.3. and 4.4. should be followed. Domestic sheep and goats in the PPR free *compartment* should be separated from any other susceptible *animals* by the application of an effective biosecurity management system.

A Member Country wishing to establish a PPR free *compartment* should:

- 1) have a record of regular and prompt animal *disease* reporting and if not PPR free, have an *official control programme* and a *surveillance* system for PPR in place according to Articles 14.8.27. to 14.8.33. that allows an accurate knowledge of the prevalence of PPR in the country or *zone*;
- 2) declare for the PPR free *compartment* that:
  - a) there has been no *outbreak* of PPR during the past 24 months;
  - b) no evidence of PPRV *infection* has been found during the past 24 months;
  - c) *vaccination* against PPR is prohibited;
  - d) no small ruminant in the *compartment* has been vaccinated against PPR within the past 24 months;
  - e) *animals*, semen and embryos should only enter the *compartment* in accordance with relevant articles in this chapter;
  - f) documented evidence shows that *surveillance* in accordance with Articles 14.8.27. to 14.8.33. is in place;
  - g) an *animal identification* and *traceability* system in accordance with Chapters 4.1. and 4.2. is in place;
- 3) describe in detail the animal subpopulation in the *compartment* and the biosecurity plan for PPRV *infection*.

The *compartment* should be approved by the *Veterinary Authority*.

#### Article 14.8.5.

#### PPRV infected country or zone

A country or *zone* shall be considered as PPRV infected when the requirements for acceptance as a PPR free country or *zone* are not fulfilled.

Article 14.8.6.

**Establishment of a containment zone within a PPR free country or zone**

In the event of limited *outbreaks* within a PPR free country or *zone*, including within a *protection zone*, a single *containment zone*, which includes all cases, can be established for the purpose of minimising the impact on the entire country or *zone*.

For this to be achieved and for the Member Country to take full advantage of this process, the *Veterinary Authority* should submit documented evidence as soon as possible to the OIE that:

- 1) the *outbreaks* are limited based on the following factors:
  - a) immediately on suspicion, a rapid response including *notification* has been made;
  - b) standstill of animal movements has been imposed, and effective controls on the movement of other *commodities* mentioned in this chapter are in place;
  - c) epidemiological investigation (trace-back, trace-forward) has been completed;
  - d) the *infection* has been confirmed;
  - e) the primary *outbreak* has been identified, and investigations on the likely source of the *outbreak* have been carried out;
  - f) all cases have been shown to be epidemiologically linked;
  - g) no new cases have been found in the *containment zone* with a minimum of two *incubation periods* as defined in Article 14.8.1. after the stamping-out of the last detected case is completed;
- 2) a *stamping-out policy* has been applied;
- 3) the susceptible animal population within the *containment zones* is clearly identifiable as belonging to the *containment zone*;
- 4) increased passive and targeted *surveillance* in accordance with Articles 14.8.27. to 14.8.33. in the rest of the country or *zone* has not detected any evidence of *infection*;
- 5) animal health measures that effectively prevent the spread of the PPRV to the rest of the country or *zone*, taking into consideration physical and geographical barriers, are in place;
- 6) ongoing *surveillance* is in place in the *containment zone*.

The free status of the areas outside the *containment zone* is suspended while the *containment zone* is being established. The free status of these areas may be reinstated irrespective of the provisions of Article 14.8.7., once the *containment zone* is clearly established, by complying with points 1 to 6 above. It should be demonstrated that *commodities* for *international trade* have originated outside the *containment zone*.

The recovery of the PPR free status of the *containment zone* should follow the provisions of Article 14.8.7.

Article 14.8.7.

**Recovery of free status**

When a PPR *outbreak* or PPRV *infection* occurs in a PPR free country or *zone* and when a *stamping-out policy* is practised with or without *vaccination*, the recovery period shall be six months after the *slaughter* of the last affected *animal* provided that Article 14.8.32. has been complied with.

If a *stamping-out policy* is not applied, the provisions of Article 14.8.3. apply.

Article 14.8.8.

**Recommendations for importation from PPR free countries or zones**

For domestic sheep and goats

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

- 1) showed no clinical sign of PPR on the day of shipment;
- 2) were kept in a PPR free country or *zone* since birth or for at least the past 21 days.

Article 14.8.9.

**Recommendations for importation from PPR free countries or zones**

For wild ruminants

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

- 1) showed no clinical sign suggestive of PPRV *infection* on the day of shipment;
- 2) come from a PPR free country or *zone*;
- 3) if the country or *zone* of origin has a common border with a country considered infected with PPRV:
  - a) were captured at a distance from the border that precludes any contact with *animals* in an infected country, the distance should be defined according to the biology of the species exported, including home range and long distance movements;

OR

- b) were kept in a *quarantine station* for at least the 21 days prior to shipment.

Article 14.8.10.

**Recommendations for importation from countries or zones considered infected with PPRV**

For domestic sheep and goats

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

- 1) showed no clinical sign suggestive of PPRV *infection* for at least the 21 days prior to shipment;
- 2) were kept since birth, or for at least the 21 days prior to shipment, in an *establishment* where no case of PPR was reported during that period, and that the *establishment* was not situated in a PPRV *infected zone*; or
- 3) were kept in a *quarantine station* for at least the 21 days prior to shipment;
- 4) were not vaccinated against PPR and were submitted to a diagnostic test for PPRV *infection* with negative result no more than 21 days prior to shipment;

OR

- were vaccinated against PPR with live attenuated PPRV vaccines at least 21 days prior to shipment.

Article 14.8.11.

**Recommendations for importation from countries or zones considered infected with PPRV**

For wild ruminants

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

- 1) showed no clinical sign suggestive of PPRV *infection* for at least the 21 days prior to shipment;
- 2) were submitted to a diagnostic test for PPRV *infection* with negative results no more than 21 days prior to shipment;
- 3) were kept in a *quarantine station* for at least the 21 days prior to shipment.

Article 14.8.12.

**Recommendations for importation from PPR free countries or zones**

For semen of domestic sheep and goats

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

- 1) showed no clinical sign of PPR on the day of the collection of the semen and during the following 21 days;
- 2) were kept in a PPR free country or *zone* for at least the 21 days prior to collection.



Article 14.8.13.

**Recommendations for importation from countries or zones considered infected with PPRV**

For semen of domestic sheep and goats

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

- 1) showed no clinical sign suggestive of PPRV infection for at least the 21 days prior to collection of the semen and during the following 21 days;
- 2) were kept, for at least the 21 days prior to collection, in an *establishment* or *artificial insemination centre* where no case of PPR was reported during that period, which was not situated in a PPRV *infected zone* and to which no *animals* had been added during the 21 days prior to collection;
- 3) were not vaccinated against PPR and were submitted to a diagnostic test for PPRV *infection* with negative results at least 21 days prior to collection of the semen;

OR

- 4) were vaccinated against PPR with live attenuated PPRV vaccines at least 21 days prior to semen collection.

Article 14.8.14.

**Recommendations for importation from PPR free countries or zones**

For embryos of domestic sheep and goats and captive wild ruminants

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

- 1) the donor *animals* were kept in an *establishment* located in a PPR free country or *zone* at least 21 days prior to embryo collection;
- 2) the embryos were collected, processed and stored in conformity with the relevant provisions of Chapters 4.7., 4.8. and 4.9.

Article 14.8.15.

**Recommendations for importation from countries or zones considered infected with PPRV**

For embryos of domestic sheep and goats

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

- 1) the donor *animals*:
  - a) and all other *animals* in the *establishment* showed no clinical sign suggestive of PPRV *infection* at the time of collection and during the following 21 days;
  - b) were kept, for at least the 21 days prior to collection, in an *establishment* where no case of PPR was reported during that period, and to which no susceptible *animals* had been added during the 21 days prior to collection;
  - c) were not vaccinated against PPR and were subjected to a diagnostic test for PPRV *infection* with negative results at least 21 days prior to collection;

OR

- d) were vaccinated against PPR with live attenuated PPRV vaccines at least 21 days prior to embryo collection;
- 2) the embryos were collected, processed and stored in conformity with the relevant provisions of Chapters 4.7., 4.8. and 4.9.

Article 14.8.16.

**Recommendations for importation from countries or zones considered infected with PPRV**

For embryos of captive wild ruminants

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

- 1) the donor *animals*:
  - a) showed no clinical signs suggestive of *infection* with PPRV for at least the 21 days prior to embryo collection;
  - b) were not vaccinated against PPR and were subjected to a diagnostic test for PPRV *infection* with negative results at least 21 days prior to collection;
  - c) were kept, for at least the 21 days prior to collection, in an *establishment* where no *case* of PPR or of *infection* with PPRV was reported during that period, and to which no susceptible *animals* had been added during the 21 days prior to collection;
- 2) the embryos were collected, processed and stored in conformity with the relevant provisions of Chapters 4.7., 4.8. and 4.9.

Article 14.8.17.

**Recommendation for importation of fresh meat and meat products from sheep and goats**

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

- 1) showed no clinical signs of PPR within 24 hours before *slaughter*;
- 2) have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections with favourable results.

Article 14.8.18.

**Recommendations for importation from PPR free countries or zones**

For milk and milk products from sheep and goats

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that these products come from *animals* which have been kept in a PPR free country or *zone* for at least the 21 days prior to milking.

Article 14.8.19.

**Recommendations for importation from countries or zones considered infected with PPRV**

For milk from sheep and goats

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

- 1) the *milk*:
  - a) originates from *herds* or *flocks* which were not subjected to any restrictions due to PPR at the time of *milk* collection;OR
  - b) has been processed to ensure the destruction of the PPRV in conformity with one of the procedures referred to in Articles 8.6.38. and 8.6.39.;
- 2) the necessary precautions were taken to avoid contact of the products with any potential source of PPRV.

Article 14.8.20.

