WORLD ORGANISATION FOR ANIMAL HEALTH

Protecting animals, preserving our future

TERRESTRIAL ANIMAL HEALTH CODE

VOLUME I

General provisions

Twenty-second edition, 2013
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General provisions

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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 22nd edition incorporates modifications to the Terrestrial Code agreed at the 81st 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 Chlamyphilia abortus (encephalitis abortion of ewes); infection with pest 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.
Foreword

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 22nd edition of the Terrestrial Code.

Members of the OIE Code Commission (2013):
President: Dr A. Thiermann
Vice-President: Dr E. Bonbon
Secretary General: Dr J. Caetano
Members: Dr S.C. MacDiarmid, Dr Salah Hammami and Dr Toshiyuki Tsutsui

August 2013
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

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.
Glossary

**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.

**Eradiation**

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.

Infecitive 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.
Glossary

**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.
Glossary

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.
Glossary

**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.
SECTION 1.

ANIMAL DISEASE DIAGNOSIS, SURVEILLANCE AND NOTIFICATION

CHAPTER 1.1.

NOTIFICATION OF DISEASES, INFECTIONS, INFESTATIONS AND EPIDEMIOLOGICAL INFORMATION

Article 1.1.1.

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

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

Article 1.1.2.

1) Member Countries shall make available to other Member Countries, through the OIE, whatever information is necessary to minimise the spread of important animal diseases, and their aetiological agents, and to assist in achieving better worldwide control of these diseases.

2) To achieve this, Member Countries shall comply with the notification requirements specified in Article 1.1.3.

3) To assist in the clear and concise exchange of information, reports shall conform as closely as possible to the official OIE disease reporting format.

4) Recognising that scientific knowledge concerning the relationship between diseases and their aetiological agents is constantly developing and that the presence of an aetiological agent does not necessarily imply the presence of a disease, Member Countries shall ensure through their reports that they comply with the spirit and intention of point 1 above. This means that the detection of the aetiological agent of a listed disease in an animal should be reported, even in the absence of clinical disease.

5) In addition to notifying new findings in accordance with Article 1.1.3., Member Countries shall also provide information on the measures taken to prevent the spread of diseases, infections and infestations; including quarantine measures and restrictions on the movement of animals, animal products, biological products and other miscellaneous objects which could by their nature be responsible for their transmission. In the case of diseases transmitted by vectors, the measures taken against such vectors shall also be specified.

Article 1.1.3.

Veterinary Authorities shall, under the responsibility of the Delegate, send to the Headquarters:

1) in accordance with relevant provisions in the disease-specific chapters, notification through the World Animal Health Information System (WAHIS) or by fax or e-mail, within 24 hours, of any of the following events:

a) first occurrence of a listed disease, infection or infestation in a country, a zone or a compartment;
Chapter 1.1.- Notification of diseases, infections, infestations and epidemiological information

b) re-occurrence of a listed disease, infection or infestation in a country, a zone or a compartment following a report declared the outbreak ended;

c) first occurrence of a new strain of a pathogen of a listed disease, infection or infestation in a country, a zone or a compartment;

d) a sudden and unexpected increase in the distribution, incidence, morbidity or mortality of a listed disease, infection and infestation prevalent within a country, a zone or a compartment;

e) an emerging disease with significant morbidity or mortality, or zoonotic potential;

f) evidence of change in the epidemiology of a listed disease, infection or infestation (including host range, pathogenicity, strain) in particular if there is a zoonotic impact;

2) weekly reports subsequent to a notification under point 1 above, to provide further information on the evolution of the event which justified the notification. These reports should continue until the disease, infection or infestation has been eradicated or the situation has become sufficiently stable so that six-monthly reporting under point 3 will satisfy the obligation of the Member Country; in any case, a final report on the event should be submitted;

3) six-monthly reports on the absence or presence, and evolution of listed diseases, infections or infestations and information of epidemiological significance to other Member Countries;

4) annual reports concerning any other information of significance to other Member Countries.

Although Member Countries are only required to notify listed diseases, infections and infestations and emerging diseases according to points 1 to 4 above, they are encouraged to inform the OIE of other important animal health events.

Article 1.1.4.

1) The Veterinary Authority of a country in which an infected zone was located shall inform the Headquarters when this zone is free from the disease, infection or infestation.

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

3) A Member Country may be considered to regain freedom from a specific disease, infection or infestation when all conditions given in the relevant chapters of the Terrestrial Code have been fulfilled.

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

Article 1.1.5.

1) The Headquarters shall communicate by e-mail or World Animal Health Information Database (WAHID) to Veterinary Authorities all notifications received as provided in Articles 1.1.2. to 1.1.4. and other relevant information.
CHAPTER 1.2.

CRITERIA FOR THE INCLUSION OF DISEASES, INFECTIONS AND INFESTATIONS ON THE OIE LIST

Article 1.2.1.

Introduction

The aim of this chapter is to describe the criteria for the inclusion of diseases, infections and infestations on the OIE list. The objective of listing is to support Member Countries' efforts to prevent the transboundary spread of important animal diseases, including zoonoses, through transparent and consistent reporting. Each listed disease normally has a corresponding chapter to assist Member Countries in the harmonisation of disease detection, prevention and control. Requirements for notification are detailed in Chapter 1.1. and notifications are to be made through WAHIS or, if not possible, by fax or e-mail as described in Article 1.1.3.

Article 1.2.2.

The criteria for the inclusion of a disease, infection or infestation in the OIE list are as follows:

1) International spread of the agent (via live animals or their products, vectors or fomites) has been proven.

AND

2) At least one country has demonstrated freedom or impending freedom from the disease, infection or infestation in populations of susceptible animals, based on the animal health surveillance provisions of the Terrestrial Code, in particular those contained in Chapter 1.4.

AND

3)

a) Natural transmission to humans has been proven, and human infection is associated with severe consequences.

OR

b) The disease has been shown to cause significant morbidity or mortality in domestic animals at the level of a country or a zone.

OR

c) The disease has been shown to, or scientific evidence indicates that it would, cause significant morbidity or mortality in wild animal populations.

AND

4) A reliable means of detection and diagnosis exists and a precise case definition is available to clearly identify cases and allow them to be distinguished from other diseases, infections and infestations.

OR

5) The disease or infection is an emerging disease with evidence of zoonotic properties, rapid spread, or significant morbidity or mortality and a case definition is available to clearly identify cases and allow them to be distinguished from other diseases or infections.
Article 1.2.3.

The following diseases, infections and infestations are included in the OIE list.

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

1) The following are included within the category of multiple species diseases, infections and infestations:
   - Anthrax
   - Bluetongue
   - Brucellosis (Brucella abortus)
   - Brucellosis (Brucella melitensis)
   - Brucellosis (Brucella suis)
   - Crimean Congo haemorrhagic fever
   - Epizootic haemorrhagic disease
   - Equine encephalomyelitis (Eastern)
   - Foot and mouth disease
   - Heartwater
   - Infection with Aujeszky's disease virus
   - Infection with Echinococcus granulosus
   - Infection with Echinococcus multilocularis
   - Infection with rabies virus
   - Infection with rinderpest virus
   - Infection with Trichinella spp.
   - Japanese encephalitis
   - New World screwworm (Cochliomyia hominivorax)
   - Old World screwworm (Chrysomya bezziana)
   - Paratuberculosis
   - Q fever
   - Rift Valley fever
   - Surra (Trypanosoma evansi)
   - Tularemia
   - Vesicular stomatitis (under study)
   - West Nile fever.

2) The following are included within the category of cattle diseases and infections:
   - Bovine anaplasmosis
   - Bovine babesiosis
   - Bovine genital campylobacteriosis
   - Bovine spongiform encephalopathy
   - Bovine tuberculosis
   - Bovine viral diarrhoea
   - Enzootic bovine leukosis
   - Haemorrhagic septicaemia
   - Infectious bovine rhinotrachetitis/infectious pustular vulvovaginitis
   - Infection with Mycoplasma mycoides subsp. mycoides SC (Contagious bovine pleuropneumonia)
   - Lumpy skin disease
   - Theileriosis
   - Trichomonosis
   - Trypanosomosis (tsetse-transmitted).

3) The following are included within the category of sheep and goat diseases and infections:
   - Caprine arthritis/encephalitis
   - Contagious agalactia
Chapter 1.2. Criteria for the inclusion of diseases, infections and infestations on the OIE list

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- Contagious caprine pleuropneumonia
- Infection with *Chlamydophila abortus* (Enzootic abortion of ewes, ovine chlamydiosis)
- Infection with peste des petits ruminants virus
- Maedi–visna
- Nairobi sheep disease
- Ovine epididymitis (*Brucella ovis*)
- Salmonellosis (*S. abortusovis*)
- Scrapie
- Sheep pox and goat pox.

4) The following are included within the category of equine diseases and infections:
- Contagious equine metritis
- Dourine
- Equine encephalomyelitis (Western)
- Equine infectious anaemia
- Equine influenza
- Equine piroplasmosis
- Glanders
- Infection with African horse sickness virus
- Infection with equid herpesvirus-1 (EHV-1)
- Infection with equine arteritis virus
- Venezuelan equine encephalomyelitis.

5) The following are included within the category of swine diseases and infections:
- African swine fever
- Infection with classical swine fever virus
- Nipah virus encephalitis
- Porcine cysticercosis
- Porcine reproductive and respiratory syndrome
- Swine vesicular disease (under study)
- Transmissible gastroenteritis.

6) The following are included within the category of avian diseases and infections:
- Avian chlamydiosis
- Avian infectious bronchitis
- Avian infectious laryngotracheitis
- Avian mycoplasmosis (*Mycoplasma gallisepticum*)
- Avian mycoplasmosis (*Mycoplasma synoviae*)
- Duck virus hepatitis
- Fowl typhoid
- Infection with avian influenza viruses and infection with influenza A viruses of high pathogenicity in birds other than poultry including wild birds
- Infectious bursal disease (Gumboro disease)
- Newcastle disease
- Pullorum disease
- Turkey rhinotracheitis.

7) The following are included within the category of lagomorph diseases and infections:
- Myxomatosis
- Rabbit haemorrhagic disease.

8) The following are included within the category of bee diseases, infections and infestations:
- Infection of honey bees with *Melissococcus plutonius* (European foulbrood)
- Infection of honey bees with *Paenibacillus larvae* (American foulbrood)
9) The following are included within the category of other diseases and infections:

- Camelpox
- Leishmaniosis.
Chapter 1.2. - Criteria for the inclusion of diseases, infections and infestations on the OIE list

The infection or infestation is classified as an EMERGING DISEASE\(^1\)

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1 With evidence of zoonotic properties, rapid spread or significant morbidity or mortality and with case definition available
CHAPTER 1.3.

PRESCRIBED AND ALTERNATIVE DIAGNOSTIC TESTS FOR OIE LISTED DISEASES

NOTE

In many of the Terrestrial Code Chapters relating to specific diseases, the reader is referred to the Terrestrial Manual for information on OIE standards for the relevant diagnostic tests and vaccines.

However, some readers of the Terrestrial Code may need to know which diagnostic tests are recommended by the OIE for use in the international trade of animals or animal products, without requiring the details of how these tests should be performed.

The tables in this chapter have been included to meet this need. These tables show, for each OIE listed diseases, the diagnostic tests which can be used when the Terrestrial Code recommends a testing procedure.

These tests should be performed according to the specifications in the Terrestrial Manual, in order to avoid any differences between the exporting and importing countries in the interpretation of results.

In the tables, the diagnostic tests have been divided into two categories - ‘prescribed tests’ and ‘alternative tests’ (a similar categorisation is made in the Terrestrial Manual). The ‘prescribed tests’ are those which are considered optimal for determining the health status of animals before shipment. ‘Alternative tests’ do not demonstrate the absence of infection in the tested animals with the same level of confidence as the prescribed tests do. However, the OIE Terrestrial Animal Health Standards Commission considers that an ‘alternative test’, chosen by mutual agreement between the importing and exporting countries, can provide valuable information for evaluating the risks of any proposed trade in animals or animal products. The disease for which the Terrestrial Code does not require any test are not included in the tables.

ABBREVIATIONS AND ACRONYMS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agent id.</td>
<td>Agent identification</td>
</tr>
<tr>
<td>Agg.</td>
<td>Agglutination test</td>
</tr>
<tr>
<td>AGID</td>
<td>Agar gel immunodiffusion</td>
</tr>
<tr>
<td>BBAT</td>
<td>Buffered Brucella antigen test</td>
</tr>
<tr>
<td>CF</td>
<td>Complement fixation (test)</td>
</tr>
<tr>
<td>DTH</td>
<td>Delayed-type hypersensitivity</td>
</tr>
<tr>
<td>ELISA</td>
<td>Enzyme-linked immunosorbent assay</td>
</tr>
<tr>
<td>FAV/N</td>
<td>Fluorescent antibody virus neutralisation</td>
</tr>
<tr>
<td>FPA</td>
<td>Fluorescence polarisation assay</td>
</tr>
<tr>
<td>HI</td>
<td>Haemagglutination inhibition</td>
</tr>
<tr>
<td>IFA</td>
<td>Indirect fluorescent antibody (test)</td>
</tr>
<tr>
<td>MAT</td>
<td>Microscopic agglutination test</td>
</tr>
<tr>
<td>NPLA</td>
<td>Neutralising peroxidase-linked assay</td>
</tr>
<tr>
<td>PCR</td>
<td>Polymerase chain reaction</td>
</tr>
<tr>
<td>PRN</td>
<td>Plaque reduction neutralisation</td>
</tr>
<tr>
<td>VN</td>
<td>Virus neutralisation</td>
</tr>
<tr>
<td>-</td>
<td>No test designated yet</td>
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### OIE listed diseases

#### Multiple species

<table>
<thead>
<tr>
<th>Chapter Code</th>
<th>Terrestrial Manual Chapter No.</th>
<th>Disease name</th>
<th>Prescribed tests</th>
<th>Alternative tests</th>
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<tr>
<td>8.2.</td>
<td>2.1.2.</td>
<td>Aujeszky's disease</td>
<td>ELISA, VN</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>2.1.9.</td>
<td>Leptospirosis</td>
<td>-</td>
<td>MAT</td>
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<tr>
<td>8.11.</td>
<td>2.1.13.</td>
<td>Rabies</td>
<td>VN, ELISA</td>
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<tr>
<td>8.10.</td>
<td>2.1.11.</td>
<td>Paratuberculosis</td>
<td>-</td>
<td>DTH, ELISA</td>
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<tr>
<td>8.7.</td>
<td>2.1.6.</td>
<td>Heartwater</td>
<td>-</td>
<td>ELISA, IFA</td>
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<tr>
<td>8.9.</td>
<td>2.1.10.</td>
<td>New world screwworm (Cochliomyia hominivorax) and old world screwworm (Chrysomya bezziana)</td>
<td>-</td>
<td>Agent id.</td>
</tr>
<tr>
<td>8.14.</td>
<td>2.1.16.</td>
<td>Trichinellosis</td>
<td>Agent id.</td>
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<tr>
<td>8.8.</td>
<td>2.1.5.</td>
<td>Foot and mouth disease</td>
<td>ELISA¹, VN</td>
<td>CF</td>
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<tr>
<td>8.16.</td>
<td>2.1.19.</td>
<td>Vesicular stomatitis</td>
<td>CF, ELISA, VN</td>
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<tr>
<td>8.13.</td>
<td>2.1.15.</td>
<td>Rinderpest</td>
<td>ELISA</td>
<td>VN</td>
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<td>8.3.</td>
<td>2.1.3.</td>
<td>Bluetongue</td>
<td>Agent id., ELISA, PCR</td>
<td>AGID, VN</td>
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<tr>
<td>8.12.</td>
<td>2.1.14.</td>
<td>Rift Valley fever</td>
<td>VN</td>
<td>HI, ELISA</td>
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<tr>
<td>8.15.</td>
<td>2.1.18.</td>
<td>Tularemia</td>
<td>-</td>
<td>Agent id.</td>
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#### Bovidae

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<tr>
<th>Chapter Code</th>
<th>Terrestrial Manual Chapter No.</th>
<th>Disease name</th>
<th>Prescribed tests</th>
<th>Alternative tests</th>
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<tbody>
<tr>
<td>11.3.</td>
<td>2.4.3.</td>
<td>Bovine brucellosis</td>
<td>BBAT, CF, ELISA, FPA</td>
<td>-</td>
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<tr>
<td>11.4.</td>
<td>2.4.5.</td>
<td>Bovine genital campylobacteriosis</td>
<td>Agent id.</td>
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<tr>
<td>11.6.</td>
<td>2.4.7.</td>
<td>Bovine tuberculosis</td>
<td>Tuberculin test</td>
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<tr>
<td>11.9.</td>
<td>2.4.11.</td>
<td>Enzootic bovine leukemia</td>
<td>AGID, ELISA</td>
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<tr>
<td>11.11.</td>
<td>2.4.13.</td>
<td>Infectious bovine rhinotracheitis/ infectious pustular vulvovaginitis</td>
<td>VN, ELISA, Agent id. (semen only), PCR</td>
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<tr>
<td>11.1.</td>
<td>2.4.1.</td>
<td>Bovine anaplasmosis</td>
<td>-</td>
<td>CF, Agg. card</td>
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<tr>
<td>11.2.</td>
<td>2.4.2.</td>
<td>Bovine babesiosis</td>
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<td>ELISA, IFA, CF</td>
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<tr>
<td>11.13.</td>
<td>2.4.16.</td>
<td>Theileriosis</td>
<td>Agent id., IFA</td>
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<td>11.10.</td>
<td>2.4.12.</td>
<td>Haemorrhagic septicaemia</td>
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<td>11.12.</td>
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<td>Lumpy skin disease</td>
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<td>VN</td>
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<td>11.8.</td>
<td>2.4.9.</td>
<td>Contagious bovine pleuropneumonia</td>
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#### Ovidae and capridae

<table>
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<th>Chapter Code</th>
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<th>Disease name</th>
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**Aves**

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Chapter 1.3.- Prescribed and alternative diagnostic tests for OIE listed diseases

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<table>
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<tr>
<th>Disease name</th>
<th>Prescribed tests</th>
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<td></td>
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<tr>
<td>13.1. Myxomatosis</td>
<td>-</td>
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</tr>
<tr>
<td>13.2. Rabbit haemorrhagic disease</td>
<td>-</td>
<td>ELISA, HI</td>
</tr>
</tbody>
</table>

1 Please refer to the relevant Chapters in the Terrestrial Manual to verify which method is prescribed (this addition refers to reinstating the liquid-phase blocking ELISA as a prescribed test).
CHAPTER 1.4.

ANIMAL HEALTH SURVEILLANCE

Article 1.4.1.

Introduction and objectives

1) In general, surveillance is aimed at demonstrating the absence of disease or infection, determining the presence or distribution of disease or infection or detecting as early as possible exotic or emerging diseases. The type of surveillance applied depends on the outputs needed to support decision-making. The following recommendations may be applied to all diseases or infections and all susceptible species (including wildlife). The general recommendations in this chapter may be refined by the specific approaches described in the disease chapters. Where detailed disease or infection-specific information is not available, suitable approaches should be based on the recommendations in this chapter.

2) Animal health surveillance is also a tool to monitor disease trends, to facilitate the control of disease or infection, to provide data for use in risk analysis, for animal or public health purposes, and to substantiate the rationale for sanitary measures. Both domestic animals and wildlife are susceptible to certain diseases or infections. However, the presence of a disease or infection in wildlife does not mean it is necessarily present in domestic animals in the same country or zone or vice versa. Wildlife may be included in a surveillance system because they can serve as reservoirs of infection and as indicators of disease risk to humans and domestic animals. Surveillance in wildlife presents challenges that may differ significantly from those in surveillance in domestic animals.

3) Prerequisites to enable a Member Country to provide information for the evaluation of its animal health status are:
   a) that the Member Country complies with the provisions of Chapter 3.1.;
   b) that, where possible, surveillance data be complemented by other sources of information, such as scientific publications, research data, documented field observations and other non-survey data;
   c) that transparency in the planning and execution of surveillance activities and the analysis and availability of data and information, be maintained at all times, in accordance with Chapter 1.1.

4) The objectives of this chapter are to:
   a) provide guidance to the type of outputs that a surveillance system should generate;
   b) provide recommendations to assess the quality of surveillance systems.

Article 1.4.2.

Definitions

The following definitions apply for the purposes of this chapter:

Bias: means a tendency of an estimate to deviate in one direction from a true value.

Confidence: means the probability that the type of surveillance applied would detect the presence of infection if the population were infected and is equivalent to the sensitivity of the surveillance. Confidence depends on, among other parameters, the assumed prevalence of infection.

Probability sampling: means a sampling strategy in which every unit has a known non-zero probability of inclusion in the sample.

Sample: means the group of elements (sampling units) drawn from a population, on which tests are performed or parameters measured to provide surveillance information.

Sampling unit: means the unit that is sampled, either in a random survey or in non-random surveillance. This may be an individual animal or a group of animals, such as an epidemiological unit. Together, they comprise the sampling frame.

Sensitivity: means the proportion of truly positive units that are correctly identified as positive by a test.

Specificity: means the proportion of truly negative units that are correctly identified as negative by a test.
Study population: means the population from which surveillance data are derived. This may be the same as the target population or a subset of it.

Surveillance system: means a method of surveillance that may involve one or more component activities that generates information on the health or disease status of animal populations.

Survey: means an investigation in which information is collected systematically usually carried out on a sample of a defined population group, within a defined time period.

Target population: means the population about which conclusions are to be inferred.

Test: means a procedure used to classify a unit as either positive, negative or suspect with respect to a disease or an infection.

Test system: means a combination of multiple tests and rules of interpretation which are used for the same purpose as a test.

Article 1.4.3.

Principles of surveillance

1. Types of surveillance
   a) Surveillance may be based on many different data sources and can be classified in a number of ways, including:
      i) the means by which data are collected (active versus passive surveillance);
      ii) the disease focus (pathogen-specific versus general surveillance); and
      iii) the way in which units for observation are selected (structured surveys versus non-random data sources).
   b) In this chapter, surveillance activities are classified as being based on:
      EITHER
      i) structured population-based surveys, such as:
         – systematic sampling at slaughter;
         – random surveys;
         – surveys for infection in clinically normal animals, including wildlife;
      OR
      ii) structured non-random surveillance activities, such as:
         – disease reporting or notifications;
         – control programmes or health schemes;
         – targeted testing or screening;
         – ante-mortem and post-mortem inspections;
         – laboratory investigation records;
         – biological specimen banks;
         – sentinel units;
         – field observations;
         – farm production records;
         – wildlife disease data.
   c) In addition, surveillance data should be supported by related information, such as:
      i) data on the epidemiology of the disease or infection, including environmental, host population distribution, and climatic information;
      ii) data on animal movements, including transhumance and natural wildlife migrations;
      iii) trading patterns for animals and animal products;
      iv) national animal health regulations, including information on compliance with them and their effectiveness;
      v) history of imports of potentially infected material;
      vi) biosecurity measures in place; and
vii) the likelihood and consequence of disease or infection introduction.

d) The sources of evidence should be fully described. In the case of a structured survey, this should include a description of the sampling strategy used for the selection of units for testing. For structured non-random data sources, a full description of the system is required including the source(s) of the data, when the data were collected, and a consideration of any biases that may be inherent in the system.

2. Critical elements

In assessing the quality of a surveillance system, the following critical elements need to be addressed over and above quality of Veterinary Services (Chapter 3.1.).

a) Populations

Ideally, surveillance should be carried out in such a way as to take into account all animal species susceptible to the infection in a country, zone or compartment. The surveillance activity may cover all individuals in the population or part of them. When surveillance is conducted only on a subpopulation, care should be taken regarding the inferences made from the results.

Definitions of appropriate populations should be based on the specific recommendations of the disease chapters of the Terrestrial Code.

b) Time frame (or temporal values of surveillance data)

Surveillance should be carried out at a frequency that reflects the biology of the infection and the risks of its introduction.

c) Epidemiological unit

The relevant epidemiological unit(s) for the surveillance system should be defined to ensure that it is appropriate to meet the objectives of surveillance. Therefore, it should be chosen taking into account factors such as carriers, reservoirs, vectors, immune status, genetic resistance and age, sex, and other host criteria.

d) Clustering

Infection in a country, zone or compartment usually clusters rather than being uniformly or randomly distributed through a population. Clustering may occur at a number of different levels (e.g. a cluster of infected animals within a herd, a cluster of pens in a building, or a cluster of farms in a compartment). Clustering should be taken into account in the design of surveillance activities and the statistical analysis of surveillance data, at least at what is judged to be the most significant level of clustering for the particular animal population and infection.

e) Case definition

Where one exists, the case definition in the specific chapter of the Terrestrial Code should be used. If the Terrestrial Code does not give a case definition, a case should be defined using clear criteria for each disease or infection under surveillance. For wildlife disease or infection surveillance, it is essential to correctly identify and report host animal taxonomy (including genus and species).

f) Analytical methodologies

Surveillance data should be analysed using appropriate methodologies, and at the appropriate organisational level to facilitate effective decision making, whether it be planning interventions or demonstrating status.

Methodologies for the analysis of surveillance data should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. Different methodologies may be needed to accommodate different host species, pathogens, production systems and surveillance systems, and types and amounts of data and information available.

The methodology used should be based on the best information available. It should also be in accordance with this chapter, fully documented and supported by reference to the scientific literature and other sources, including expert opinion. Sophisticated mathematical or statistical analyses should only be carried out when justified by the proper amount and quality of field data.

Consistency in the application of different methodologies should be encouraged and transparency is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding. The uncertainties, assumptions made, and the effect of these on the final conclusions should be documented.

g) Testing

Surveillance involves the detection of disease or infection according to appropriate case definitions and based on the results of one or more tests for evidence of infection or immune status. In this context, a test may range from detailed laboratory examinations to field observations and the analysis of production records. The performance of a test at the population level (including field observations) may be described in terms of its sensitivity, specificity and predictive values. Imperfect sensitivity or specificity will have an impact on the conclusions from surveillance. Therefore, these parameters should be taken into account in the design of surveillance systems and analysis of surveillance data.

The sensitivity and specificity values of the tests used should be specified for each species in which they may be used, and the method used to estimate these values should be documented. Alternatively, where
sensitivity or specificity values of a particular test are specified in the Terrestrial Manual, these may be used as a guide.

Samples from a number of animals or units may be pooled and subjected to a testing protocol. The results should be interpreted using sensitivity and specificity values that have been determined or estimated for that particular pool size and testing procedure.

h) Quality assurance

Surveillance systems should incorporate the principles of quality assurance. They should be subjected to periodic auditing to ensure that all components of the system function and provide verifiable documentation of procedures and basic checks to detect significant deviations of procedures from those documented in the design.

i) Validation

Results from animal health surveillance systems are subject to one or more potential biases. When assessing the results, care should be taken to identify potential biases that can inadvertently lead to an over-estimate or an under-estimate of the parameters of interest.

j) Data collection and management

The success of a surveillance system is dependent on a reliable process for data collection and management. The process may be based on paper records or computerised. Even where data are collected for non-survey purposes (e.g. during disease control interventions, inspections for movement control or during disease eradication schemes), the consistency and quality of data collection and event reporting in a format that facilitates analysis is critical. Factors influencing the quality of collected data include:

- the distribution of, and communication between, those involved in generating and transferring data from the field to a centralised location; this requires effective collaboration among all stakeholders, such as governmental or non-governmental organisations, and others, particularly for data involving wildlife;
- the ability of the data processing system to detect missing, inconsistent or inaccurate data, and to address these problems;
- maintenance of disaggregated data rather than the compilation of summary data;
- minimisation of transcription errors during data processing and communication.