**Recommendations for importation from countries or zones considered infected with PPRV**

For milk products from sheep and goats

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

- 1) these products are derived from *milk* complying with the requirements of Article 14.8.19.;
- 2) the necessary precautions were taken after processing to avoid contact of the *milk products* with any potential source of PPRV.

Article 14.8.21.

**Recommendations for importation from PPR free countries or zones**

For products of sheep and goats, other than milk, fresh meat and their products

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

- 1) which have been kept in a PPR free country or *zone* since birth or for at least the past 21 days;
- 2) which have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections with favourable results.

Article 14.8.22.

**Recommendations for importation from countries or zones considered infected with PPRV**

For meal and flour from blood, meat, defatted bones, hooves, claws and horns from sheep and goats

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

- 1) the products were processed using heat treatment to a minimum internal temperature of 70°C for at least 30 minutes;
- 2) the necessary precautions were taken after processing to avoid contact of the *commodities* with any potential source of PPRV.

Article 14.8.23.

**Recommendations for importation from countries or zones considered infected with PPRV**

For hooves, claws, bones and horns, hunting trophies and preparations destined for museums from sheep and goats

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

- 1) the products were completely dried and had no trace on them of skin, flesh or tendon or were adequately disinfected; and
- 2) the necessary precautions were taken after processing to avoid contact of the *commodities* with any potential source of PPRV.

Article 14.8.24.

**Recommendations for importation from countries or zones considered infected with PPRV**

For wool, hair, raw hides and skins from sheep and goats

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

- 1) the products were adequately processed in conformity with one of the procedures referred to in Article 8.6.37. in premises controlled and approved by the *Veterinary Authority* of the *exporting country*;
- 2) the necessary precautions were taken after processing to avoid contact of the *commodities* with any potential source of PPRV.

Article 14.8.25.

**Recommendations for importation from countries or zones considered infected with PPRV**

For products of animal origin from sheep and goats intended for pharmaceutical or surgical use

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

- 1) come from *animals* which were slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections with favourable results;
- 2) were processed to ensure the destruction of the PPRV in conformity with one of the procedures referred to in Article 8.6.29. or in Articles 8.6.34. to 8.6.37. as appropriate and in premises controlled and approved by the *Veterinary Authority* of the *exporting country*.

Article 14.8.26.

**Procedures for the inactivation of the PPRV in casings of sheep and goats**

For the inactivation of viruses present in casings of sheep and goats, the following procedures should be used: salting for at least 30 days either with dry salt (NaCl) or with saturated brine ( $A_w < 0.80$ ), and kept at a temperature of greater than 20°C during this entire period.

Article 14.8.27.

**Surveillance: introduction**

Articles 14.8.27. to 14.8.33. define the principles and provide a guide for the *surveillance* of PPR in accordance with Chapter 1.4. applicable to Member Countries seeking recognition of country or zonal freedom from PPR. Guidance is provided for Member Countries seeking reestablishment of freedom following an *outbreak* and for the maintenance of PPR free status.

*Surveillance* strategies employed for demonstrating freedom from PPR at an acceptable level of confidence will need to be adapted to the local situation. *Outbreaks* of PPR may vary in severity with differing clinical presentations believed to reflect variations in host resistance and variations in the virulence of the attacking strain. Experience has shown that *surveillance* based on a predefined set of clinical signs (e.g. searching for 'pneumo-enteritis syndrome') increases the sensitivity of the system. In the case of peracute cases the presenting sign may be sudden death. In the case of sub-acute (mild) cases, clinical signs are displayed irregularly and are difficult to detect.

Where they exist, susceptible domestic species, and feral populations of these species, should be included in the design of the *surveillance* strategy.

*Surveillance* for PPR should be in the form of a continuing programme designed to establish that the whole country or zone is free from PPRV *infection*.

Article 14.8.28.

**Surveillance: general conditions and methods**

- 1) A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. A procedure should be in place for the rapid collection and transport of samples from suspected cases to a *laboratory* for PPR diagnosis.
- 2) The PPR *surveillance* programme should:
  - a) include an early warning system throughout the production, marketing and processing chain for reporting suspected cases. Farmers and workers who have day-to-day contact with livestock, as well as diagnosticians, should report promptly any suspicion of PPR. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All significant epidemiological events consistent with PPR, such as pneumo-enteritis syndrome, should be reported and investigated immediately. Where suspicion cannot be resolved by epidemiological and clinical investigation, samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment be available to those responsible for *surveillance*. Personnel

responsible for *surveillance* should be able to call for assistance from a team with expertise in PPR diagnosis and control;

- b) implement, when relevant, regular and frequent clinical inspection and serological testing of high-risk groups of *animals*, such as those adjacent to a PPRV infected country.

An effective *surveillance* system will periodically identify *animals* with signs suggestive of PPR that require follow-up and investigation to confirm or exclude that the cause of the condition is PPRV. The rate at which such suspected cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from PPRV *infection* should, in consequence, provide details of the occurrence of suspected cases and how they were investigated and dealt with. This should include the results of *laboratory* testing and the control measures to which the *animals* concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

#### Article 14.8.29.

### Surveillance strategies

#### 1. Clinical surveillance

Clinical *surveillance* aims to detect clinical signs of PPR by close physical examination. Clinical *surveillance* and epidemiological investigations are the cornerstone of all *surveillance* systems and should be supported by additional strategies such as virological and serological *surveillance*. Clinical *surveillance* may be able to provide a high level of confidence of detection of *disease* if sufficiently large numbers of clinically susceptible *animals* are examined. It is essential that clinical cases detected be followed up by the collection of appropriate samples such as ocular and nasal swabs, blood or other tissues for virus isolation or virus detection by other means. Sampling units within which suspicious *animals* are detected should be classified as infected until fully investigated.

Active search for clinical *disease* can include participatory *disease* searching, tracing backwards and forwards, and follow-up investigations. Participatory *surveillance* is a form of targeted active *surveillance* based upon methods to capture livestock owners' perceptions on the prevalence and patterns of *disease*.

The labour requirements and the logistical difficulties involved in conducting clinical examinations should be taken into account.

PPRV isolates may be sent to an OIE Reference Laboratory for further characterisation.

#### 2. Virological surveillance

Given that PPR is an acute *infection* with no known carrier state, virological *surveillance* should only be conducted as a follow-up to clinically suspected cases.

#### 3. Serological surveillance

Serological *surveillance* aims to detect antibodies against PPRV. Positive antibody test results can have four possible causes:

- a) natural *infection* with PPRV;
- b) *vaccination* against PPR;
- c) maternal antibodies derived from an immune dam (maternal antibodies in small ruminants can be found only up to six months of age);
- d) heterophile (cross) and other non-specific reactions.

It may be possible to use serum collected for other survey purposes for PPR *surveillance*. However, the principles of survey design described in this chapter and the requirement for a statistically valid survey for the presence of PPRV should not be compromised.

The discovery of clustering of seropositive reactions should be foreseen. It may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of field strain *infection*. As clustering may signal field strain *infection*, the investigation of all instances must be incorporated in the survey design.

The results of random or targeted serological surveys are important in providing reliable evidence that PPRV *infection* is not present in a country or *zone*. It is therefore essential that the survey be adequately documented.

Article 14.8.30.

**Surveillance in wildlife**

Where a population of a susceptible *wildlife* species may act as sentinels indicating the spill over of PPRV from domestic sheep and goats, serosurveillance data should be collected.

Obtaining meaningful data from *surveillance* in *wildlife* can be enhanced by close coordination of activities in a region. Both purposive and opportunistic samplings are used to obtain material for analysis in national or reference *laboratories*. The latter are required because many countries do not have adequate facilities to perform the full testing protocol for detecting antibodies against PPRV in *wildlife* sera.

Targeted sampling is the preferred method to provide *wildlife* data to evaluate the status of *infection* with PPRV. In reality, the capacity to perform *wildlife* sampling is minimal in most countries. However, samples can be obtained from hunted *animals*, and these may provide useful background information.

Article 14.8.31.

**Additional surveillance procedures for Member Countries applying for OIE recognition of PPR free status**

The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances in and around the country or *zone* and should be planned and implemented according to the conditions for status recognition described in Article 14.8.3. and methods in this chapter, to demonstrate absence of PPRV *infection* during the preceding 24 months. This requires the support of a *laboratory* able to undertake identification of PPRV *infection* through virus, antigen or viral nucleic acid detection and antibody tests.

The target population for *surveillance* aimed at identifying *disease* and *infection* should cover significant populations within the country or *zone* to be recognised as free from PPRV *infection*.

The strategy employed should be based on an appropriate combination of randomised and targeted sampling requiring *surveillance* consistent with demonstrating the absence of PPRV *infection* at an acceptable level of statistical confidence. The frequency of sampling should be dependent on the epidemiological situation. Risk-based approaches (e.g. based on the increased likelihood of *infection* in particular localities or species) may be appropriate to refine the *surveillance* strategy. The Member Country should justify the *surveillance* strategy chosen as adequate to detect the presence of PPRV *infection* in accordance with Chapter 1.4. and the epidemiological situation. It may, for example, be appropriate to target clinical *surveillance* at particular subpopulations likely to exhibit clear clinical signs.

Consideration should be given to the risk factors for the presence of PPRV, including:

- 1) historical *disease* patterns;
- 2) critical population size, structure and density;
- 3) livestock husbandry and farming systems;
- 4) movement and contact patterns, such as market and other trade-related movements;
- 5) virulence and infectivity of the strain.

The sample size selected for testing will need to be large enough to detect *infection* if it were to occur at a predetermined minimum rate. The sample size and predetermined minimum *disease* prevalence determine the level of confidence in the results of the survey. The applicant Member Country should justify the choice of design, minimum prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the minimum prevalence in particular should be based on the prevailing or historical epidemiological situation.

Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained.