Article 1.4.4.

Structured population-based surveys

In addition to the principles discussed in Article 1.4.3., the following should be considered when planning, implementing and analysing surveys.

1. Types of surveys

Surveys may be conducted on the entire target population (i.e. a census) or on a sample. A sample may be selected in either of two ways:

a) non-probability based sampling methods, such as:
   i) convenience;
   ii) expert choice;
   iii) quota;

b) probability based sampling methods, such as:
   i) simple random selection;
   ii) cluster sampling;
   iii) stratified sampling;
   iv) systematic sampling.

Periodic or repeated surveys conducted in order to document disease freedom should be conducted using probability based sampling methods so that data from the study population can be extrapolated to the target population in a statistically valid manner.

The sources of information should be fully described and should include a detailed description of the sampling strategy used for the selection of units for testing. Also, consideration should be given to any biases that may be inherent in the survey design.
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2. Survey design

The population of epidemiological units should first be clearly defined; hereafter appropriate sampling units should be defined for each stage, depending on the design of the survey.

The design of the survey will depend on the size, structure and degree of understanding of the population being studied, the epidemiology of the infection and the resources available.

Data on wildlife population size often do not exist. However, they should be determined to the extent possible before the survey is designed. The expertise of wildlife biologists may be sought in the gathering and interpretation of such population data. Historical population data should be updated since these may not reflect current populations.

3. Sampling

The objective of sampling from a population is to select a subset of units that is representative of the population of interest with respect to the objective of the study. Sampling should provide the best likelihood that the sample will be representative of the population, within the practical constraints imposed by different environments and production systems.

Specimens of wildlife may be available from sources such as hunters and trappers, road-kills, wild animal meat markets, sanitary inspection of hunted animals, morbidity-mortality observations by the general public, wildlife rehabilitation centres, wildlife biologists and wildlife agency field personnel, farmers, and other landholders, naturalists and conservationists. Wildlife data such as census data, trends over time, and reproductive success can be used in a manner similar to farm production records for epidemiological purposes.

4. Sampling methods

When selecting epidemiological units from within a population, probability sampling, such as simple random selection, should be used. When this is not possible, sampling should provide the best practical chance of generating a sample that is representative of the target population.

In any case, the sampling method used at all stages should be fully documented.

5. Sample size

In general, surveys are conducted either to demonstrate the presence or absence of a factor (e.g. infection) or to estimate a parameter (e.g. the prevalence of infection). The method used to calculate sample size for surveys depends on the purpose of the survey, the expected prevalence, the level of confidence desired of the survey results and the performance of the tests used.

Article 1.4.5.

Structured non-random surveillance

Surveillance systems routinely use structured non-random data, either alone or in combination with surveys.

1. Common non-random surveillance sources

A wide variety of non-random surveillance sources may be available. These vary in their primary purpose and the type of surveillance information they are able to provide. Some surveillance systems are primarily established as early detection systems, but may also provide valuable information to demonstrate freedom from infection. Other systems provide cross-sectional information suitable for prevalence estimation, either once or repeatedly, while yet others provide continuous information, suitable for the estimate of incidence data, such as disease reporting systems, sentinel sites and testing schemes.

a) Disease reporting or notification systems

Data derived from disease reporting systems can be used in combination with other data sources to substantiate claims of animal health status, to generate data for risk analysis, or for early detection. Effective laboratory support is an important component of any reporting system. Reporting systems relying on laboratory confirmation of suspect clinical cases should use tests that have a high specificity. Reports should be released by the laboratory in a timely manner, with the amount of time from disease detection to report generation minimized (to hours in the case of introduction of a foreign animal disease).

Whenever the responsibility for disease notification falls outside the scope of the Veterinary Authority, for example in some countries for diseases in wildlife, effective communication and data sharing should be established with the relevant authorities to ensure comprehensive and timely disease reporting.
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b) Control programmes and health schemes

Animal disease control programmes or health schemes, while focusing on the control or eradication of specific diseases, should be planned and structured in such a manner as to generate data that are scientifically verifiable and contribute to structured surveillance.

c) Targeted testing and screening

This may involve testing targeted to selected sections of the population (subpopulations), in which disease is more likely to be introduced or found. Examples include testing culled and dead animals, swill fed animals, those exhibiting clinical signs, animals located in a defined geographic area and specific age or commodity group.

d) Ante-mortem and post-mortem inspections

Inspections of animals at slaughterhouses may provide valuable surveillance data. The sensitivity and specificity of slaughterhouse inspection for detecting the presence of specified diseases should be pre-determined for the inspection system in place. The accuracy of the inspection system will be influenced by:

i) the training, experience and number of the inspection staff;

ii) the involvement of the Competent Authority in the supervision of ante-mortem and post-mortem inspections;

iii) the quality of construction of the slaughterhouse, speed of the slaughter chain, lighting quality, etc.; and

iv) staff morale and motivation for efficient performance.

Slaughterhouse inspections are likely to provide good coverage for particular age groups and geographical areas only. Slaughterhouse surveillance data are subject to biases in relation to target populations (e.g. only animals of a particular class and age are likely to be slaughtered for human consumption in significant numbers). Such biases need to be recognised when analysing surveillance data.

For traceback and analysis of spatial and herd-level coverage, there should be, if possible, an effective identification system that relates animals in the slaughterhouse to their locality of origin.

e) Laboratory investigation records

Analysis of laboratory investigation records may provide useful surveillance information. The coverage of the system will be increased if analysis is able to incorporate records from national, accredited, university and private sector laboratories. Valid analysis of data from different laboratories depends on the existence of standardised diagnostic procedures and standardised methods for interpretation and data recording. As with abattoir inspections, there needs to be a mechanism to relate specimens to the farm of origin.

f) Biological specimen banks

Specimen banks consist of stored specimens, gathered either through representative sampling or opportunistic collection or both. Specimen banks may contribute to retrospective studies, including providing support for claims of historical freedom from infection, and may allow certain studies to be conducted more quickly and at lower cost than alternative approaches.

g) Sentinel units

Sentinel units or sites involve the identification and regular testing of one or more of animals of known health or immune status in a specified geographical location to detect the occurrence of disease or infection (usually serologically). They are particularly useful for surveillance for diseases or infections which have a strong spatial component, such as vector-borne diseases or infections. Sentinel units provide the opportunity to target surveillance depending on the likelihood of infection (related to vector habitats and host population distribution), cost and other practical constraints. Sentinel units may provide evidence of freedom from infection, or provide data on prevalence and incidence as well as the distribution of disease or infection.

h) Field observations

Clinical observations of animals in the field are an important source of surveillance data. The sensitivity and specificity of field observations may be relatively low, but these can be more easily determined and controlled if a clear standardised case definition is applied. Education of potential field observers in application of the case definition and reporting is important. Ideally, both the number of positive observations and the total number of observations should be recorded.

i) Farm production records

Systematic analysis of farm production records may be used as an indicator of the presence or absence of disease or infection at the herd or flock level. In general, the sensitivity of this approach may be quite high (depending on the disease), but the specificity is often quite low.

j) Wildlife data

Specimens from wildlife for disease or infection surveillance may be available from sources such as hunters and trappers, road-kills, wild animal meat markets, sanitary inspection of hunted animals, morbidity and mortality observations by the general public, wildlife rehabilitation centres, wildlife biologists and wildlife
agency field personnel, farmers and other landholders, naturalists and conservationists. Wildlife data such as census data, trends over time, and reproductive success can be used in a manner similar to farm production records for epidemiological purposes.

2. Critical elements for structured non-random surveillance

There are a number of critical factors which should be taken into account when using structured non-random surveillance data. These include coverage of the population, duplication of data, and sensitivity and specificity of tests that may give rise to difficulties in the interpretation of data. Surveillance data from non-random sources can, however, be a cost-efficient method of early detection, and may increase the level of confidence or detect a lower level of prevalence compared to random sampling surveys.

3. Analytical methodologies

Different scientifically valid methodologies may be used for the analysis of non-random surveillance data. Where no data are available, estimates based on expert opinions, gathered and combined using a formal, documented and scientifically valid methodology may be used.

4. Combination of multiple sources of data

The methodology used to combine the evidence from multiple data sources should be scientifically valid, and fully documented, including references to published material.

Surveillance information gathered from the same country, zone or compartment at different times may provide cumulative evidence of animal health status. Such evidence gathered over time may be combined to provide an overall level of confidence. For instance, repeated annual surveys may be analysed to provide a cumulative level of confidence. However, a single larger survey, or the combination of data collected during the same time period from multiple random or non-random sources, may be able to achieve the same level of confidence in a shorter period of time.

Analysis of surveillance information gathered intermittently or continuously over time should, where possible, incorporate the time of collection of the information to take the decreased value of older information into account. The sensitivity, specificity and completeness of data from each source should also be taken into account for the final overall confidence level estimation.

Article 1.4.6.

Surveillance to demonstrate freedom from disease or infection

1. Requirements to declare a country or a zone free from disease or infection without pathogen specific surveillance

This article provides general principles for declaring a country or a zone free from disease or infection in relation to the time of last occurrence and in particular for the recognition of historical freedom.

The provisions of this article are based on Article 1.4.3. and the following premises:

- in the absence of disease and vaccination, the animal population would become susceptible over a period of time;
- the disease agents to which these provisions apply are likely to produce identifiable clinical signs in susceptible animals;
- competent and effective Veterinary Services will be able to investigate, diagnosed and report disease, if present;
- disease or infection can affect both domestic animals and wildlife;
- the absence of disease or infection over a long period of time in a susceptible population can be substantiated by effective disease investigation and reporting by a Member Country.

a) Historically free

Unless otherwise specified in the relevant disease chapter, a country or zone may be recognised as free from infection without formally applying a pathogen-specific surveillance programme when:

i) there has never been occurrence of disease, or
ii) eradication has been achieved or the disease or infection has ceased to occur for at least 25 years, provided that for at least the past 10 years:
iii) the disease has been a notifiable disease;
iv) an early detection system has been in place for all relevant species;
v) measures to prevent disease or infection introduction have been in place; no vaccination against the disease has been carried out unless otherwise provided for in the Terrestrial Code;

vi) infection is not known to be established in wildlife within the country or zone. A country or zone cannot apply for historical freedom if there is any evidence of infection in wildlife.

b) Last occurrence within the previous 25 years
Countries or zones that have achieved eradication (or in which the disease or infection has ceased to occur) within the previous 25 years, should follow the pathogen-specific surveillance requirements in the Terrestrial Code if they exist. In the absence of specific requirements, countries should follow the general recommendations on surveillance outlined in this chapter provided that for at least the past 10 years:

i) the disease has been a notifiable disease;

ii) an early detection system has been in place;

iii) measures to prevent the introduction of the disease or infection introduction have been in place;

iv) no vaccination against the disease has been carried out unless otherwise provided for in the Terrestrial Code;

v) infection is not known to be established in wildlife within the country or zone. A country or zone cannot apply for recognition of freedom if there is any evidence of infection in wildlife.

2. Recommendations for the discontinuation of pathogen-specific screening after recognition of freedom from infection
A country, zone or compartment that has been recognised as free from infection following the provisions of the Terrestrial Code may discontinue pathogen-specific screening while maintaining the infection-free status provided that:

a) the disease is a notifiable disease;

b) an early detection system is in place;

c) measures to prevent the introduction of the disease or infection are in place;

d) vaccination against the disease is not applied;

e) infection is known not to be established in wildlife. It can be difficult to collect sufficient epidemiological data to prove absence of disease or infection in wild animal populations. In such circumstances, a range of supporting evidence should be used to make this assessment.

3. Self declaration of freedom from disease or infection
A Member Country may make a self declaration according to Chapter 1.6. that its entire territory, a zone or a compartment is free from a listed disease, based on the implementation of the provisions of the Terrestrial Code and the Terrestrial Manual. The Veterinary Authority may wish to transmit this information to the OIE Headquarters, which may publish the information.

4. International recognition of disease or infection free status
For diseases for which procedures exist whereby the OIE can officially recognise the existence of a disease or infection free country or zone, a Member Country wishing to apply for recognition of this status should, via its Permanent Delegate, send to the OIE all the relevant documentation relating to the country or zone concerned. Such documentation should be presented according to the recommendations prescribed by the OIE for the appropriate animal diseases.

5. Demonstration of freedom from infection
A surveillance system to demonstrate freedom from infection should meet the following requirements in addition to the general requirements outlined in Article 1.4.3.

Freedom from infection implies the absence of the pathogenic agent in the country, zone or compartment. Scientific methods cannot provide absolute certainty of the absence of infection. Therefore, demonstrating freedom from infection involves providing sufficient evidence to demonstrate (to a level of confidence acceptable to Member Countries) that infection with a specified pathogen, if present, is present in less than a specified proportion of the population.

However, finding evidence of infection at any prevalence in the target population automatically invalidates any freedom from infection claim unless otherwise stated in the relevant disease chapter. The implications for the status
of domestic animals of disease or infection present in wildlife in the same country or zone should be assessed in each situation, as indicated in the relevant chapter on each disease in the Terrestrial Code.

Evidence from targeted, random or non-random data sources, as stated before, may increase the level of confidence or be able to detect a lower level of prevalence with the same level of confidence compared to structured surveys.

Article 1.4.7.

Surveillance for distribution and occurrence of infection

Surveillance to determine the distribution and occurrence of infection, disease or of other relevant health-related events is used to assess progress and aid in decision making in the control or eradication of selected diseases or infections. It also has relevance for the international movement of animals and products.