Irrespective of the testing system employed, *surveillance* design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following-up positives to subsequently determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as *herds* or *flocks* which may be epidemiologically linked to it.

The principles involved in *surveillance* for *disease* or *infection* are technically well defined in Chapter 1.4. The design of *surveillance* programmes to demonstrate the absence of PPRV *infection* needs to be carefully followed to ensure the reliability of results. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.

Article 14.8.32.

**Additional surveillance procedures for recovery of free status**

Following an *outbreak* of PPR in a Member Country at any time after recognition of PPR freedom, the origin of the virus strain should be thoroughly investigated. In particular it is important to determine if this is due to the re-introduction of virus or re-emergence from an undetected focus of *infection*. Ideally, the virus should be isolated and compared with historical strains from the same area as well as those representatives of other possible sources.

After elimination of the *outbreak*, a Member Country wishing to regain the free status should undertake *surveillance* according to this chapter to demonstrate the absence of PPRV *infection*.

Article 14.8.33.

**The use and interpretation of serological tests for serosurveillance of PPR**

Serological testing is an appropriate tool to use for PPR *surveillance* where *vaccination* has not been practised. There is only one serotype of virus and the tests will detect antibodies elicited by *infection* with all PPRV but the tests cannot discriminate between antibodies against field *infection* and those from *vaccination* with attenuated vaccines. This fact compromises serosurveillance in vaccinated populations and meaningful serosurveillance can only commence once *vaccination* has ceased for several years. Antibodies against virulent and vaccine strains of PPRV can be detected in small ruminants from about 14 days post *infection* or *vaccination* and peak around 30 to 40 days. Antibodies then persist for many years, possibly for life, although titres decline with time.

It is necessary to demonstrate that positive serological results have been adequately investigated.

Article 14.8.34.

**OIE endorsed official control programme for PPR**

The objective of an OIE endorsed *official control programme* for PPR is for Member Countries to progressively improve the situation in their territories and eventually attain free status for PPR.

Member Countries may, on a voluntary basis, apply for endorsement of their *official control programme* for PPR when they have implemented measures in accordance with this article.

For a Member Country's *official control programme* for PPR to be endorsed by the OIE, the Member Country should:

- 1) submit documented evidence on the capacity of its *Veterinary Services* to control PPR; this evidence can be provided by countries following the OIE PVS Pathway;
- 2) submit documentation indicating that the *official control programme* for PPR is applicable to the entire territory (even if it is on a zonal basis);
- 3) have a record of regular and prompt animal *disease* reporting according to the requirements in Chapter 1.1.;
- 4) submit a dossier on the status of PPR in the country describing the following:
  - a) the general epidemiology of PPR in the country highlighting the current knowledge and gaps;
  - b) the measures implemented to prevent introduction of *infection*, the rapid detection of, and response to, all PPR *outbreaks* in order to reduce the incidence of *outbreaks* and to eliminate virus circulation in domestic sheep and goats in at least one *zone* in the country;
  - c) the main livestock production systems and movement patterns of sheep and goats and their products within and into the country and, where applicable, the specific *zone(s)*;
- 5) submit a detailed plan of the programme to control and eventually eradicate PPR in the country or *zone* including:
  - a) the timeline for the programme;
  - b) the performance indicators that will be used to assess the efficacy of the control measures;

- 6) submit evidence that PPR *surveillance* is in place, taking into account the provisions in Chapter 1.4. and the provisions on *surveillance* in this chapter;
- 7) have diagnostic capability and procedures in place, including regular submission of samples to a *laboratory*;
- 8) where *vaccination* is practised as a part of the *official control programme* for PPR, provide evidence (such as copies of legislation) that *vaccination* of sheep and goats in the country or *zone* is compulsory;
- 9) if applicable, provide detailed information on *vaccination* campaigns, in particular on:
  - a) the strategy that is adopted for the *vaccination* campaign;
  - b) monitoring of *vaccination* coverage, including serological monitoring of population immunity;
  - c) serosurveillance in other susceptible species, including *wildlife* to serve as sentinels for PPRV circulation in the country;
  - d) *disease surveillance* in sheep and goat populations;
  - e) the proposed timeline for the transition to the cessation of the use of *vaccination* in order to enable demonstration of absence of virus circulation;
- 10) provide an emergency preparedness and contingency response plan to be implemented in case of PPR *outbreak(s)*.

The Member Country's *official control programme* for PPR will be included in the list of programmes endorsed by the OIE only after the submitted evidence has been accepted by the OIE. Retention on the list requires an annual update on the progress of the *official control programme* and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

The OIE may withdraw the endorsement of the *official control programme* if there is evidence of:

- non-compliance with the timelines or performance indicators of the programme; or
  - significant problems with the performance of the *Veterinary Services*; or
  - an increase in the incidence of PPR that cannot be addressed by the programme.
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## CHAPTER 14.9.

### SCRAPIE

#### Article 14.9.1.

##### General provisions and safe commodities

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.

Scrapie is not considered to pose a risk to human health. The recommendations in this chapter are intended to manage the animal health risks associated with the presence of the scrapie agent in sheep and goats. The chapter excludes so-called 'atypical' scrapie because this condition is clinically, pathologically, biochemically and epidemiologically unrelated to 'classical' scrapie, may not be contagious and may, in fact, be a spontaneous degenerative condition of older sheep.

- 1) When authorising import or transit of the following *commodities* derived from sheep or goats and any products made from these *commodities* and containing no other tissues from sheep or goats, *Veterinary Authorities* should not require any scrapie-related conditions, regardless of the scrapie risk status of the sheep and goat populations of the *exporting country, zone or compartment*:
  - a) *in vivo* derived sheep embryos handled in accordance with Chapter 4.7. of this *Terrestrial Code*;
  - b) *meat* (excluding materials as referred to in Article 14.9.12.);
  - c) hides and skins;
  - d) gelatine;
  - e) collagen prepared from hides or skins;
  - f) tallow (maximum level of insoluble impurities of 0.15 percent in weight) and derivatives made from this tallow;
  - g) dicalcium phosphate (with no trace of protein or fat);
  - h) wool or fibre.
- 2) When authorising import or transit of other *commodities* listed in this chapter, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the scrapie risk status of the sheep and goat populations of the *exporting country, zone or compartment*.

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

#### Article 14.9.2.

##### Determination of the scrapie status of the sheep and goat populations of a country, zone, compartment or establishment

The scrapie status of the sheep and goat populations of a country, *zone, compartment or establishment* should 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) importation or introduction of sheep and goats or their semen, *in vivo* derived goat embryos or *in vitro* processed sheep and goat embryos/oocytes potentially infected with scrapie;
  - b) extent of knowledge of the population structure and husbandry practices of sheep and goats;
  - c) feeding practices, including consumption of *meat-and-bone meal* or *greaves* derived from ruminants;
  - d) importation of *milk* and *milk products* of sheep or goats origin intended for use in feeding of sheep and goats;

- 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 1.4.;
  - b) a *Veterinary Authority* with current knowledge of, and authority over, all *establishments* which contain sheep and goats in the whole country;
  - c) compulsory notification and clinical investigation of sheep and goats showing clinical signs compatible with scrapie;
  - d) examination, in accordance with the *Terrestrial Manual*, in a *laboratory* of appropriate material from sheep and goats older than 18 months displaying clinical signs compatible with scrapie;
  - e) maintenance of records including the number and results of all investigations for at least seven years.

Article 14.9.3.

**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 14.9.2., has been conducted, and it has been demonstrated that appropriate measures are currently in place and have been taken for the relevant period of time to manage any *risk* identified and points 2 and 3 have been complied with for the preceding seven years;

AND

- 2) one of the following conditions should be met:
  - a) the country or the *zone* have demonstrated historical freedom as follows:
    - i) scrapie has been notifiable for at least 25 years; and
    - ii) a formal programme of targeted *surveillance* and monitoring, which includes testing of sheep and goats displaying clinical signs compatible with scrapie and those over 18 months of age slaughtered, culled or found dead on farm, can be documented as having been in place for at least 10 years; and
    - iii) appropriate measures to prevent scrapie introduction can be documented as having been in place for at least 25 years; and
      - either scrapie has never been reported; or
      - no case of scrapie has been reported for at least 25 years;
  - b) for at least seven years, sheep and goats displaying clinical signs compatible with scrapie have been tested. Also a sufficient number of sheep and goats over 18 months of age, representative of slaughtered, culled or found dead on farm, have been tested annually, to provide a 95 percent level of confidence of detecting scrapie if it is present in that population at a prevalence rate exceeding 0.1 percent and no case of scrapie has been reported during this period; or
  - c) all *establishments* containing sheep or goats have been accredited free as described in Article 14.9.5.;

AND

- 3) the feeding to sheep and goats of *meat-and-bone meal* or *greaves* of ruminant origin has been banned and effectively enforced in the whole country for at least seven years;

AND

- 4) introductions of sheep and goats or their semen, *in vivo* derived goat embryos or *in vitro* processed sheep and goat embryos/oocytes from countries or *zones* not free from scrapie are carried out in accordance with Articles 14.9.6., 14.9.7., 14.9.8. or 14.9.9., as relevant.

## Article 14.9.4.

**Compartment free from scrapie**

To qualify as a *compartment* free from scrapie, all sheep and goats in a *compartment* should be certified by the *Veterinary Authority* as satisfying the following requirements:

- 1) all *establishments* within the *compartment* are free from scrapie according to Article 14.9.5.;
- 2) all *establishments* within the *compartment* are managed under a common *biosecurity plan* protecting them from introduction of scrapie, and the *compartment* has been approved by the *Veterinary Authority* in accordance with Chapters 4.3. and 4.4.;
- 3) introductions of sheep and goats are allowed only from free *establishments* or free countries;
- 4) introductions of *in vivo* derived goat embryos and *in vitro* processed sheep and goat embryos/oocytes are allowed either from free *establishments* or in accordance with Article 14.9.9.;
- 5) sheep and goat semen should be introduced into the *compartment* in accordance with Article 14.9.8.;
- 6) sheep and goats in the *compartment* should have no direct or indirect contact, including shared grazing, with sheep or goats from *establishments* not within the *compartment*.