In contrast to surveillance to demonstrate freedom from infection, surveillance used to assess progress in control or eradication of selected diseases or infections is usually designed to collect data about a number of variables such as:

1) prevalence or incidence of infection;
2) morbidity and mortality rates;
3) frequency of disease or infection risk factors and their quantification;
4) frequency distribution of herd sizes or the sizes of other epidemiological units;
5) frequency distribution of antibody titres;
6) proportion of immunised animals after a vaccination campaign;
7) frequency distribution of the number of days elapsing between suspicion of infection and laboratory confirmation of the diagnosis and the adoption of control measures;
8) farm production records;
9) role of wildlife in maintenance or transmission of the infection.
CHAPTER 1.5.

SURVEILLANCE FOR ARTHROPOD VECTORS OF ANIMAL DISEASES

Article 1.5.1.

Introduction

Vector-borne diseases are of increasing importance economically and to human and animal health.

Environmental (including climate change), sociological and economical changes may affect the distribution and impact of these diseases.

Improved understanding of the distribution and population dynamics of the vectors is a key element for assessing and managing the risks associated with vector-borne animal and zoonotic diseases.

The Terrestrial Code contains recommendations for the surveillance of several vector-borne diseases and general recommendations for animal health surveillance.

The need has arisen to complement these general recommendations on surveillance with advice on the surveillance for vectors themselves. This chapter only addresses surveillance for arthropod vectors.

For the purpose of trade, it should be noted that there is no conclusive relationship between the presence of a vector(s) and the disease status of a country/zone, and also that the apparent absence of a vector(s) does not by itself confirm vector-free status.

A decision tree for vector surveillance is presented in Figure 1.

Article 1.5.2.

Objectives

The objective of these recommendations is to provide methods for:

1) gathering up-to-date information on the spatial and temporal distribution and abundance of vectors of the arthropod-borne listed diseases and emerging diseases;

2) monitoring changes in the spatial and temporal distribution and abundance of these vectors;

3) collecting relevant data to inform risk assessment (including vector competency) and risk management of these vector-borne diseases;

4) detecting the presence of specific vectors or confirming their absence;

5) understanding pathways of entry for vectors and vector-borne pathogenic agents.
Article 1.5.3.

Sampling methodology

1. Sampling plan
   a) The objective of the surveillance programme should be determined and stated before planning begins.
   b) Available historical data on the vector or the disease for the country or zone should be collated and assessed.
   c) The sampling plan should consider the following:
      i) the biology and ecology of the vector(s),
      ii) the presence, distribution and abundance of the vectors' host animal population(s),
      iii) the environmental, climatic, ecological and topographic conditions of relevance to vector ecology,
      iv) the need for a risk assessment to indicate the areas at highest risk of introduction of a vector that is unlikely to be present.
   d) Sampling should be aimed at:
      i) establishing vector presence or confirming vector absence in the country or zone,
      ii) describing the distribution of the vector(s) within the country or zone,
      iii) providing additional information on vector density and spatial/temporal variability (both over the short- and the long-term),

![Decision tree for vector surveillance](image-url)
iv) early detection of vectors or vector-borne pathogenic agents in areas with risks of entry and establishment.

e) The sampling plan should be designed to provide appropriate estimates of the indicators listed above. Consideration should be given to the following:

i) The recommended general approach to sampling is via a three-stage hierarchy:
- Stratification based on ecological criteria (where possible), and risk assessment for vector introduction,
- subdivision of strata into spatial sampling units, and
- establishment of actual sampling sites within selected spatial sampling units.

ii) If adequate entomological, epidemiological and historical data and/or expert opinion exists, the sampling plan may be refined or targeted by defining strata which are as homogeneous as possible with respect to the following known or suspected risk-factors, as appropriate for the country or zone:
- domestic or wild populations of host animals preferred by the vector,
- vector habitat suitability,
- climatic patterns (including seasonal),
- areas endemically and/or epidemically affected by the disease(s) of concern,
- areas of known vector occurrences,
- fringe zone(s) around areas of known vector occurrences or other high risks areas for vector introduction, such as ports,
- areas in which the disease(s) or vector(s) of concern have not been reported currently or historically,
- each stratum (or the whole country or zone, if not stratified) should be divided into spatial sampling units according to standard methodologies such as a grid system,
- the number and size of the spatial sampling units should be defined to provide appropriate estimates of the indicators listed above,
- the number and location of actual sampling sites within each spatial sampling unit also should be defined to provide appropriate estimates of the indicators listed above,
- different levels of sampling intensity (spatial sampling unit size, number of units sampled, number of sites sampled within units, and sampling frequency) may be applied to different strata into which the country or zone has been divided. For example, more intensive sampling might be carried out in strata where vector presence seems most likely, based on biological or statistical criteria.

2. Sampling methods

Many sampling methods have been developed for the capture of vector arthropods, and these differ according to the disease/vector system under consideration.

a) The collection methods used should be adapted as required to ensure reasonable confidence of collecting the vector(s) of concern.

b) Collection methods should obtain the various developmental stages (such as eggs, larvae, nymphs, adults) and adult age categories, as appropriate to the species in question and the objectives of the surveillance. For example, if a vector is not believed to be present, collection methods should target the developmental stages most likely to be introduced, or that are most readily detected. If the vector is present, life stages required to estimate population survival rates and population dynamics in relation to disease transmission should be collected.

c) Different collection methods may be required to obtain samples from a single vector species, depending on the life stage or place of capture (such as from the environment or from the host animals). The collection method should be appropriate to the species and life stage of interest.

The collection methods should preserve the vector(s) in a manner suitable for their morphological identification or identification with molecular techniques. Where the purpose of sampling is to detect or isolate a pathogenic agent(s), specific protocols should be followed to ensure the samples are suitable for these assays.

3. Data management, analysis and interpretation

Data management and analytical methodologies should be done in accordance with Chapter 1.4.
CHAPTER 1.6.

PROCEDURES FOR SELF DECLARATION AND FOR OFFICIAL RECOGNITION BY THE OIE

Article 1.6.1.

General principles

Member Countries may wish to make a self declaration as to the freedom of a country, zone or compartment from an OIE listed disease. The Member Country may inform the OIE of its claimed status and the OIE may publish the claim. Publication does not imply endorsement of the claim. The OIE does not publish self declaration for bovine spongiform encephalopathy (BSE), foot and mouth disease (FMD), contagious bovine pleuropneumonia (CBPP), African horse sickness (AHS), pestes des petits ruminants (PPR) and classical swine fever (CSF).

Member Countries may request official recognition by the OIE as to:

1) the risk status of a country or zone with regard to BSE;
2) the freedom of a country or zone from FMD, with or without vaccination;
3) the freedom of a country or zone from CBPP;
4) the freedom of a country or zone from AHS;
5) the freedom of a country or zone from PPR;
6) the freedom of a country or zone from CSF.

The OIE does not grant official recognition for other diseases.

In these cases, Member Countries should present documentation setting out the compliance of the Veterinary Services of the applicant country or zone with the provisions of Chapters 1.1., 3.1. and 3.2. of the Terrestrial Code and with the provisions of the relevant disease chapters in the Terrestrial Code and the Terrestrial Manual.

When requesting official recognition of disease status, the Member Country should submit to the OIE Scientific and Technical Department a dossier providing the information requested (as appropriate) in Articles 1.6.4. (for BSE), 1.6.5. (for FMD), 1.6.6. (for CBPP), 1.6.7. (for AHS), 1.6.8. (for PPR) or 1.6.9. (for CSF).

The OIE framework for the official recognition and maintenance of disease status is described in Resolution N° XXII (administrative procedures) and Resolution N° XXIII (financial obligations) adopted during the 76th General Session in May 2008.

Article 1.6.2.

Endorsement by the OIE of an official control programme for FMD

Member Countries may wish to request an endorsement by the OIE of their official control programme for FMD.

When requesting endorsement by the OIE of an official control programme for FMD, the Member Country should submit to the OIE Scientific and Technical Department a dossier providing the information requested in Article 1.6.10.

Article 1.6.3.

Endorsement by the OIE of an official control programme for PPR

Member Countries may wish to request an endorsement by the OIE of their official control programme for PPR.

When requesting endorsement by the OIE of an official control programme for PPR, the Member Country should submit to the OIE Scientific and Technical Department a dossier providing the information requested in Article 1.6.11.
Article 1.6.4.

**Questionnaire on BSE**

**GENERAL INTRODUCTION**

Acceptance of this submission is based on the compliance of the Veterinary Service of the applicant country or zone with the provisions of Chapter 3.1. of the Terrestrial Code and the compliance of BSE diagnostic laboratories with the provisions of Chapter 1.1.3. of the Terrestrial Manual. Documentary evidence should be provided to support this based on Chapter 3.2. of the Terrestrial Code.

Article 11.5.2. of the Terrestrial Code Chapter on BSE prescribes the criteria to determine the BSE risk status of the cattle population of a country or zone. This document is the means whereby a claim for negligible risk (Article 11.5.3.) or controlled risk (Article 11.5.4.) can be made to the OIE.

The document comprises the following:

- Section 1 – Risk assessment (see Section 1 of Article 11.5.2.)
- Section 2 – Other requirements of Sections 2 to 4 of Article 11.5.2.
  - Ongoing awareness programme
  - Compulsory notification and investigation
  - Diagnostic capability
- Section 3 – Surveillance (Article 11.5.2. and Articles 11.5.20. to 11.5.22.)
- Section 4 – BSE history of the country or zone (Articles 11.5.3. and 11.5.4.).

N.B. Where, during the completion of this questionnaire, the submitting Veterinary Service provides documentation regarding the legislation under which it is mandated, it should provide the content of any legal act described (in one of the three official languages of OIE), as well as the dates of official publication and implementation. Submitting countries are encouraged to follow the format and numbering used in this document.

**SECTION 1: RISK ASSESSMENT (see point 1 of Article 11.5.2.)**

**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 Sections 2 and 3 and Chapter 4.3. of the Terrestrial Code, identifying all potential factors for BSE occurrence and their historic perspective.

**Documentation guidelines**

This section provides guidance on the data gathering and presentation of information required to support the risk entry and exposure assessments in respect of:

**Entry assessment:**

1) The potential for the entry of the BSE agent through importation of meat-and-bone meal or greaves.
2) The potential for the entry of the BSE agent through the importation of potentially infected live cattle.
3) The potential for the entry of the BSE agent through the importation of potentially infected products of bovine origin.

**Exposure assessment:**

4) The origin of bovine carcasses, by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of cattle feed production.
5) The potential for the exposure of cattle to the BSE agent through consumption of meat-and-bone meal or greaves of bovine origin.

In each of the five areas of entry and exposure assessment that follow, the contributor is guided in terms of the question, the rationale and the evidence required to support the country or zone status claim.

**Entry assessment**

1) **The potential for the entry of the BSE agent through importation of meat-and-bone meal or greaves**
   
   *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 risk of entry of BSE agent. Meat-and-bone meal and greaves
Chapter 1.6.- Procedures for self declaration and for official recognition by the OIE

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 entry risk.

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 cattle.

Evidence required:

a) 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
b) Documentation on annual volume, by country of origin, of meat-and-bone meal, greaves or feedstuffs containing them imported during the past eight years.

c) Documentation describing the species composition of the imported meat-and-bone meal, greaves or feedstuffs containing them.

d) Documentation, from the Veterinary Service of 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.

2) The potential for the entry of the BSE agent through the importation of potentially infected live cattle

Question to be answered: Have live cattle been imported within the past seven years?

Rationale: The likelihood of entry is dependent on:

– country or zone 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 imported cattle in the country or zone 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 cattle 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;

– dairy versus meat breeds, where there are differences in exposure in the country or zone of origin because feeding practices result in greater exposure of one category;

– age at slaughter.

Evidence required:

a) Documentation including tables on the country or zone of origin of imports. This should identify the country or zone of origin of the cattle, the length of time they lived in that country or zone and of any other country in which they have resided during their lifetime.

b) Documentation including tables describing origin and volume of imports.

c) Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country or zone of origin.

3) The potential for the entry of the BSE agent through the importation of potentially infected products of bovine origin

Question to be answered: What products of bovine origin have been imported within the past seven years?

Rationale: The likelihood of entry is dependent on:

– the origin of the cattle products and whether these products contain tissues known to contain BSE infectivity (Article 11.5.13.);

– country or zone 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 cattle in the country or zone 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 cattle 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;

– dairy versus meat breeds, where there are differences in exposure in the country or zone of origin because feeding practices result in greater exposure of one category;
Chapter 1.6.- Procedures for self declaration and for official recognition by the OIE

– age at slaughter.

Evidence required:

a) Documentation on the country or zone of origin of imports. This should identify the country or zone of origin of cattle from which the products were derived, the length of time they lived in that country or zone and of any other country in which they have resided during their lifetime.

b) Documentation describing origin and volume of imports.

c) Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country or zone of origin.

Exposure assessment

4) The origin of bovine carcasses, by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of cattle feed production

Question to be answered: How have bovine carcasses, by-products and slaughterhouse waste been processed over the past eight years?

Rationale: 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 of negligible or controlled BSE risk, it must have demonstrated that appropriate measures have been taken to manage any risks identified. If potentially infected cattle 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 cattle feed, the risk of cross-contamination exists.

Evidence required:

a) Documentation describing the collection and disposal of fallen stock and materials condemned as unfit for human consumption.

b) Documentation including tables describing the fate of imported cattle, including their age at slaughter or death.

c) Documentation describing the definition and disposal of specified risk material, if any.

d) Documentation describing the rendering process and parameters used to produce meat-and-bone meal and greaves.

e) 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.

f) Documentation describing the end use of imported cattle products and the disposal of waste.

g) Documentation describing monitoring and enforcement of the above.

5) The potential for the exposure of cattle to the BSE agent through consumption of meat-and-bone meal or greaves of bovine origin

Question to be answered: Has meat-and-bone meal or greaves of bovine origin been fed to cattle within the past eight years (Articles 11.5.3. and 11.5.4. in the Terrestrial Code)?

Rationale: If cattle have not been fed products of bovine origin (other than milk or blood) potentially containing meat-and-bone meal or greaves of bovine origin within the past eight years, meat-and-bone meal and greaves can be dismissed as a risk.

In the case of countries applying for negligible risk status, it will be required to demonstrate that the ruminant feed ban has been effective for at least eight years following the birth of the youngest case.

Evidence required:

a) Documentation describing the use of imported meat-and-bone meal and greaves, including the feeding of any animal species.

b) Documentation describing the use made of meat-and-bone meal and greaves produced from domestic cattle, including the feeding of any animal species.
c) Documentation on the measures taken to control cross-contamination of cattle feedstuffs with the *meat-and-bone meal* and *greaves* including the risk of cross-contamination during production, transport, storage and feeding.

d) Documentation, in the form of the following table, on the audit findings in rendering plants and feed mills processing ruminant material or mixed species containing ruminant material, related to the prohibition of the feeding to ruminants of *meat-and-bone meal* and *greaves*.

<table>
<thead>
<tr>
<th>Year (information should be provided for each of the 8 years for effectiveness is claimed)</th>
<th>Type of plant (renderer or feed mill)</th>
<th>Number of plants processing ruminant material</th>
<th>Number of plants in (A) inspected</th>
<th>Total number of visual inspections in (B)</th>
<th>Total number of plants in (B) with infractions</th>
<th>Total number of inspected plants in (B) with sampling</th>
<th>Total number of plants in (C) with positive test results</th>
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<td>Feed mill</td>
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e) Documentation, in the form of the following table, on the audit findings in rendering plants and feed mills processing non-ruminant material, related to the prohibition of the feeding of *meat-and-bone meal* and *greaves* to ruminants.

<table>
<thead>
<tr>
<th>Year (information should be provided for each of the 8 years for effectiveness is claimed)</th>
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f) Documentation, in the form of the following table, on each plant above processing ruminant material or mixed species containing ruminant material with infractions, specifying the type of infraction and the method of resolution.

<table>
<thead>
<tr>
<th>Year (information should be provided for each of the 8 years for effectiveness is claimed)</th>
<th>Type of plant (renderer or feed mill)</th>
<th>Plant ID</th>
<th>Nature of infraction</th>
<th>Method of resolution</th>
<th>Follow-up results</th>
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<td>Feed mill</td>
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</table>

h) Documentation explaining why, in light of the findings displayed in the preceding four tables, it is considered that there has been no significant exposure of cattle to the BSE agent through consumption of meat-and-bone meal or greaves of bovine origin.

i) Documentation of husbandry practices (multiple species farms) which could lend themselves to cross-contamination of cattle feed with meat-and-bone meal and greaves destined to other species.

SECTION 2: OTHER REQUIREMENTS (see points 2 to 4 of Article 11.5.2.)

1) Awareness programme (see point 2 of Article 11.5.2.)

   Questions to be answered:
   - Is there an awareness programme?
   - What is the target audience?
   - What is the curriculum and how long has it been in place?
   - Is there a contingency and/or preparedness plan that deals with BSE?

   Rationale:
   An awareness programme is essential to ensure detection and reporting of BSE, especially in countries of low prevalence and competing differential diagnoses.

   Evidence required:
   a) Documentation indicating when the awareness programme was instituted and its continuous application and geographical coverage.
   b) Documentation on the number and occupation of persons who have participated in the awareness programme (veterinarians, producers, workers at auctions, slaughterhouses, etc.).
   c) Documentation of materials used in the awareness programme (the manual, supportive documents, or other teaching materials).
   d) Documentation on the contingency plan.

2) Compulsory notification and investigation (see point 3 of Article 11.5.2.)

   Questions to be answered:
   - What guidance is given to veterinarians, producers, workers at auctions, slaughterhouses, etc. in terms of the criteria that would initiate the investigation of an animal as a BSE suspect? Have these criteria evolved?
   - What were the date and content of the legal act making notification of BSE suspects compulsory?
   - What are the measures in place to stimulate notification, such as compensation payments or penalties for not notifying a suspect?

   Rationale:
   The socio-economic implications associated with BSE require that there be incentives and/or obligations to notify and investigate suspect cases.

   Evidence required:
   a) Documentation on the date of official publication and implementation of compulsory notification. Including a brief description of incentives and penalties.
b) Documentation on the manual of procedures for investigation of suspect animals and follow-up of positive findings.

3) Examination in an approved laboratory of brain or other tissues collected within the framework of the aforementioned surveillance system (see point 4 of Article 11.5.2.)

Questions to be answered:
- Are the diagnostic procedures and methods those described in Chapter 2.4.6. of the Terrestrial Manual?
- Have these diagnostic procedures and methods been applied through the entire surveillance period?

Rationale:
The OIE only recognizes for the purpose of this submission samples that have been tested in accordance with the Terrestrial Manual.

Evidence required:
- Documentation as to the approved laboratories where samples of cattle tissues from the country or zone are examined for BSE. (If this is located outside the country, information should be provided on the cooperation agreement).
- Documentation of the diagnostic procedures and methods used.
- Documentation that the diagnostic procedures and methods have been applied through the entire surveillance period.

SECTION 3: BSE SURVEILLANCE AND MONITORING SYSTEMS (see point 4 of Article 11.5.2.)

Questions to be answered:
- Does the BSE surveillance programme comply with the guidelines in Articles 11.5.20. to 11.5.22. of the Terrestrial Code?
- What were the results of the investigations?

Rationale:
Point 4 of Article 11.5.2. and Articles 11.5.20. to 11.5.22. prescribe the number of cattle, by subpopulation, that need to be tested in order to ensure the detection of BSE at or above a minimal threshold prevalence.

Evidence required:
1) Documentation that the samples collected are representative of the distribution of cattle population in the country or zone.
2) Documentation of the methods applied to assess the ages of animals sampled and the proportions for each method (individual identification, dentition, other methods to be specified).
3) Documentation of the means and procedures whereby samples were assigned to the cattle subpopulations described in Article 11.5.21., including the specific provisions applied to ensure that animals described as clinical met the conditions of point 1 of Article 11.5.21.
4) Documentation of the number of animals meeting the conditions in point 1 of Article 11.5.21. as compared to the numbers of clinical samples submitted in previous years in accordance to the former provisions in the Terrestrial Code, and explanation of possible differences.
5) Documentation, based on the following table, of all clinically suspect cases notified complying with the definition in point 1 of Article 11.5.21.

<table>
<thead>
<tr>
<th>Laboratory identification number</th>
<th>Age</th>
<th>Clinical signs</th>
<th>Point of detection (farm, market channels, slaughterhouse)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


6) Documentation according to the following table, that the number of target points applicable to the country or zone and its BSE surveillance requirements (Type A or type B surveillance as a result of the risk assessment of section 1) are met as described in Articles 11.5.21. and 11.5.22.

<table>
<thead>
<tr>
<th>SUMMARY TABLE FOR BSE SURVEILLANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year: (complete a separate table for each year of surveillance)</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>&gt;1 and &lt;2 years</td>
</tr>
<tr>
<td>&gt;2 and &lt;4 years</td>
</tr>
<tr>
<td>&gt;4 and &lt;7 years</td>
</tr>
<tr>
<td>&gt;7 and &lt;9 years</td>
</tr>
<tr>
<td>&gt;9 years</td>
</tr>
<tr>
<td>Subtotals</td>
</tr>
<tr>
<td>Total points</td>
</tr>
</tbody>
</table>

7) Indicate the number of adult cattle (over 24 months of age) in the country or zone.

SECTION 4: BSE HISTORY OF THE COUNTRY OR ZONE (see Articles 11.5.3. and 11.5.4.)

Questions to be answered:
– Has BSE occurred in the country or zone?
– How has it been dealt with?

Rationale:
The categorization of a country or zone in either negligible or controlled risk is dependent upon, the outcome of the risk assessment described in Section 1, compliance with the provisions described in Section 2, the results of surveillance described in Section 3, and the history of BSE in the country or zone. This section provides the opportunity to describe the BSE history in the country or zone.

Evidence required:
1) Documentation of whether a case of BSE has ever been diagnosed in the country or zone.
   In the case of positive BSE findings:
2) Documentation on the origin of each BSE case in respect to the country or zone. Indicate the birth date and place of birth.
3) Indicate the most recent year of birth in relation to all BSE cases.
4) Documentation that:
   – the case(s) and all the progeny of female cases, born within two years prior to or after clinical onset of the disease, and
   – 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 or zone, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.
Chapter 1.6.- Procedures for self declaration and for official recognition by the OIE

Article 1.6.5.

Questionnaires on FMD

FMD FREE COUNTRY WHERE VACCINATION IS NOT PRACTISED

Report of a Member Country which applies for recognition of status, under Chapter 8.6. of the Terrestrial Code, as an FMD free country not practising vaccination

Please address concisely the following topics. National regulations and laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction
   a) Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to FMD dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of disease. Provide a map identifying the factors above.
   b) Livestock industry. Provide a general description of the livestock industry in the country.

2. Veterinary system
   a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to FMD.
   b) Veterinary Services. Provide documentation on the compliance of the Veterinary Service of the country with the provisions of Chapters 3.1. and 3.2. of the Terrestrial Code and 1.1.3. of the Terrestrial Manual and describe how the Veterinary Services supervise and control all FMD related activities. Provide maps and tables wherever possible.
   c) Role of farmers, industry and other relevant groups in FMD surveillance and control (include a description of training and awareness programmes on FMD).
   d) Role of private veterinary profession in FMD surveillance and control.

3. FMD eradication
   a) History. Provide a description of the FMD history in the country, date of first detection, origin of infection, date of eradication (date of last case), types and subtypes present.
   b) Strategy. Describe how FMD was controlled and eradicated (e.g. stamping-out policy, modified stamping-out policy, zoning), provide time frame for eradication.
   c) Vaccines and vaccination. Was FMD vaccine ever used? If so, when was the last vaccination carried out? What species were vaccinated?
   d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.
   e) Animal identification and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of animal identification, herd registration and traceability. How are animal movements controlled in the country? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and related paths of movement.

4. FMD diagnosis
   Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. of the Terrestrial Manual are applied. In particular, the following points should be addressed:
   a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results.
5. FMD surveillance

Provide documentary evidence that surveillance for FMD in the country complies with the provisions of Articles 8.6.42. to 8.6.47. and Article 8.6.49. of the Terrestrial Code and Chapter 2.1.5. of the Terrestrial Manual. In particular, the following points should be addressed:

a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspect cases, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis).

b) Serological surveillance. Are serological surveys conducted? If so, provide detailed information on the survey design (confidence level, sample size, stratification). How frequently are they conducted? Are wildlife susceptible species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted surveillance and numbers of animals examined and samples tested. Provide details on the methods applied for monitoring the performance of the surveillance system including indicators.

c) Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many herds, flocks, etc. of each susceptible species are in the country? How are they distributed (e.g. herd density, etc.)? Provide tables and maps as appropriate.

d) Wildlife demographics. What susceptible species are present in the country? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and wildlife susceptible species?

e) Slaughterhouses and markets. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the animals transported and handled during these transactions?

6. FMD prevention

a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries or zones that should be taken into account (e.g. size, distance from adjacent border to affected herds or animals)? Describe coordination, collaboration and information sharing activities with neighbouring countries.

b) Are there controls in place for the feeding of swill containing animal products to pigs? If so provide information on the extent of the practice, and describe controls and surveillance measures.

c) Import control procedures

From what countries or zones does the country authorize the import of susceptible animals or their products? What criteria are applied to approve such countries or zones? What controls are applied on entry of such animals and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported animals of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible animals and their products for the past two years, specifying country or zone of origin, species and volume.

i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central Veterinary Services. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of.

iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:

- animals,
Chapter 1.6.- Procedures for self declaration and for official recognition by the OIE

- genetic material (semen and embryos),
- animal products,
- veterinary medicinal products (i.e. biologics).

iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning
   a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed outbreaks of FMD.
   b) Is quarantine imposed on premises with suspicious cases, pending final diagnosis? What other procedures are followed regarding suspicious cases?
   c) In the event of an FMD outbreak:
      i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;
      ii) describe the actions taken to control the disease situation in and around any holdings found to be infected with FMD;
      iii) indicate the control and/or eradication procedures (e.g. vaccination, stamping-out policy, partial slaughter/vaccination, etc.) that would be taken. Include details on antigen and vaccine banks;
      iv) describe the procedures used to confirm that an outbreak has been successfully controlled/eradicated, including any restrictions on restocking;
      v) give details of any compensation payments made available to farmers, etc. when animals are slaughtered for disease control/eradication purposes and their prescribed timetable.

8. Compliance with the Terrestrial Code
   a) In addition to the documentary evidence that the provisions of Article 8.6.2. are properly implemented and supervised, the Delegate of the Member Country must submit a declaration indicating:
      i) there has been no outbreak of FMD during the past 12 months;
      ii) no evidence of FMDV infection has been found during the past 12 months;
      iii) no vaccination against FMD has been carried out during the past 12 months,
   b) and should confirm that since the cessation of vaccination no animals vaccinated against FMD have been imported.

9. Recovery of status
   Member Countries applying for recovery of status should comply with the provisions of Article 8.6.9. of the Terrestrial Code and provide detailed information as specified in sections 3.a), 3.b), 3.c) and 5.b) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

FMD FREE COUNTRY WHERE VACCINATION IS PRACTISED

Report of a Member Country which applies for recognition of status, under Chapter 8.6. of the Terrestrial Code, as an FMD free country practising vaccination

Please address concisely the following topics. National regulations and laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction
   a) Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to FMD dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of disease. Provide a map identifying the factors above.
   b) Livestock industry. Provide a general description of the livestock industry in the country.

2. Veterinary system
   a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to FMD.
b) **Veterinary Services.** Provide documentation on the compliance of the Veterinary Service of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how the Veterinary Services supervise and control all FMD related activities. Provide maps and tables wherever possible.

c) Role of farmers, industry and other relevant groups in FMD surveillance and control (include a description of training and awareness programmes on FMD).

d) Role of private veterinary profession in FMD surveillance and control.