## Article 14.9.5.

**Scrapie free establishment**

To qualify as free from scrapie, an *establishment* of sheep and goats should satisfy the following requirements:

- 1) in the country or *zone* where the *establishment* is situated, the following conditions are fulfilled:
  - a) the *disease* is compulsorily notifiable;
  - b) an awareness, *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;
  - c) affected sheep and goats are killed and completely destroyed;
  - d) the feeding to sheep and goats of *meat-and-bone meal* or *greaves* of ruminant origin has been banned and effectively enforced in the whole country for at least seven years;
  - e) an official accreditation scheme is in operation under the supervision of the *Veterinary Authority*, including the measures described in point 2 below;
- 2) in the *establishment* the following conditions have been complied with for at least seven years:
  - a) sheep and goats are 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 maintained;
  - c) introductions of sheep and goats are allowed only from free *establishments* or *establishment* at an equal or higher stage in the process of accreditation;
  - d) introduction of *in vivo* derived goat embryos and *in vitro* processed sheep and goat embryos /oocytes should comply with Article 14.9.9.;
  - e) sheep and goat semen should be introduced into the *establishment* in accordance with Article 14.9.8.;
  - f) an *Official Veterinarian* inspects sheep and goats in the *establishments* and audits the records at least once a year;
  - g) no case of scrapie has been reported;
  - h) sheep and goats of the *establishments* should have no direct or indirect contact, including shared grazing, with sheep or goats from *establishments* of a lower status;
  - i) all culled sheep and goats over 18 months of age are inspected by an *Official Veterinarian*, and a proportion of those exhibiting wasting signs and all those exhibiting neurological signs are tested in a *laboratory* for scrapie. The selection of the sheep and goats to be tested should be made by the *Official Veterinarian*. Sheep and goats 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 those sent for emergency *slaughter*).

Article 14.9.6.

**Recommendations for importation from countries or zones not considered free from scrapie**

For sheep and goats for breeding or rearing

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the *animals* come from an *establishment* free from scrapie as described in Article 14.9.5.

Article 14.9.7.

**Recommendations for importation from countries or zones not considered free from scrapie**

For sheep and goats for slaughter

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

- 1) in the country or *zone*:
  - a) the *disease* is compulsorily notifiable;
  - b) an awareness, *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;
  - c) affected sheep and goats are killed and completely destroyed;
- 2) the sheep and goats selected for export showed no clinical sign of scrapie on the day of shipment.

Article 14.9.8.

**Recommendations for importation from countries or zones not considered free from scrapie**

For semen of sheep and goats

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

- 1) the donor *animals*:
  - a) are permanently identified to enable trace back to their *establishment* of origin;
  - b) showed no clinical sign of scrapie at the time of semen collection;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 14.9.9.

**Recommendations for importation from countries or zones not considered free from scrapie**

For *in vivo* derived goat embryos and *in vitro* processed sheep and goat embryos/oocytes

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

- 1) in the country or *zone*:
  - a) the *disease* is compulsorily notifiable;
  - b) an awareness, *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;
  - c) affected sheep and goats are killed and completely destroyed;
  - d) the feeding to sheep and goats of *meat-and-bone meal* or *greaves* of ruminant origin has been banned and effectively enforced in the whole country;
- 2) the donor *animals* either have been kept since birth in a free *establishment*, or meet the following conditions:
  - 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 Chapters 4.7., 4.8. and 4.9., as relevant.

Article 14.9.10.

**Recommendations for importation from countries or zones not considered free from scrapie**

For milk and milk products of sheep or goat origin intended for use in feeding of sheep and goats

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the *milk* and *milk products* come from scrapie free *establishments*.

Article 14.9.11.

**Recommendations on meat-and-bone meal**

*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 14.9.12.

**Recommendations for importation from countries or zones not considered free from scrapie**

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

- 1) These *commodities* should not be traded for use in ruminant feeds.
- 2) For purposes other than ruminant feeding, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:
  - a) in the country or zone:
    - i) the *disease* is compulsorily notifiable;
    - ii) an awareness, *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;
    - iii) affected sheep and goats are killed and completely destroyed;
  - b) the materials come from sheep and goats that showed no clinical sign of scrapie on the day of *slaughter*.

Article 14.9.13.

**Recommendations for the importation of ovine and caprine materials destined for the preparation of biologicals**

*Veterinary Authorities of importing countries* should require 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*.

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## CHAPTER 14.10.

# SHEEP POX AND GOAT POX

### Article 14.10.1.

#### General provisions

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 14.10.2.

#### 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 three years.

This period shall be six months after the *slaughter* of the last affected *animal* for countries in which a *stamping-out policy* is practised with or without *vaccination* against sheep pox and goat pox.

### Article 14.10.3.

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

### Article 14.10.4.

#### Trade in commodities

*Veterinary Authorities* of sheep pox and goat pox free countries may prohibit importation or transit through their territory, from countries considered infected with sheep pox and goat pox, of domestic sheep and goats.

### Article 14.10.5.

#### Recommendations for importation from sheep pox and goat pox free countries

##### For domestic sheep and goats

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

- 1) showed no clinical sign of 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 14.10.6.

**Recommendations for importation from countries considered infected with sheep pox and goat pox**

For domestic sheep and goats

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

- 1) showed no clinical sign of 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 14.10.7.

**Recommendations for importation from sheep pox and goat pox free countries**

For semen of sheep and goats

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

- 1) showed no clinical sign of 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 14.10.8.

**Recommendations for importation from countries considered infected with sheep pox and goat pox**

For semen of sheep and goats

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

- 1) showed no clinical sign of 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 14.10.9.

**Recommendations for importation from countries considered infected with sheep pox and goat pox**

For skins, fur, wool and hair (from sheep or goats)

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

- 1) come from *animals* which have not been kept in a sheep pox and goat pox *infected zone*; or

- 2) have been processed to ensure the destruction of the sheep pox and goat pox virus, in premises controlled and approved by the *Veterinary Authority* of the *exporting country*.
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## SECTION 15.

### SUIDAE

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#### CHAPTER 15.1.

### AFRICAN SWINE FEVER

#### Article 15.1.1.

##### General provisions

The pig and its close relatives are the only natural hosts for African swine fever virus (ASFV). These include all varieties of *Sus scrofa*, both domestic and wild, warthogs (*Phacochoerus* spp.), bushpigs (*Potamochoerus* spp.) and giant forest hog (*Hylochoerus meinertzhageni*). For the purposes of this chapter, a distinction is made between domestic pigs (permanently captive and farmed free-range pigs) and wild pigs (including feral pigs and wild boar) as well as between *Sus scrofa* and African pig species.

All varieties of *Sus scrofa* are susceptible to the pathogenic effects of ASFV, while the African wild pigs are not and act as reservoirs of the *infection*. Ticks of the genus *Ornithodoros* are natural hosts of the virus and act as biological vectors of the *infection*.

For the purpose of the *Terrestrial Code*, the *incubation period* in *Sus scrofa* is 15 days.

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

#### Article 15.1.2.

##### Determination of the ASF status of a country, zone or compartment

The African swine fever (ASF) status of a country, *zone* or *compartment* can only be determined after considering the following criteria in domestic and wild pigs, as applicable:

- 1) ASF should be notifiable in the whole country, and all clinical signs suggestive of ASF should be subjected to appropriate field and *laboratory* investigations;
- 2) an on-going awareness programme should be in place to encourage reporting of all cases suggestive of ASF;
- 3) the *Veterinary Authority* should have current knowledge of, and authority over, all domestic pigs in the country, *zone* or *compartment*;
- 4) the *Veterinary Authority* should have current knowledge about the species, population and habitat of wild pigs in the country or *zone*.

#### Article 15.1.3.

##### ASF free country, zone or compartment

###### 1. Historically free status

A country or *zone* may be considered free from ASF without formally applying a specific *surveillance* programme if the provisions of Article 1.4.6. are complied with.

2. Free status as a result of an eradication programme

A country or *zone* which does not meet the conditions of point 1 above or a *compartment* may be considered free from ASF when:

- a) there has been no *outbreak* of ASF during the past three years; this period can be reduced to 12 months when there is no evidence of tick involvement in the epidemiology of the *infection*;
- b) no evidence of ASFV *infection* has been found during the past 12 months;
- c) *surveillance* has been in place in domestic pigs for the past 12 months;
- d) imported domestic pigs comply with the requirements in Article 15.1.5. or Article 15.1.6.

AND

Based on *surveillance*, ASF *infection* has been demonstrated not to be present in any wild pig population in the country or *zone*, and:

- e) there has been no clinical evidence, nor virological evidence of ASF in wild pigs during the past 12 months;
- f) no seropositive wild pigs have been detected in the age class 6–12 months during the past 12 months;
- g) imported wild pigs comply with the requirements in Article 15.1.7.

Article 15.1.4.

**Recovery of free status**

Should an ASF *outbreak* occur in a free country, *zone* or *compartment*, the free status may be restored where *surveillance* has been carried out with negative results, either:

- 1) three months after the last *case* where a *stamping-out policy* is practised and in the case where ticks are suspected to be involved in the epidemiology of the *infection*, followed by acaricide treatment and the use of sentinel pigs; or
- 2) where a *stamping-out policy* is not practised, the provisions of point 2 of Article 15.1.3. should be followed.

AND

Based on *surveillance*, ASF *infection* has been demonstrated not to be present in any wild pig population in the country or *zone*.

Article 15.1.5.

**Recommendations for importation from ASF free countries, zones or compartments**

For domestic pigs

*Veterinary Authorities* should require 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, *zone* or *compartment* since birth or for at least the past 40 days.