3. **FMD eradication**

   a) **History.** Provide a description of the FMD history in the country, date of first detection, origin of infection, date of eradication (date of last case), types and subtypes present.

   b) **Strategy.** Describe how FMD was controlled and eradicated (e.g. stamping-out policy, modified stamping-out policy, zoning), provide time frame for eradication.

   c) **Vaccines and vaccination.** What type of vaccine is used? What species are vaccinated? Provide evidence that the vaccine used complies with Chapter 2.1.5. of the *Terrestrial Manual*. Describe the vaccination programme, including records kept, and provide evidence to show its effectiveness (e.g. vaccination coverage, serosurveillance, etc.).

   d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.

   e) **Animal identification and movement control.** Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of animal identification, herd registration and traceability, including vaccination data. How are animal movements controlled in the country? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and related paths of movement.

4. **FMD diagnosis**

   Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

   a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to and the follow-up procedures and the time frame for obtaining results.

   b) Provide an overview of the FMD approved laboratories, in particular to address the following points:

   i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.

   ii) Give details of participation in inter-laboratory validation tests (ring tests).

   iii) Is live virus handled?

   iv) Biosecurity measures applied.

   v) Details of the type of tests undertaken.

5. **FMD surveillance**

   Provide documentary evidence that surveillance for FMD in the country complies with the provisions of Articles 8.6.42. to 8.6.47. and Article 8.6.49. of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

   a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspect cases, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis).

   b) **Surveillance.** Are serological and virological surveys conducted, in particular applying the provisions of Article 8.6.46.? If so, provide detailed information on the survey design (confidence level, sample size, stratification). How frequently are they conducted? Are wildlife susceptible species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMD and FMDV, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted surveillance and numbers of animals examined and samples tested. Provide details on the methods applied for monitoring the performance of the surveillance system including indicators.
c) Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many herds, flocks, etc. of each susceptible species are in the country? How are they distributed (e.g. herd density, etc.)? Provide tables and maps as appropriate.

d) Wildlife demographics. What susceptible species are present in the country? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and wildlife susceptible species?

e) Slaughterhouses and markets. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the animals transported and handled during these transactions?

6. FMD prevention

a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries or zones that should be taken into account (e.g. size, distance from adjacent border to affected herds or animals)? Describe coordination, collaboration and information sharing activities with neighbouring countries.

b) Are there controls in place for the feeding of swill containing animal products to pigs? If so provide information on the extent of the practice, and describe controls and surveillance measures.

c) Import control procedures

From what countries or zones does the country authorize the import of susceptible animals or their products? What criteria are applied to approve such countries or zones? What controls are applied on entry of such animals and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported animals of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible animals and their products for the past two years, specifying country or zone of origin, species and volume.

i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central Veterinary Services. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of.

iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:

- animals,
- genetic material (semen and embryos),
- animal products,
- veterinary medicinal products (i.e. biologics).

iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed outbreaks of FMD.

b) Is quarantine imposed on premises with suspicious cases, pending final diagnosis? What other procedures are followed regarding suspicious cases?

c) In the event of an FMD outbreak:

i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;

ii) describe the actions taken to control the disease situation in and around any holdings found to be infected with FMD;

iii) indicate the control and/or eradication procedures (e.g. vaccination, stamping-out policy, partial slaughter/vaccination, etc.) that would be taken. Include details on antigen and vaccine banks;

iv) describe the procedures used to confirm that an outbreak has been successfully controlled/eradicated, including any restrictions on restocking;

v) give details of any compensation payments made available to farmers, etc. when animals are slaughtered for disease control/eradication purposes and their prescribed timetable.
8. **Compliance with the *Terrestrial Code***

In addition to the documentary evidence that the provisions of Article 8.6.3. are properly implemented and supervised, the Delegate of the Member Country must submit a declaration indicating that there has been no *outbreak* of FMD for the past two years and no evidence of FMDV circulation for the past 12 months, with documented evidence that:

a) *surveillance* for FMD and FMDV circulation in accordance with Articles 8.6.42. to 8.6.47. and Article 8.6.49. is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;

b) routine *vaccination* is carried out for the purpose of the prevention of FMD;

c) the vaccine used complies with the standards described in the *Terrestrial Manual*.

9. **Recovery of status**

Member Countries applying for recovery of status should comply with the provisions of Article 8.6.9. of the *Terrestrial Code* and provide detailed information as specified in sections 3.a), 3.b), 3.c) and 5.b) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

**FMD FREE ZONE WHERE VACCINATION IS NOT PRACTISED**

Report of a Member Country which applies for recognition of status, under Chapter 8.6. of the *Terrestrial Code*, as an FMD free zone not practising vaccination

Please address concisely the following topics. National regulations and laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. **Introduction**

   a) Geographical factors. Provide a general description of the country and the *zone* including physical, geographical and other factors that are relevant to FMD dissemination, countries or zones sharing common borders and other countries or zones that although may not be adjacent share a link for the potential introduction of disease. The boundaries of the *zone* must be clearly defined, including a *protection zone* if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zone*.

   b) Livestock industry. Provide a general description of the livestock industry in the country and the *zone*.

2. **Veterinary system**

   a) **Legislation.** Provide a list and summary of all relevant veterinary legislations in relation to FMD.

   b) **Veterinary Services.** Provide documentation on the compliance of the Veterinary Service of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how the Veterinary Services supervise and control all FMD related activities in the country and in the *zone*. Provide maps and tables wherever possible.

   c) Role of farmers, industry and other relevant groups in FMD surveillance and control (include a description of training and awareness programmes on FMD).

   d) Role of private veterinary profession in FMD surveillance and control.

3. **FMD eradication**

   a) History. Provide a description of the FMD history in the country and *zone*, provide date of first detection, origin of infection, date of eradication in the *zone* (date of last case), types and subtypes present.

   b) Strategy. Describe how FMD was controlled and eradicated in the *zone* (e.g. stamping-out policy, modified stamping-out policy), provide time frame for eradication.

   c) Vaccines and vaccination. If *vaccination* is used in the rest of the country, what type of vaccine is used? What species are vaccinated? Provide evidence that the vaccine used complies with Chapter 2.1.5. of the *Terrestrial Manual*. Describe the vaccination programme, including records kept, and provide evidence to show its effectiveness (e.g. vaccination coverage, serosurveillance, etc.).
d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.

e) Animal identification and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of animal identification, herd registration and traceability. How are animal movements controlled in and between zones of the same or different status, in particular if the provisions of the Terrestrial Code in Article 8.6.10. are applied? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and related paths of movement.

4. FMD diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. of the Terrestrial Manual are applied. In particular, the following points should be addressed:

a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of the arrangements with the laboratory(ies) samples are sent to. Indicate the laboratory(ies) where samples originating from the zone are diagnosed, the follow-up procedures and the time frame for obtaining results.

b) Provide an overview of the FMD approved laboratories, in particular to address the following points:
   i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.
   ii) Give details of participation in inter-laboratory validation tests (ring tests).
   iii) Is live virus handled?
   iv) Biosecurity measures applied.
   v) Details of the type of tests undertaken.

5. FMD surveillance

Provide documentary evidence that surveillance for FMD in the zone complies with the provisions of Articles 8.6.42. to 8.6.47. and Article 8.6.49. of the Terrestrial Code and Chapter 2.1.5. of the Terrestrial Manual. In particular, the following points should be addressed:

a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspect cases, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis).

b) Serological surveillance. Are serological surveys conducted? If so, provide detailed information on the survey design (confidence level, sample size, stratification). How frequently are they conducted? Are wildlife susceptible species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted surveillance and numbers of animals examined and samples tested. Provide details on the methods applied for monitoring the performance of the surveillance system including indicators.

c) Livestock demographics and economics. What is the susceptible animal population by species and production systems in the country and the zone? How many herds, flocks, etc. of each susceptible species are in the country? How are they distributed (e.g. herd density, etc.)? Provide tables and maps as appropriate.

d) Wildlife demographics. What susceptible species are present in the country and the zone? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and wildlife susceptible species?

e) Slaughterhouses and markets. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the animals transported and handled during these transactions?

6. FMD prevention

a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries and zones that should be taken into account (e.g. size, distance from adjacent border to affected herds or
animals)? Describe coordination, collaboration and information sharing activities with neighbouring countries and zones.

If the FMD free zone without vaccination is situated in an FMD infected country or borders an infected country or zone, describe the animal health measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers.

b) Are there controls in place for the feeding of swill containing animal products to pigs? If so, provide information on the extent of the practice, and describe controls and surveillance measures.

c) Import control procedures

From what countries or zones does the country authorize the import of susceptible animals or their products into a free zone? What criteria are applied to approve such countries or zones? What controls are applied on entry of such animals and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported animals of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible animals and their products for the past two years, specifying country or zone of origin, species and volume.

i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central Veterinary Services. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of.

iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:

- animals,
- genetic material (semen and embryos),
- animal products,
- veterinary medicinal products (i.e. biologics).

iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed outbreaks of FMD.

b) Is quarantine imposed on premises with suspicious cases, pending final diagnosis? What other procedures are followed regarding suspicious cases?

c) In the event of an FMD outbreak:

i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;

ii) describe the actions taken to control the disease situation in and around any holdings found to be infected with FMD;

iii) indicate the control and/or eradication procedures (e.g. vaccination, stamping-out policy, partial slaughter/vaccination, etc.) that would be taken. Include details on antigen and vaccine banks;

iv) describe the procedures used to confirm that an outbreak has been successfully controlled/eradicated, including any restrictions on restocking;

v) give details of any compensation payments made available to farmers, etc. when animals are slaughtered for disease control/eradication purposes and their prescribed timetable.

8. Compliance with the Terrestrial Code

In addition to the documentary evidence that the provisions of Article 8.6.4. are properly implemented and supervised, the Delegate of the Member Country must submit a declaration indicating:

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.
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9. Recovery of status

Member Countries applying for recovery of status should comply with the provisions of Article 8.6.9. of the Terrestrial Code and provide detailed information as specified in sections 3.a), 3.b), 3.c) and 5.b) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

FMD FREE ZONE WHERE VACCINATION IS PRACTISED

Report of a Member Country which applies for recognition of status, under Chapter 8.6. of the Terrestrial Code, as an FMD free zone practising vaccination

Please address concisely the following topics. National regulations and laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction
   a) Geographical factors. Provide a general description of the country and the zone including physical, geographical and other factors that are relevant to FMD dissemination, countries or zones sharing common borders and other countries or zones that although may not be adjacent share a link for the potential introduction of disease. The boundaries of the zone must be clearly defined, including a protection zone if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the zone.
   b) Livestock industry. Provide a general description of the livestock industry in the country and the zone.

2. Veterinary system
   a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to FMD.
   b) Veterinary Services. Provide documentation on the compliance of the Veterinary Service of the country with the provisions of Chapters 3.1. and 3.2. of the Terrestrial Code and 1.1.3. of the Terrestrial Manual and describe how the Veterinary Services supervise and control all FMD related activities in the country and in the zone. Provide maps and tables wherever possible.
   c) Role of farmers, industry and other relevant groups in FMD surveillance and control (include a description of training and awareness programmes on FMD).
   d) Role of private veterinary profession in FMD surveillance and control.

3. FMD eradication
   a) History. Provide a description of the FMD history in the country and zone, provide date of first detection, origin of infection, date of eradication in the zone (date of last case), types and subtypes present.
   b) Strategy. Describe how FMD was controlled and eradicated in the zone (e.g. stamping-out policy, modified stamping-out policy), provide time frame for eradication.
   c) Vaccines and vaccination. What type of vaccine is used? What species are vaccinated? Provide evidence that the vaccine used complies with Chapter 2.1.5. of the Terrestrial Manual. Describe the vaccination programme in the country and in the zone, including records kept, and provide evidence to show its effectiveness (e.g. vaccination coverage, serosurveillance, etc.).
   d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.
   e) Animal identification and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of animal identification, herd registration and traceability, including vaccination data. How are animal movements controlled in and between zones of the same or different status, in particular if the provisions of the Terrestrial Code in Article 8.6.10. are applied? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and related paths of movement.
4. FMD diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. of the Terrestrial Manual are applied. In particular, the following points should be addressed:

a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results. Indicate the laboratory(ies) where samples originating from the zone are diagnosed.

b) Provide an overview of the FMD approved laboratories, in particular to address the following points.

   i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.

   ii) Give details of participation in inter-laboratory validation tests (ring tests).

   iii) Is live virus handled?

   iv) Biosafety measures applied.

   v) Details of the type of tests undertaken.

5. FMD surveillance

Provide documentary evidence that surveillance for FMD in the zone complies with the provisions of Articles 8.6.42. to 8.6.47. and Article 8.6.49. of the Terrestrial Code and Chapter 2.1.5. of the Terrestrial Manual. In particular, the following points should be addressed:

a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspect cases, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis).

b) Surveillance. Are serological and virological surveys conducted, in particular applying the provisions of Article 8.6.46.? If so, provide detailed information on the survey design (confidence level, sample size, stratification). How frequently are they conducted? Are wildlife susceptible species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMD and FMDV, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted surveillance and numbers of animals examined and samples tested. Provide details on the methods applied for monitoring the performance of the surveillance system including indicators.

c) Livestock demographics and economics. What is the susceptible animal population by species and production systems in the country and the zone? How many herds, flocks, etc. of each susceptible species are in the country? How are they distributed (e.g. herd density, etc.)? Provide tables and maps as appropriate.

d) Wildlife demographics. What susceptible species are present in the country and in the zone? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and wildlife susceptible species?

e) Slaughterhouses and markets. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the animals transported and handled during these transactions?

6. FMD prevention

a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries and zones that should be taken into account (e.g. size, distance from adjacent border to affected herds or animals)? Describe coordination, collaboration and information sharing activities with neighbouring countries and zones.