Article 15.1.6.

**Recommendations for importation from countries or zones considered infected with ASF**

For domestic pigs

*Veterinary Authorities* should require 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 ASF free *compartment*.

Article 15.1.7.

**Recommendations for importation from ASF free countries or zones**

For wild pigs

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

- 1) showed no clinical sign of ASF on the day of shipment;
- 2) have been captured in an ASF free country or zone;

and, if the zone where the *animal* has been captured is adjacent to a zone with *infection* in wild pigs:

- 3) 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 15.1.8.

**Recommendations for importation from ASF free countries, zones or compartments**

For semen of domestic pigs

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

- 1) the donor *animals*:
  - a) were kept in an ASF free country, zone or compartment since birth or for at least 40 days prior to collection;
  - b) showed no clinical sign of ASF on the day of collection of the semen;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 15.1.9.

**Recommendations for importation from countries or zones considered infected with ASF**

For semen of domestic pigs

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

- 1) the donor *animals*:
  - a) were kept in an ASF free compartment since birth or for at least 40 days prior to collection;
  - b) showed no clinical sign of ASF 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 Chapters 4.5. and 4.6.

Article 15.1.10.

**Recommendations for importation from ASF free countries, zones or compartments**

For *in vivo* derived embryos of domestic pigs

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

- 1) the donor females:
  - a) were kept in an ASF free country, zone or compartment since birth or for at least 40 days prior to collection;
  - b) showed no clinical sign of ASF on the day of collection of the embryos;
- 2) the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 15.1.11.

**Recommendations for importation from countries or zones considered infected with ASF**

For *in vivo* derived embryos of domestic pigs

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

- 1) the donor females:
  - a) were kept in an ASF free *compartment* since birth or for at least 40 days prior to collection;
  - b) showed no clinical sign of ASF on the day of collection of the embryos and for the following 40 days;
- 2) the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 15.1.12.

**Recommendations for importation from ASF free countries, zones or compartments**

For fresh meat of domestic pigs

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

- 1) have been kept in an ASF free country, *zone* or *compartment* since birth or for at least the past 40 days, or which have been imported in accordance with Article 15.1.5. or Article 15.1.6.;
- 2) have been slaughtered in an approved *abattoir*, have been subjected to ante- and post-mortem inspections in accordance with Chapter 6.2., and have been found free of any sign suggestive of ASF.

Article 15.1.13.

**Recommendations for importation from ASF free countries or zones**

For fresh meat of wild pigs

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

- 1) the entire consignment of *fresh meat* comes from *animals* which:
  - a) have been killed in an ASF free country or *zone*;
  - b) have been subjected to a post-mortem inspection in accordance with Chapter 6.2. in an approved examination centre, and have been found free of any sign suggestive of ASF;

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* killed and has been subjected to a virological test and a serological test for ASF, with negative results.

Article 15.1.14.

**Recommendations for the importation of 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**

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

- 1) have been prepared:
  - a) exclusively from *fresh meat* meeting the conditions laid down in Articles 15.1.12. or 15.1.13., as relevant;
  - b) in a processing establishment:
    - i) approved by the *Veterinary Authority* for export purposes;
    - ii) processing only *meat* meeting the conditions laid down in Articles 15.1.12. or 15.1.13., as relevant;

OR

- 2) have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the ASFV, and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASFV.

Article 15.1.15.

**Recommendations for the importation of products of animal origin (from pigs, but not derived from fresh meat) intended for use in animal feeding and for agricultural or industrial use**

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

- 1) have been prepared:
  - a) exclusively from *fresh meat* meeting the conditions laid down in Articles 15.1.12. or 15.1.13., as relevant;
  - b) in a processing establishment:
    - i) approved by the *Veterinary Authority* for export purposes;
    - ii) processing only *meat* meeting the conditions laid down in Articles 15.1.12. or 15.1.13., as relevant;

OR

- 2) have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the ASFV, and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASFV.

Article 15.1.16.

**Recommendations for the importation of bristles (from pigs)**

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

- 1) come from an ASF free country, *zone* or *compartment*; or
- 2) have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the ASFV, and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASFV.

Article 15.1.17.

**Recommendations for the importation of litter and manure (from pigs)**

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

- 1) come from an ASF free country, *zone* or *compartment*; or
  - 2) have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the ASFV, and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASFV.
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## CHAPTER 15.2.

# CLASSICAL SWINE FEVER

### Article 15.2.1.

#### General provisions

For the purposes of the *Terrestrial Code*, classical swine fever (CSF) is defined as an *infection* of pigs with classical swine fever virus (CSFV).

The following defines *infection* with CSFV:

- 1) a strain of CSFV (excluding vaccine strains) has been isolated from samples from a pig;

OR

- 2) viral antigen (excluding vaccine strains) has been identified, or viral ribonucleic acid (RNA) specific to a strain of CSFV has been demonstrated to be present, in samples from one or more pigs epidemiologically linked to a confirmed or suspected *outbreak* of CSF, or giving cause for suspicion of previous association or contact with CSFV, with or without clinical signs consistent with CSF;

OR

- 3) virus specific antibodies to CSFV that are not a consequence of *vaccination* or *infection* with other pestiviruses, have been identified in samples from one or more pigs in a *herd* showing clinical signs consistent with CSF, or epidemiologically linked to a confirmed or suspected *outbreak* of CSF, or giving cause for suspicion of previous association or contact with CSFV.

The pig is the only natural host for CSFV. The definition of pig includes all varieties of *Sus scrofa*, both domestic and wild. For the purposes of this chapter, a distinction is made between:

- domestic and captive wild pigs, permanently captive or farmed free range, used for the production of *meat*, or other commercial products or use, or for breeding these categories of pigs;
- wild and feral pigs.

Pigs exposed to CSFV prenatally may be persistently infected throughout life and may have an *incubation period* of several months before showing signs of *disease*. Pigs exposed postnatally have an *incubation period* of 2–14 days, and are usually infective between post-*infection* days 5 and 14, but up to 3 months in cases of chronic *infections*.

A Member Country should not impose bans on the trade in *commodities* of domestic and captive wild pigs in response to a *notification of infection* with CSFV in wild and feral pigs provided that Article 15.2.2. is implemented.

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

### Article 15.2.2.

#### General criteria for the determination of the CSF status of a country, zone or compartment

- 1) CSF should be notifiable in the whole territory, and all pigs showing clinical signs suggestive of CSF should be subjected to appropriate field or *laboratory* investigations;
- 2) an on-going awareness programme should be in place to encourage reporting of all cases suggestive of CSF;
- 3) the *Veterinary Authority* should have current knowledge of, and authority over, all domestic and captive wild pig *herds* in the country, *zone* or *compartment*;
- 4) the *Veterinary Authority* should have current knowledge about the population and habitat of wild and feral pigs in the country or *zone*;
- 5) for domestic and captive wild pigs, appropriate *surveillance* in accordance with Articles 15.2.26. to 15.2.32. is in place;
- 6) for wild and feral pigs, if present in the country or *zone*, a *surveillance* programme is in place according to Article 15.2.31., taking into account the presence of natural and artificial boundaries, the ecology of the wild and feral pig population, and an assessment of the *risks* of *disease* spread.

- 7) Based on the assessed *risk* of spread within the wild and feral pig population, and according to Article 15.2.29., the domestic and captive wild pig population should be separated from the wild and feral pig population by appropriate measures.

## Article 15.2.3.

**CSF free country or zone**

A country or *zone* may be considered free from CSF when Article 15.2.2. is complied with, and when:

- 1) *surveillance* in accordance with Articles 15.2.26. to 15.2.32. has been in place for at least 12 months;
- 2) there has been no *outbreak* of CSF in domestic and captive wild pigs during the past 12 months;
- 3) no evidence of *infection* with CSFV has been found in domestic and captive wild pigs during the past 12 months;
- 4) no *vaccination* against CSF has been carried out in domestic and captive wild pigs during the past 12 months unless there are means, validated according to Chapter 2.8.3. of the *Terrestrial Manual*, of distinguishing between vaccinated and infected pigs;
- 5) imported pigs and pig *commodities* comply with the requirements in Articles 15.2.7. to 15.2.14.

The country or the proposed free *zone* will be included in the list of CSF free countries or *zones* only after the submitted evidence, based on the provisions of Article 1.6.9., has been accepted by the OIE.

Retention on the list requires that the information in points 1 to 5 above be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

## Article 15.2.4.

**CSF free compartment**

The bilateral recognition of a CSF free *compartment* should follow the relevant requirements of this chapter and the principles laid down in Chapters 4.3. and 4.4.

## Article 15.2.5.

**Establishment of a containment zone within a CSF free country or zone**

In the event of limited *outbreaks* or *cases* of CSF within a CSF free country or *zone*, including within a *protection zone*, a *containment zone*, which includes all *outbreaks*, can be established for the purpose of minimising the impact on the entire country or *zone*.

For this to be achieved and for the Member Country to take full advantage of this process, the *Veterinary Authority* should submit documented evidence as soon as possible to the OIE.

In addition to the requirements for the establishment of a *containment zone* outlined in point 3 of Article 4.3.3., the *surveillance* programme should take into consideration the involvement of wild and feral pigs and measures to avoid their dispersion.

The free status of the areas outside the *containment zone* is suspended while the *containment zone* is being established. The free status of these areas may be reinstated irrespective of the provisions of Article 15.2.6., once the *containment zone* is clearly established. It should be demonstrated that *commodities* for *international trade* have originated outside the *containment zone*.

In the event of the recurrence of CSF in the *containment zone*, the approval of the *containment zone* is withdrawn.

The recovery of the CSF free status of the *containment zone* should follow the provisions of Article 15.2.6.

Article 15.2.6.