If the FMD free zone with vaccination is situated in an FMD infected country or borders an infected country or zone, describe the animal health measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers.

b) Are there controls in place for the feeding of swill containing animal products to pigs? If so, provide information on the extent of the practice, and describe controls and surveillance measures.

c) Import control procedures

From what countries or zones does the country authorize the import of susceptible animals or their products into a free zone? What criteria are applied to approve such countries or zones? What controls are applied on entry of such animals and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported animals of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What
other procedures are used? Provide summary statistics of imports of susceptible animals and their products for the past two years, specifying the country or zone of origin, the species and the volume.

i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central Veterinary Services. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of.

iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:

- animals,
- genetic material (semen and embryos),
- animal products,
- veterinary medicinal products (i.e. biologics).

iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning
   a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed outbreaks of FMD.
   b) Is quarantine imposed on premises with suspicious cases, pending final diagnosis? What other procedures are followed regarding suspicious cases?
   c) In the event of an FMD outbreak:
      i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;
      ii) describe the actions taken to control the disease situation in and around any holdings found to be infected with FMD;
      iii) indicate the control and/or eradication procedures (e.g. vaccination, stamping-out policy, partial slaughter/vaccination, etc.) that would be taken. Include details on antigen and vaccine banks;
      iv) describe the procedures used to confirm that an outbreak has been successfully controlled/eradicated, including any restrictions on restocking;
      v) give details of any compensation payments made available to farmers, etc. when animals are slaughtered for disease control/eradication purposes and their prescribed timetable.

8. Compliance with the Terrestrial Code
   In addition to the documentary evidence that the provisions of Article 8.6.5. are properly implemented and supervised, the Delegate of the Member Country must submit a declaration indicating:
   a) that there has been no outbreak of FMD for the past two years,
   b) no evidence of FMDV circulation for the past 12 months,
   c) 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.

9. Recovery of status
   Member Countries applying for recovery of status should comply with the provisions of Article 8.6.9. of the Terrestrial Code and provide detailed information as specified in sections 3.a), 3.b), 3.c) and 5.b) of this questionnaire. Information in relation to other sections need only be supplied if relevant.
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Article 1.6.6.

Questionnaires on CBPP

CBPP FREE COUNTRY
Report of a Member Country which applies for recognition of status,
under Chapter 11.8. of the Terrestrial Code,
as a CBPP infection free country

Please address concisely the following topics. National regulations and laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction
   a) Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to CBPP dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of disease. Provide a map identifying the factors above.
   b) Livestock industry. Provide a general description of the livestock industry in the country.

2. Veterinary system
   a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to CBPP.
   b) Veterinary Services. Provide documentation on the compliance of the Veterinary Service of the country with the provisions of Chapters 3.1. and 3.2. of the Terrestrial Code and 1.1.3. of the Terrestrial Manual and describe how the Veterinary Services supervise and control all CBPP related activities. Provide maps and tables wherever possible.
   c) Role of farmers, industry and other relevant groups in CBPP surveillance and control (include a description of training and awareness programmes on CBPP).
   d) Role of private veterinary profession in CBPP surveillance and control.

3. CBPP eradication
   a) History. Provide a description of the CBPP history in the country, date of first detection, origin of infection, date of eradication (date of last case).
   b) Strategy. Describe how CBPP was controlled and eradicated (e.g. stamping-out policy, modified stamping-out policy, zoning), provide time frame for eradication.
   c) Vaccines and vaccination. Was CBPP vaccine ever used? If so, when was the last vaccination carried out?
   d) Legislation, organisation and implementation of the CBPP eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.
   e) Animal identification and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of animal identification, herd registration and traceability. How are animal movements controlled in the country? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and related paths of movement.

4. CBPP diagnosis
   Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.4.9. of the Terrestrial Manual are applied. In particular, the following points should be addressed:
   a) Is CBPP laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results.
   b) Provide an overview of the CBPP approved laboratories, in particular to address the following points:
      i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.
      ii) Give details of participation in inter-laboratory validation tests (ring tests).
iii) Biosecurity measures applied.
iv) Details of the type of tests undertaken including procedures to isolate and identify *M. mycoides* subsp. *mycoides* SC as opposed to *M. mycoides* subsp. *mycoides* LC.

5. CBPP surveillance

Provide documentary evidence that *surveillance* for CBPP in the country complies with the provisions of Articles 11.8.12. to 11.8.17. of the *Terrestrial Code* and Chapter 2.4.9. of the *Terrestrial Manual*. In particular, the following points should be addressed:

a) Clinical *surveillance*. What are the criteria for raising a suspicion of CBPP? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspect cases, the number of samples tested for CBPP agent, species, type of sample, testing method(s) and results (including differential diagnosis).

b) *Slaughterhouses*, slaughter slabs, abattoirs. What are the criteria for raising a suspicion of CBPP lesion? What is the procedure to notify (by whom and to whom)? Provide a summary table indicating, for the past two years, the number of suspect cases, the number of samples tested for CBPP agent, species, type of sample, testing method(s) and results (including differential diagnosis).

c) Provide details on training programmes for personnel involved in clinical and *slaughter facilities surveillance*, and the approaches used to increase community involvement in CBPP *surveillance* programmes.

d) For countries where a significant proportion of *animals* are not slaughtered in controlled *abattoirs*, what are the alternative *surveillance* measures applied to detect CBPP (e.g. active clinical *surveillance* programmes, laboratory follow-up).

e) Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many herds of each susceptible species are in the country? How are they distributed (e.g. herd density, etc.)? Provide tables and maps as appropriate.

f) *Slaughterhouses* and markets. Where are the major livestock marketing or collection centers? What are the patterns of livestock movement within the country? How are the *animals* transported and handled during these transactions?

g) Provide a description of the means employed during the two years preceding this application to rule out the presence of any *Mmm*SC strain in the susceptible population. Provide criteria for selection of populations for targeted *surveillance* and numbers of *animals* examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.

6. CBPP prevention

a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries that should be taken into account (e.g. size, distance from adjacent border to affected *herds or animals*)? Describe coordination, collaboration and information sharing activities with neighbouring countries.

b) Import control procedures

From what countries or zones does the country authorize the import of susceptible *animals*? What criteria are applied to approve such countries or zones? What controls are applied on entry of such *animals*, and subsequent internal movement? What import conditions and test procedures are required? Are imported *animals* of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible *animals* for the past two years, specifying country or zone of origin, species and volume.

i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

ii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:

- *animals*,
- semen, embryos and oocytes,
- *veterinary medicinal products*, i.e. biologics.

iii) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.
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7. Control measures and contingency planning
   a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed outbreaks of CBPP.
   b) Is quarantine imposed on premises with suspicious cases, pending final diagnosis? What other procedures are followed regarding suspicious cases?
   c) In the event of a CBPP outbreak:
      i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;
      ii) describe the actions taken to control the disease situation in and around any holdings found to be infected with CBPP;
      iii) indicate the control and/or eradication procedures (e.g. vaccination, stamping-out policy, partial slaughter/vaccination, etc.) that would be taken;
      iv) describe the procedures used to confirm that an outbreak has been successfully controlled/eradicated, including any restrictions on restocking;
      v) give details of any compensation payments made available to farmers, etc. when animals are slaughtered for disease control/eradication purposes and their prescribed timetable.

8. Compliance with the Terrestrial Code
   In addition to the documentary evidence that the provisions of Article 11.8.3. are properly implemented and supervised, the Delegate of the Member Country must submit a declaration indicating:
   a) no clinical CBPP has been detected for at least two years;
   b) no CBPP vaccines have been used for at least two years in any susceptible species;
   c) the country operates both clinical surveillance and disease reporting systems for CBPP adequate to detect clinical disease if it were present;
   d) all clinical and pathological evidence suggestive of CBPP is investigated by field and laboratory methods (including serological assessment) to refute a possible diagnosis of CBPP;
   e) there are effective measures in force to prevent the re-introduction of the disease.

9. Recovery of status
   Member Countries applying for recovery of status should comply with the provisions of Article 11.8.4. of the Terrestrial Code and provide detailed information as specified in Sections 3.a), 3.b), 3.c), 5.b), 5.c) and 5.d) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Please address concisely the following topics. National regulations and laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction
   a) Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to CBPP dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of disease. Provide a map identifying the factors above. The boundaries of the zone must be clearly defined. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the zone.
   b) Livestock industry. Provide a general description of the livestock industry in the country.

2. Veterinary system
   a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to CBPP.
   b) Veterinary Services. Provide documentation on the compliance of the Veterinary Service of the country with the provisions of Chapters 3.1. and 3.2. of the Terrestrial Code and 1.1.3. of the Terrestrial Manual and
describe how the Veterinary Services supervise and control all CBPP related activities. Provide maps and tables wherever possible.

c) Role of farmers, industry and other relevant groups in CBPP surveillance and control (include a description of training and awareness programmes on CBPP).

d) Role of private veterinary profession in CBPP surveillance and control.

3. CBPP eradication

a) History. Provide a description of the CBPP history in the country, date of first detection, origin of infection, date of eradication (date of last case).

b) Strategy. Describe how CBPP was controlled and eradicated in the zone (e.g. stamping-out policy, modified stamping-out policy, zoning) and provide time frame for eradication.

c) Vaccines and vaccination. Was CBPP vaccine ever used? In the entire country? If vaccination was used, when was the last vaccination carried out? Where in the country?

d) Legislation, organisation and implementation of the CBPP eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.

e) Animal identification and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of animal identification, herd registration and traceability. How are animal movements controlled in the zone? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and related paths of movement.

4. CBPP diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.4.9. of the Terrestrial Manual are applied. In particular, the following points should be addressed:

a) Is CBPP laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results.

b) Provide an overview of the CBPP approved laboratories, in particular to address the following points:
   i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.
   ii) Give details of participation in inter-laboratory validation tests (ring tests).
   iii) Biosecurity measures applied.
   iv) Details of the type of tests undertaken including procedures to isolate and identify M. mycoides subsp. mycoides SC as opposed to M. mycoides subsp. mycoides LC.

5. CBPP surveillance

Provide documentary evidence that surveillance for CBPP in the country complies with the provisions of Articles 11.8.12. to 11.8.17. of the Terrestrial Code and Chapter 2.4.9. of the Terrestrial Manual. In particular, the following points should be addressed:

a) Clinical surveillance. What are the criteria for raising a suspicion of CBPP? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspect cases, the number of samples tested for CBPP agent, species, type of sample, testing method(s) and results (including differential diagnosis).

b) Slaughterhouses, slaughter slabs, abattoirs. What are the criteria for raising a suspicion of CBPP lesion? What is the procedure to notify (by whom and to whom)? Provide a summary table indicating, for the past two years, the number of suspect cases, the number of samples tested for CBPP agent, species, type of sample, testing method(s) and results (including differential diagnosis).

c) Provide details on training programmes for personnel involved in clinical and slaughter facilities surveillance, and the approaches used to increase community involvement in CBPP surveillance programmes.

d) For countries where a significant proportion of animals in the zone are not slaughtered in controlled abattoirs, what are the alternative surveillance measures applied to detect CBPP (e.g. active clinical surveillance programme, laboratory follow-up).

e) Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many herds of each susceptible species are in the zone? How are they distributed (e.g. herd density, etc.)? Provide tables and maps as appropriate.
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f) Slaughterhouses and markets. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country and the zone? How are the animals transported and handled during these transactions?

g) Provide a description of the means employed during the two years preceding this application to rule out the presence of any MmmSC strain in the susceptible population of the zone. Provide criteria for selection of populations for targeted surveillance and numbers of animals examined and samples tested. Provide details on the methods applied for monitoring the performance of the surveillance system including indicators.

6. CBPP prevention

a) Coordination with neighbouring countries and zones. Are there any relevant factors about the adjacent countries and zones that should be taken into account (e.g. size, distance from adjacent border to affected herds or animals)? Describe coordination, collaboration and information sharing activities with neighbouring countries and zones. If the CBPP free zone is situated in a CBPP infected country or borders an infected country or zone, describe the animal health measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers.

b) Import control procedures
From what countries or zones does the country authorize the import of susceptible animals? What criteria are applied to approve such countries or zones? What controls are applied on entry of such animals, and subsequent internal movement? What import conditions and test procedures are required? Are imported animals of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible animals for the past two years, specifying country or zone of origin, species and volume.

i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central Veterinary Services. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

ii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the zone and/or their final destination, concerning the import and follow-up of the following:
– animals,
– semen, embryos and oocytes,
– veterinary medicinal products, i.e. biologics.

iii) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed outbreaks of CBPP.

b) Is quarantine imposed on premises with suspicious cases, pending final diagnosis? What other procedures are followed regarding suspicious cases?

c) In the event of a CBPP outbreak:

i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;

ii) describe the actions taken to control the disease situation in and around any holdings found to be infected with CBPP;

iii) indicate the control and/or eradication procedures (e.g. vaccination, stamping-out policy, partial slaughter/vaccination, etc.) that would be taken;

iv) describe the procedures used to confirm that an outbreak has been successfully controlled/eradicated, including any restrictions on restocking;

v) give details of any compensation payments made available to farmers, etc. when animals are slaughtered for disease control/eradication purposes.

8. Compliance with the Terrestrial Code

In addition to the documentary evidence that the provisions of Article 11.8.3. are properly implemented and supervised, the Delegate of the Member Country must submit a declaration indicating that in the zone:

a) no clinical CBPP has been detected for at least two years;
b) no CBPP vaccines have been used for at least two years in any susceptible species;
c) the country operates both clinical surveillance and disease reporting systems for CBPP adequate to detect clinical disease if it were present in the zone;
d) all clinical and pathological evidence suggestive of CBPP is investigated by field and laboratory methods (including serological assessment) to refute a possible diagnosis of CBPP;
e) there are effective measures in force to prevent the re-introduction of the disease.