**Recovery of free status**

Should a CSF *outbreak* occur in a free country or *zone*, the free status may be restored where *surveillance* in accordance with Articles 15.2.26. to 15.2.32. has been carried out with negative results either:

1) three months after the last *case* where a *stamping-out policy* without *vaccination* is practised;

OR

2) where a *stamping-out policy* with emergency *vaccination* is practised:

a) three months after the last *case* and the *slaughter* of all vaccinated *animals*, or

b) three months after the last *case* without the *slaughter* of vaccinated *animals* where there are means, validated according to Chapter 2.8.3. of the *Terrestrial Manual*, of distinguishing between vaccinated and infected pigs;

OR

3) where a *stamping-out policy* is not practised, the provisions of Article 15.2.3. should be followed.

The country or *zone* will regain CSF free status only after the submitted evidence, based on the provisions of Article 1.6.9., has been accepted by the OIE.

Article 15.2.7.

**Recommendations for importation from countries, zones or compartments free from CSF**

For domestic and captive wild pigs

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

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

2) were kept in a country, *zone* or *compartment* free from CSF since birth or for at least the past three months;

3) have not been vaccinated against CSF, nor are they the progeny of vaccinated sows, unless there are means, validated according to Chapter 2.8.3. of the *Terrestrial Manual*, of distinguishing between vaccinated and infected pigs.

Article 15.2.8.

**Recommendations for importation from countries or zones considered infected with CSF**

For domestic and captive wild pigs

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

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

2) were kept since birth or for the past three months in a CSF free *compartment*;

3) have not been vaccinated against CSF nor are they the progeny of vaccinated sows, unless there are means, validated according to Chapter 2.8.3. of the *Terrestrial Manual*, of distinguishing between vaccinated and infected pigs.

Article 15.2.9.

**Recommendations for the importation of wild and feral pigs**

Regardless of the CSF status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the *animals*:

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

2) were kept in a *quarantine station* for 40 days prior to shipment, and were subjected to a virological test and a serological test performed at least 21 days after entry into the *quarantine station*, with negative results;

3) have not been vaccinated against CSF, unless there are means, validated according to Chapter 2.8.3. of the *Terrestrial Manual*, of distinguishing between vaccinated and infected pigs.



Article 15.2.10.

**Recommendations for importation from countries, zones or compartments free from CSF**

For semen of domestic and captive wild pigs

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

- 1) the donor *animals*:
  - a) were kept in a country, *zone* or *compartment* free from CSF since birth or for at least three months prior to collection;
  - b) showed no clinical sign of CSF on the day of collection of the semen;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 15.2.11.

**Recommendations for importation from countries or zones considered infected with CSF**

For semen of domestic and captive wild pigs

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

- 1) the donor *animals*:
  - a) were kept in a *compartment* free from CSF since birth or for at least three months prior to collection;
  - b) showed no clinical sign of CSF on the day of collection of the semen and for the following 40 days;
  - c) met one of the following conditions:
    - i) have not been vaccinated against CSF and were subjected to a serological test performed at least 21 days after collection, with negative results; or
    - ii) have been vaccinated against CSF and were subjected to a serological test performed at least 21 days after collection and it has been conclusively demonstrated that any antibody is due to the vaccine; or
    - iii) have been vaccinated against CSF and were subjected to a virological test performed on a sample taken on the day of collection and it has been conclusively demonstrated that the boar is negative for virus genome;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 15.2.12.

**Recommendations for importation from countries, zones or compartments free from CSF**

For *in vivo* derived embryos of domestic pigs

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

- 1) the donor females showed no clinical sign of CSF on the day of collection of the embryos;
- 2) the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 15.2.13.

**Recommendations for importation from countries or zones considered infected with CSF**

For *in vivo* derived embryos of domestic pigs

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

- 1) the donor females:
  - a) were kept in a *compartment* free from CSF since birth or for at least three months prior to collection;
  - b) showed no clinical sign of CSF on the day of collection of the embryos and for the following 40 days;
  - c) and either:
    - i) have not been vaccinated against CSF and were subjected, with negative results, to a serological test performed at least 21 days after collection; or

- ii) have been vaccinated against CSF and were subjected to a serological test performed at least 21 days after collection and it has been conclusively demonstrated by means, validated according to Chapter 2.8.3. of the *Terrestrial Manual*, that any antibody is due to the vaccine;
- 2) the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 15.2.14.

#### **Recommendations for importation from countries, zones or compartments free from CSF**

##### For fresh meat of domestic and captive wild pigs

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

- 1) have been kept in a country, *zone* or *compartment* free from CSF, or which have been imported in accordance with Article 15.2.7. or Article 15.2.8.;
- 2) have been slaughtered in an approved *slaughterhouse/abattoir*, have been subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. and have been found free from any sign suggestive of CSF.

Article 15.2.15.

#### **Recommendations for the importation of fresh meat of wild and feral pigs**

Regardless of the CSF status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat* comes from *animals*:

- 1) which have been subjected to a post-mortem inspection in accordance with Chapter 6.2. in an approved examination centre, and have been found free from any sign suggestive of CSF;
- 2) from each of which a sample has been collected and has been subjected to a virological test and a serological test for CSF, with negative results.

Article 15.2.16.

#### **Recommendations for the importation of meat and meat products of pigs intended for use in animal feeding, for agricultural or industrial use, or for pharmaceutical or surgical use**

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

- 1) have been prepared:
  - a) exclusively from *fresh meat* meeting the conditions laid down in Article 15.2.14.;
  - b) in a processing establishment:
    - i) approved by the *Veterinary Authority* for export purposes;
    - ii) processing only *meat* meeting the conditions laid down in Article 15.2.14.;

OR

- 2) have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSFV in conformity with one of the procedures referred to in Article 15.2.23., and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSFV.

Article 15.2.17.

**Recommendations for the importation of pig products not derived from fresh meat intended for use in animal feeding**

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

- 1) originated from domestic and captive wild pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or
- 2) have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSFV in accordance with Article 15.2.22., and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSFV.

Article 15.2.18.

**Recommendations for the importation of pig products not derived from fresh meat intended for agricultural or industrial use**

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

- 1) originated from domestic and captive wild pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or
- 2) have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSFV, and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSFV.

Article 15.2.19.

**Recommendations for the importation of bristles**

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

- 1) originated from domestic and captive wild pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or
- 2) have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSFV, and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSFV.

Article 15.2.20.

**Recommendations for the importation of litter and manure**

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

- 1) originated from domestic and captive wild pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or
- 2) have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSFV, and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSFV.

Article 15.2.21.

**Recommendations for the importation of skins and trophies**

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

- 1) originated from domestic and captive wild pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or
- 2) have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSFV in conformity with one of the procedures referred to in Article 15.2.25., and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSFV.

Article 15.2.22.

**Procedures for the inactivation of the CSFV in swill**

For the inactivation of CSFV in swill, one of the following procedures should be used:

- 1) the swill should be maintained at a temperature of at least 90°C for at least 60 minutes, with continuous stirring; or
- 2) the swill should be maintained at a temperature of at least 121°C for at least 10 minutes at an absolute pressure of 3 bar.

Article 15.2.23.

**Procedures for the inactivation of the CSFV in meat**

For the inactivation of CSFV in *meat*, one of the following procedures should be used:

1. Heat treatment

*Meat* should be subjected to one of the following treatments:

- a) heat treatment in a hermetically sealed container with a  $F_0$  value of 3.00 or more;
- b) heat treatment at a minimum temperature of 70°C, which should be reached throughout the *meat*.

2. Natural fermentation and maturation

The *meat* should be subjected to a treatment consisting of natural fermentation and maturation having the following characteristics:

- a) an  $a_w$  value of not more than 0.93, or
- b) a pH value of not more than 6.0.

Hams should be subjected to a natural fermentation and maturation process for at least 190 days and loins for 140 days.

3. Dry cured pork meat

- a) Italian style hams with bone-in should be cured with salt and dried for a minimum of 313 days.
- b) Spanish style pork *meat* with bone-in should be cured with salt and dried for a minimum of 252 days for Iberian hams, 140 days for Iberian shoulders, 126 days for Iberian loin, and 140 days for Serrano hams.

Article 15.2.24.

**Procedures for the inactivation of the CSFV in casings of pigs**

For the inactivation of CSFV in casings of pigs, the following procedures should be used: salting for at least 30 days either with phosphate supplemented dry salt or saturated brine ( $A_w < 0.80$ ) containing 86.5% NaCl, 10.7%  $Na_2HPO_4$  and 2.8%  $Na_3PO_4$  (weight/weight/weight), and kept at a temperature of greater than 20°C during this entire period.

## Article 15.2.25.

**Procedures for the inactivation of the CSFV in skins and trophies**

For the inactivation of CSFV in skins and trophies, one of the following procedures should be used:

- 1) boiling in water for an appropriate time so as to ensure that any matter other than bone, tusks or teeth is removed;
- 2) gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher);
- 3) soaking, with agitation, in a 4 percent (w/v) solution of washing soda (sodium carbonate – Na<sub>2</sub>CO<sub>3</sub>) 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 percent washing soda (sodium carbonate – Na<sub>2</sub>CO<sub>3</sub>).

## Article 15.2.26.

**Surveillance: introduction**

Articles 15.2.26. to 15.2.32. define the principles and provide a guide on the *surveillance* for CSF, complementary to Chapter 1.4., applicable to Member Countries seeking the OIE recognition of CSF status. This may be for the entire country or a *zone*. Guidance is also provided for Member Countries seeking recovery of CSF status for the entire country or for a *zone* following an *outbreak* and for the maintenance of CSF status.

The impact and epidemiology of CSF may vary in different regions of the world. The *surveillance* strategies employed for demonstrating freedom from CSF at an acceptable level of confidence should be adapted to the local situation. For example, the approach should be tailored in order to prove freedom from CSF for a country or *zone* where wild and feral pigs provide a potential reservoir of *infection*, or where CSF is present in adjacent countries. The method should examine the epidemiology of CSF in the region concerned and adapt to the specific risk factors encountered. This should include provision of scientifically based supporting data. There is, therefore, latitude available to Member Countries to provide a well-reasoned argument to prove that absence of *infection* with CSFV is assured at an acceptable level of confidence.

*Surveillance* for CSF should be in the form of a continuing programme designed to establish that susceptible populations in a country, *zone* or *compartment* are free from *infection* with CSFV or to detect the introduction of CSFV into a population already defined as free. Consideration should be given to the specific characteristics of CSF epidemiology which include:

- the role of swill feeding, the impact of different production systems and the role of wild and feral pigs on *disease* spread;
- the role of semen in transmission of the virus;
- the lack of pathognomonic gross lesions and clinical signs;
- the frequency of clinically inapparent *infections*;
- the occurrence of persistent and chronic *infections*;
- the genotypic, antigenic, and virulence variability exhibited by different strains of CSFV.

## Article 15.2.27.

**Surveillance: general conditions and methods**

- 1) A *surveillance* system in accordance with Chapter 1.4. and under the responsibility of the *Veterinary Authority* should address the following aspects:
  - a) formal and ongoing system for detecting and investigating *outbreaks* of *disease* or CSFV *infection* should be in place;
  - b) a procedure should be in place for the rapid collection and transport of samples from suspected cases to a laboratory for CSF diagnosis;
  - c) a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.
- 2) The CSF *surveillance* programme should:
  - a) include an early warning system throughout the production, marketing and processing chain for reporting suspected cases. Diagnosticians and those with regular contact with pigs should report promptly any

suspicion of CSF to the *Veterinary Authority*. The *notification* system under the *Veterinary Authority* should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes. Since many strains of CSFV do not induce pathognomonic gross lesions or clinical signs, cases in which CSF cannot be ruled out should be immediately investigated. Other important *diseases* such as African swine fever should also be considered in any differential diagnosis. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in CSF diagnosis, epidemiological evaluation, and control;

- b) implement, when relevant, regular and frequent clinical inspections and laboratory testing of high-risk groups (for example, where swill feeding is practised), or those adjacent to a CSF infected country or *zone* (for example, bordering areas where infected wild and feral pigs are present).

An effective *surveillance* system will periodically identify suspected cases that require follow-up and investigation to confirm or exclude *infection* with CSFV. The rate at which such suspected cases are likely to occur will differ between epidemiological situations and cannot, therefore, be reliably predicted. Applications for recognition of CSF status should, as a consequence, provide details in accordance with Article 1.6.9. of the occurrence of suspected cases and how they were investigated and dealt with.

#### Article 15.2.28.

### Surveillance strategies

#### 1. Introduction

The population covered by *surveillance* aimed at detecting *disease* and *infection* should include domestic and wild pig populations within the country or *zone* to be recognised as free from *infection* with CSFV.

The strategy employed to establish the prevalence or absence of CSFV *infection* may be based on randomised or targeted clinical investigation or sampling at an acceptable level of statistical confidence. If an increased likelihood of *infection* in particular localities or sub-populations can be identified, targeted sampling may be an appropriate strategy. This may include:

- a) swill fed farms;
- b) pigs reared outdoors;
- c) specific high-risk wild and feral pig sub-populations and their proximity.

Risk factors may include temporal and spatial distribution of past *outbreaks*, pig movements and demographics, etc.

For reasons of cost, persistence of antibody levels and the existence of clinically inapparent *infections*, serology in unvaccinated populations is often the most effective and efficient *surveillance* methodology. In some circumstances such as differential diagnosis of other *diseases*, clinical and virological *surveillance* may also have value.

The *surveillance* strategy chosen should be justified as adequate to detect the presence of *infection* with CSFV in accordance with Chapter 1.4. and the epidemiological situation. Cumulative survey results in combination with the results of routine *surveillance*, over time, will increase the level of confidence in the *surveillance* strategy.

When applying randomised sampling, either at the level of the entire population or within targeted sub-populations, the design of the sampling strategy should incorporate epidemiologically appropriate design prevalences for the selected populations. The sample size selected for testing should be large enough to detect *infection* if it were to occur at a predefined minimum rate. The choice of design prevalence and confidence level should be justified based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular, needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the approach selected, the sensitivity and specificity of the diagnostic tests should be considered in the survey design, the sample size determination and the interpretation of the results obtained.

The *surveillance* system design should anticipate the occurrence of false positive reactions. This is especially true of the serological diagnosis of CSF because of the recognized cross-reactivity with ruminant pestiviruses. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether or not they are indicative of *infection* with CSFV. This should involve confirmatory and differential tests for pestiviruses, as well as further investigations concerning the original sampling unit as well as *animals* which may be epidemiologically linked.

#### 2. Clinical surveillance

Clinical *surveillance* continues to be the cornerstone of CSF detection. However, due to the low virulence of some CSFV strains and the spread of *diseases* such as African swine fever, and those associated with porcine circovirus

2 *infection*, clinical surveillance should be supplemented, as appropriate, by serological and virological surveillance.

Clinical signs and pathological findings are useful for early detection; in particular, any cases where clinical signs or lesions suggestive of CSF are accompanied by high morbidity or mortality, these should be investigated without delay. In CSFV *infections* involving low virulence strains, high mortality may only be seen in young *animals* and adults may not present clinical signs.

Wild and feral pigs rarely present the opportunity for clinical observation, but should form part of any surveillance scheme and should, ideally, be monitored for virus as well as antibody.

### 3. Virological surveillance

Virological surveillance should be conducted:

- a) to monitor at risk populations;
- b) to investigate clinically suspected cases;
- c) to follow up positive serological results;
- d) to investigate increased mortality.

Molecular detection methods can be applied to large-scale screening for the presence of virus. If targeted at high-risk groups, they provide an opportunity for early detection that can considerably reduce the subsequent spread of *disease*. Epidemiological understanding of the pathways of spread of CSFV can be greatly enhanced by molecular analyses of viruses in endemic areas and those involved in *outbreaks* in *disease* free areas. Therefore, CSFV isolates should be sent to an OIE Reference Laboratory for further characterisation.

### 4. Serological surveillance

Serological surveillance aims at detecting antibodies against CSFV. Positive CSFV antibody test results can have five possible causes:

- a) natural *infection* with CSFV;
- b) *vaccination* against CSF;
- c) maternal antibodies;
- d) cross-reactions with other pestiviruses;
- e) non-specific reactors.

The *infection* of pigs with other pestiviruses may complicate a surveillance strategy based on serology. Antibodies to bovine viral diarrhoea viruses (BVDV) and Border disease virus (BDV) can give positive results in serological tests for CSF, due to common antigens. Such samples will require differential tests to confirm their identity. One route by which ruminant pestiviruses can infect pigs is the use of vaccines contaminated with BVDV.

CSFV may lead to persistently infected, sero-negative young *animals*, which continuously shed virus. CSFV *infection* may also lead to chronically infected pigs which may have undetectable or fluctuating antibody levels. Even though serological methods will not detect these *animals*, such *animals* are likely to be in a minority and would not confound a diagnosis based on serology as part of a *herd* investigation.

It may be possible to use sera collected for other survey purposes for CSF surveillance. However, the principles of survey design and the requirement for statistical validity should not be compromised.

In countries or *zones* where *vaccination* has been recently discontinued, targeted serosurveillance of young unvaccinated *animals* can indicate the presence of *infection*. Maternal antibodies are usually found up to 8-10 weeks of age but may be occasionally last up to four and a half months and can interfere with the interpretation of serological results.

Marker vaccines and accompanying DIVA tests which fulfil the requirements of the *Terrestrial Manual* may allow discrimination between vaccinal antibody and that induced by natural *infection*. The serosurveillance results using DIVA techniques may be interpreted either at animal or *herd* level.

Member Countries should review their surveillance strategies whenever an increase in the *risk* of incursion of CSFV is perceived. Such changes include but are not limited to:

- a) an emergence or an increase in the prevalence of CSF in countries or *zones* from which live pigs or products are imported;
- b) an increase in the prevalence of CSF in wild or feral pigs in the country or *zone*;
- c) an increase in the prevalence of CSF in adjacent countries or *zones*;
- d) an increased entry from, or exposure to, infected wild or feral pig populations of adjacent countries or *zones*.

Article 15.2.29.

**Additional surveillance procedures for Member Countries applying for OIE recognition of CSF free status**

The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances in and around the country or *zone* and should be planned and implemented according to the conditions for status recognition described in Article 15.2.2. and 15.2.3. and methods described elsewhere in this chapter. The objective is to demonstrate the absence of *infection* with CSFV in domestic and captive wild pigs during the last 12 months and to assess the *infection* status in wild and feral pig populations as described in Article 15.2.31.

Article 15.2.30.

**Additional surveillance procedures for recovery of free status**

In addition to the general conditions described in this chapter, a Member Country seeking recovery of country or *zone* CSF free status, including a *containment zone*, should show evidence of an active *surveillance* programme to demonstrate absence of *infection* with CSFV.

Populations under this *surveillance* programme should include:

- 1) *establishments* in the proximity of the *outbreaks*;
- 2) *establishments* epidemiologically linked to the *outbreaks*;
- 3) *animals* moved from or used to re-populate affected *establishments*;
- 4) any *establishments* where contiguous culling has been carried out;
- 5) wild and feral pig populations in the area of the *outbreaks*.

The domestic and captive wild pig populations should undergo regular clinical, pathological, virological and serological examinations, planned and implemented according to the general conditions and methods described in these recommendations. Epidemiological evidence of the *infection* status in wild and feral pigs should be compiled. To regain CSF free status, the *surveillance* approach should provide at least the same level of confidence as within the original application for recognition of freedom.

Article 15.2.31.

**Surveillance for CSFV in wild and feral pigs**

- 1) The objective of a *surveillance* programme is either to demonstrate that CSFV *infection* is not present in wild and feral pigs or, if known to be present, to estimate the distribution and prevalence of the *infection*. While the same principles apply, *surveillance* in wild and feral pigs presents additional challenges including:
  - a) determination of the distribution, size and movement patterns associated with the wild and feral pig population;
  - b) relevance and practicality of assessing the possible presence of CSFV *infection* within the population;
  - c) determination of the practicability of establishing a *zone* taking into account the degree of interaction with domestic and captive wild pigs within the proposed *zone*.

The geographic distribution and estimated size of wild and feral pig populations need to be assessed as a prerequisite for designing a monitoring system. Sources of information to aid in the design of a monitoring system may include governmental and non-governmental *wildlife* organisations such as hunter associations.

- 2) For implementation of the monitoring programme, it will be necessary to define the limits of the area over which wild and feral pigs range, in order to delineate the *epidemiological units* within the monitoring programme. It is often

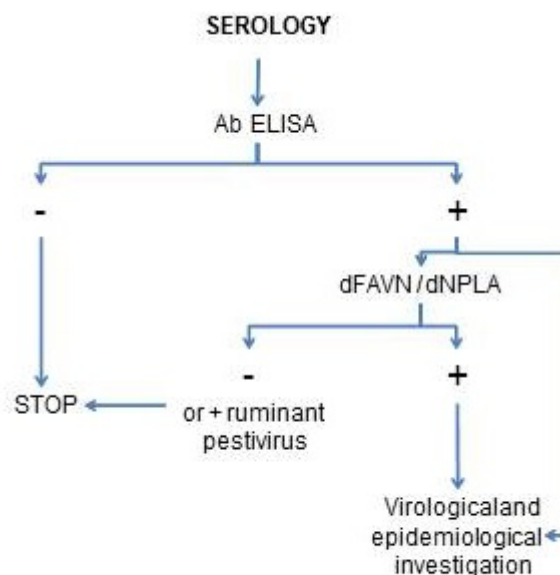


difficult to define *epidemiological units* for wild and feral pigs. The most practical approach is based on natural and artificial barriers.

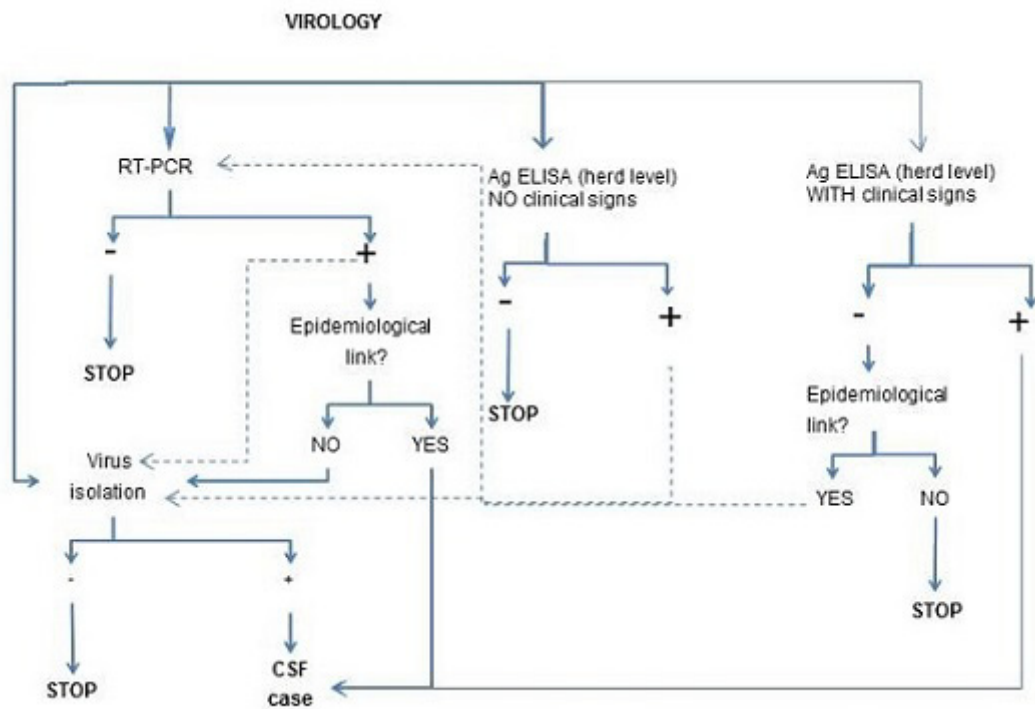
- 3) The monitoring programme should involve serological and virological testing, including *animals* found dead, road kills, *animals* showing abnormal behaviour or exhibiting gross lesions during dressing.
- 4) There may be situations where a more targeted *surveillance* programme can provide additional assurance. The criteria to define high risk areas for targeted *surveillance* include:
  - a) areas with past history of CSF;
  - b) sub-regions with large populations of wild and feral pigs;
  - c) border regions with CSF affected countries or *zones*;
  - d) interface between wild and feral pig populations, and domestic and captive wild pig populations;
  - e) farms with free-ranging pigs;
  - f) other risk areas determined by the *Veterinary Authority* such as garbage dumps and picnic and camping areas.

Article 15.2.32.

#### The use and interpretation of diagnostic tests in surveillance



Key words:	
Ab ELISA	Antibody detection ELISA
dFAVN	Differential fluorescent virus neutralisation
dNPLA	Differential neutralisation peroxidase linked assay



Key words:	
Ag ELISA	Antigen capture ELISA
RT-PCR	Reverse transcription polymerase chain reaction

## CHAPTER 15.3.

# PORCINE BRUCELLOSIS

Article 15.3.1.

### General provisions

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

Article 15.3.2.

### 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 three 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 15.3.3.

### Recommendations for the importation of pigs for breeding or rearing

*Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that the *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 15.3.4.

### Recommendations for the importation of pigs for slaughter

*Veterinary Authorities of importing countries* should require 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 15.3.5.

### Recommendations for the importation of semen of pigs

*Veterinary Authorities of importing countries* should require 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 Chapters 4.5. and 4.6.
-

## CHAPTER 15.4.

# SWINE VESICULAR DISEASE

### Article 15.4.1.

#### General provisions

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

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

### Article 15.4.2.

#### SVD free country

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

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

### Article 15.4.3.

#### SVD infected zone

A *zone* shall be considered as infected with SVD until:

- 1) at least 60 days have elapsed after the confirmation of the last *case* and the completion of a *stamping-out policy* and *disinfection* procedures, or
- 2) 12 months have elapsed after the clinical recovery or *death* of the last affected *animal* if a *stamping-out policy* was not practised.

### Article 15.4.4.

#### Trade in commodities

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

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

Article 15.4.5.

**Recommendations for importation from SVD free countries**

For domestic pigs

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

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

Article 15.4.6.

**Recommendations for importation from SVD free countries**

For wild pigs

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

- 1) showed no clinical sign of SVD on the day of shipment;
- 2) come from an SVD free country;

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 six weeks prior to shipment.

Article 15.4.7.

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

For domestic pigs

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

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

Article 15.4.8.

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

For wild pigs

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

- 1) showed no clinical sign of SVD on the day of shipment;
- 2) were kept in a *quarantine station* for the 28 days prior to shipment, and were subjected to the virus neutralisation test for SVD with negative results during that period.

Article 15.4.9.

**Recommendations for importation from SVD free countries**

For semen of pigs

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

- 1) the donor *animals*:
  - a) showed no clinical sign of SVD on the day of collection of the semen;
  - b) were kept in an SVD free country for not less than six weeks prior to collection;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 15.4.10.

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

For semen of pigs

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

- 1) the donor *animals*:
  - a) showed no clinical sign of SVD on the day of collection of the semen, and were subjected to the virus neutralisation test for SVD with negative results;
  - b) were kept in the *exporting country* for the 28 days prior to collection, in an *establishment* or *artificial insemination centre* where no case of SVD was officially reported during that period, and that the *establishment* or *artificial insemination centre* was not situated in an SVD *infected zone*;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 15.4.11.

**Recommendations for importation from SVD free countries**

For fresh meat of pigs

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

- 1) have been kept in an SVD free country since birth or for at least the past 28 days;
- 2) have been slaughtered in an approved *abattoir*, and have been subjected to ante- and post-mortem inspections for SVD with favourable results.

Article 15.4.12.

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

For fresh meat of pigs

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

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

Article 15.4.13.

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

For meat products of pigs

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

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

Article 15.4.14.

**Recommendations for importation from SVD free countries**

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

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

Article 15.4.15.

**Recommendations for importation from SVD free countries**

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

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

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

Article 15.4.16.

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

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

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

Article 15.4.17.

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

For bristles (from pigs)

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

Article 15.4.18.

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

For fertilisers of animal origin (from pigs)

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

- 1) do not come from an SVD *infected zone*; or
- 2) have been processed to ensure the destruction of the SVD virus.



Article 15.4.19.

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

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

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

- 1) have been processed to ensure the destruction of the SVD virus;
  - 2) come from *animals* which have not been kept in an SVD *infected zone*;
  - 3) come from *animals* which have been slaughtered in an approved *abattoir* and have been subjected to ante- and post-mortem inspections for SVD with favourable results.
-

## CHAPTER 15.5.

# TRANSMISSIBLE GASTROENTERITIS

### Article 15.5.1.

#### General provisions

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 15.5.2.

#### Recommendations for the importation of pigs for breeding or rearing

*Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that the *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 three years.

### Article 15.5.3.

#### Recommendations for the importation of pigs for slaughter

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

- 1) showed no clinical sign of 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 15.5.4.

#### Recommendations for the importation of semen of pigs

*Veterinary Authorities of importing countries* should require 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 three years;

and in all situations:

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