9. Recovery of status
Member Countries applying for recovery of status should comply with the provisions of Article 11.8.4. of the Terrestrial Code and provide detailed information as specified in Sections 3.a), 3.b), 3.c), 5.b), 5.c) and 5.d) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Article 1.6.7.

Questionnaires on AHS

Please address concisely the following topics. National legislation, regulations and Veterinary Authority directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction
   a) Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to AHS introduction. Provide a map identifying the factors above.
   b) Equine sectors. Provide a general description of the equine sectors and their relative economic importance in the country. Outline any recent significant changes observed within the sector grouping(s) (if relevant documents are available, please attach).
      i) Sport and race horses.
      ii) Breeding stock equids.
      iii) Working and production equids (including horses for slaughter).
      iv) Leisure equids.
      v) Captive wild, wild and feral equids.

2. Description of equine population
   a) Demographics of domestic equids. What is the equine population by species within the various sectors? Provide a description of the methods of animal identification, holding and individual animal registration systems if in place. How are they distributed (e.g. density, etc.)? Provide tables and maps as appropriate.
   b) Wildlife demographics. What captive wild, wild or feral equids are present in the country? Provide estimates of population sizes and geographic distribution.

3. Veterinary system
   a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to AHS.
   b) Veterinary Services. Provide documentation on the compliance of the Veterinary Services of the country with the provisions of Chapters 3.1. and 3.2. of the Terrestrial Code and 1.1.3. of the Terrestrial Manual and describe how Veterinary Services supervise and control all AHS related activities. Provide maps and tables wherever possible.
   c) Role of farmers, keepers, industry, regulatory bodies, and other relevant groups in AHS surveillance and control (include a description of training and awareness programmes on AHS).
   d) Role of private veterinary profession in AHS surveillance and control.
   e) Provide information on any OIE PVS evaluation of the country and follow-up steps within the PVS Pathway.
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4. AHS eradication
   a) History. Provide a description of the AHS history in the country if applicable, date of first detection, origin of infection, date of eradication (date of last case), and serotypes present.
   b) Strategy. Describe how AHS was controlled and eradicated (e.g. isolation of cases, stamping-out policy, zoning), provide time frame for eradication.
   c) Vaccines and vaccination. What type of vaccine was used? What equine species were vaccinated? Were vaccinated animals marked or was vaccination recorded in a unique identification document?
   d) Legislation, organisation and implementation of the AHS eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines were used and give a brief summary.
   e) Animal identification. Are equids identified (individually or at a group level)?
   f) Movements of equids. How are movements of equids controlled in the country? Provide evidence on the effectiveness of identification and movement controls of equids. Please provide information on pastoralism, transhumance and related movements.
   g) Leisure and competition movements of equids. How are movements of competition and leisure equids controlled in the country? Please provide information on systems including any use of registration. Provide information on any events that include international movements of equids.
   h) Describe the market systems for equids, in particular, if markets require the international movement of equids.

5. AHS diagnosis
   Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3., and 2.5.1. of the Terrestrial Manual are applied. In particular, the following points should be addressed:
   a) Is AHS laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results.
   b) Provide an overview of the AHS approved laboratories, in particular to address the following points:
      i) Details on the types of tests undertaken.
      ii) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO that exist in, or planned for, the laboratory system.
      iii) Give details of participation in inter-laboratory validation tests (ring tests).
      iv) Describe biosecurity measures applied, particularly in the case where live virus is handled.

6. AHS surveillance
   Provide documentary evidence that surveillance for AHS in the country complies with the provisions of Articles 12.1.13. to 12.1.15. of the Terrestrial Code, and Chapter 2.5.1. of the Terrestrial Manual. In particular, the following points should be addressed:
   a) Clinical suspicion. What are the criteria for raising a suspicion of AHS? What is the procedure to notify (by whom and to whom), is there a compensation system in place and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspect cases, the number of samples tested for AHS, species, type of sample, testing method(s) and results (including differential diagnosis).
   b) Surveillance. Are the following undertaken?
      i) Serological surveillance.
      ii) Virological surveillance.
      iii) Sentinel animals.
      iv) Vector surveillance.
   If so, provide detailed information on the survey designs. How frequently are they conducted? Which were the equine species included? Are wildlife species included? Provide a summary table indicating detailed results, for at least the past two years. Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted surveillance and numbers of equids examined and samples tested. Provide details on the methods selected and applied for monitoring the performance of the surveillance system.
7. AHS prevention

a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries or zones that have been taken into account (e.g. size, distance from adjacent border to infected equids)? Describe coordination, collaboration and information sharing activities with neighbouring countries.

If the AHS free country borders an infected country or zone, describe the animal health measures implemented to effectively prevent the introduction of the agent or vectors, taking into consideration the seasonal vector conditions and existing physical, geographical and ecological barriers.

b) Import control procedures

From what countries or zones does the country authorize the import of equids or their products? What criteria are applied to approve such countries or zones? What controls are applied on entry of such equids and products, and subsequent internal movement?

What import conditions (e.g. quarantine) and test procedures are required? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports, temporary admissions or re-entry of equids and their products for at least the past two years, specifying country or zone of origin and volume.

i) Provide a map with the number and location of ports, airports and land crossings. Is the service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the Competent Authority. Describe the communication systems between the Competent Authority and the border inspection posts, and between border inspection posts.

ii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country or their final destination, concerning the import and follow-up of the following:

- equids,
- genetic material (sperm, ova and embryos of the equine species),
- equine derived (by-)products and biologicals.

iii) Describe the action available under legislation, and actually taken, when an illegal introduction is detected. Provide information on detected illegal introduction.

8. Control measures and contingency planning

a) Give details of any written guidelines, contingency plans (including information on vaccine banks) available to the Veterinary Services for dealing with suspected or confirmed cases of AHS.

b) In the event of a suspected or confirmed AHS outbreak:

- is quarantine imposed on premises with suspicious cases, pending final diagnosis?
- are movement restrictions applied on suspicion?
- describe the sampling and testing procedures used to identify and confirm presence of the causative agent;
- describe the actions taken to control the disease situation in and around any holdings found to be infected with AHS;
- describe the control or eradication procedures (e.g. vaccination, modified stamping-out policy);
- describe the procedures used to confirm that an outbreak has been successfully controlled or eradicated, including conditions for restocking;
- give details of any compensation made available when equids are killed, for disease control or eradication purposes.

9. Compliance with the Terrestrial Code

a) In addition to the documentary evidence that the provisions of Article 12.1.2. are properly implemented and supervised, the Delegate of the Member Country must submit a declaration stating:

- The section under paragraph 1 (of Article 12.1.2.) on the base of which the application is made;
- there has been no outbreak of AHS during the past 24 months;
- no routine vaccination against AHS has been carried out during the past 12 months;

b) and that vaccinated equids were imported in accordance with Chapter 12.1.

10. Recovery of status

Member Countries applying for recovery of status should comply with the provisions of Article 12.1.6. of the Terrestrial Code and provide detailed information as specified in sections 4.a), 4.b), 4.c) and 6., and highlight any
measures introduced to prevent a recurrence of the *infection* under section 7 of this questionnaire. Information in relation to other sections need only be supplied if relevant.

AHS FREE ZONE

Report of a Member Country which applies for recognition of status, under Chapter 12.1. of the Terrestrial Code, as an AHS free zone

Please address concisely the following topics. National regulations and laws and Veterinary Authority directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. **Introduction**
   a) Geographical factors. Provide a general description of the country and the zone including physical, geographical and other factors that are relevant to AHS introduction. Provide a map identifying the factors above. The boundaries of the zone must be clearly defined, including a protection zone, if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the zone (and of the protection zone) established in accordance with Chapter 4.3.
   b) Equine sectors. Provide a general description of the equine sectors and their relative economic importance in the country and the zone. Outline any recent significant changes observed within the sector grouping(s) (if relevant documents are available, please attach).
      i) Sport and race horses.
      ii) Breeding stock equids.
      iii) Working and production equids (including horses for slaughter).
      iv) Leisure equids.
      v) Captive wild, wild and feral equids.

2. **Description of equine population**
   a) Demographics of domestic equids. What is the equine population by species within the various sectors in the country and the zone? Provide a description of the methods of animal identification, holding and individual animal registration systems in the country and the zone if in place. How are they distributed (e.g. density, etc.)? Provide tables and maps as appropriate.
   b) Wildlife demographics. What captive wild, wild and feral equids are present in the country and the zone? Provide estimates of population sizes and geographic distribution.

3. **Veterinary system**
   a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to AHS.
   b) Veterinary Services. Provide documentation on the compliance of the Veterinary Services of the country with the provisions of Chapters 3.1. and 3.2. of the Terrestrial Code and 1.1.3. of the Terrestrial Manual and describe how Veterinary Services supervise and control all AHS related activities in the country and in the zone. Provide maps and tables wherever possible.
   c) Role of farmers, keepers, industry, regulatory bodies, and other relevant groups in AHS surveillance and control (include a description of training and awareness programmes on AHS).
   d) Role of private veterinary profession in AHS surveillance and control.

4. **AHS eradication**
   a) History. Provide a description of the AHS history in the country and zone, if applicable, date of first detection, origin of *infection*, date of eradication in the zone (date of last case), and serotypes present.
   b) Strategy. Describe how AHS was controlled and eradicated in the zone (e.g. isolation of cases, *stamping-out policy*, zoning), provide time frame for eradication.
   c) Vaccines and *vaccination*. What type of vaccine was used in the zone and the rest of the country? What equine species were vaccinated? Were vaccinated animals marked or was *vaccination* recorded in a unique identification document?
   d) Legislation, organisation and implementation of the AHS eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines were used and give a brief summary.
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5. AHS diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3., and 2.5.1. of the Terrestrial Manual are applied in the country and the zone. In particular, the following points should be addressed:

a) Is AHS laboratory diagnosis carried out in the country and the zone? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results. Indicate the laboratory(ies) where samples originating from the zone are diagnosed.

b) Provide an overview of the AHS approved laboratories, in particular to address the following points:
   i) Details on the types of tests undertaken.
   ii) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO that exist in, or planned for, the laboratory system.
   iii) Give details of participation in inter-laboratory validation tests (ring tests).
   iv) Describe biosecurity measures applied, particularly in the case where live virus is handled.

6. AHS surveillance

Provide documentary evidence that surveillance for AHS in the zone complies with the provisions of Articles 12.1.13. to 12.1.15. of the Terrestrial Code, and Chapter 2.5.1. of the Terrestrial Manual. In particular, the following points should be addressed:

a) Clinical suspicion. What are the criteria for raising a suspicion of AHS? What is the procedure to notify (by whom and to whom), is there a compensation system in place and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspect cases, the number of samples tested for AHS, species, type of sample, testing method(s) and results (including differential diagnosis) from the zone.

b) Surveillance. Are the following undertaken?
   i) Serological surveillance.
   ii) Virological surveillance.
   iii) Sentinel animals.
   iv) Vector surveillance.

If so, provide detailed information on the survey designs. How frequently are they conducted? Which were the equine species included? Are wildlife species included? Provide a summary table indicating detailed results, for at least the past two years. Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted surveillance and numbers of equids examined and samples tested. Provide details on the methods selected and applied for monitoring the performance of the surveillance system.

7. AHS prevention

a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries or zones that have been taken into account (e.g. size, distance from adjacent border to infected equids)? Describe coordination, collaboration and information sharing activities with neighbouring countries and zones. If the AHS free zone is established in an AHS infected country or borders an infected country or infected zones, describe the animal health measures implemented to effectively prevent the introduction of the agent or vectors, taking into consideration the seasonal vector conditions and existing physical, geographical and ecological barriers.

b) Import control procedures. From what countries or zones does the country authorize the import of equids or their products into the free zone? What criteria are applied to approve such countries or zones? What controls are applied on entry of such equids and products, and subsequent internal movement? What import conditions (e.g. quarantine) and test procedures are required? Are import permits and health certificates
required? What other procedures are used? Provide summary statistics of imports, temporary admissions or re-entry of equids and their products to the free zone for at least the past two years, specifying country or zone of origin and volume.

i) Provide a map with the number and location of ports, airports and land crossings in the zone. Is the service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the Competent Authority. Describe the communication systems between the Competent Authority and the border inspection posts, and between border inspection posts.

ii) Describe the regulations, procedures, type and frequency of checks at the points of entry into the zone or their final destination, concerning the import and follow-up of the following:
   - equids,
   - genetic material (semen, ova and embryos of the equine species),
   - equine derived (by-)products and biologicals.

iii) Describe the action available under legislation, and actually taken, when an illegal introduction into the zone is detected. Provide information on detected illegal introductions into the zone.

8. Control measures and contingency planning
   a) Give details of any written guidelines, contingency plans (including information on vaccine banks) available to the Veterinary Services for dealing with suspected or confirmed cases of AHS in the country and the zone (including the protection zone if applicable).
   b) In the event of a suspected or confirmed AHS outbreak in the zone:
      i) is quarantine imposed on premises with suspicious cases, pending final diagnosis?
      ii) are movement restrictions applied on suspicion?
      iii) describe the sampling and testing procedures used to identify and confirm presence of the causative agent;
      iv) describe the actions taken to control the disease situation in and around any holdings found to be infected with AHS;
      v) describe the control or eradication procedures (e.g. vaccination, modified stamping-out policy);
      vi) describe the procedures used to confirm that an outbreak has been successfully controlled or eradicated, including conditions for restocking;
      vii) give details of any compensation made available when equids are killed, for disease control or eradication purposes.

9. Compliance with the Terrestrial Code
   a) In addition to the documentary evidence that the provisions of Article 12.1.2. are properly implemented and supervised, the Delegate of the Member Country must submit a declaration stating:
      i) the section under paragraph 1 (of Article 12.1.2.) on the base of which the application is made;
      ii) there has been no outbreak of AHS during the past 24 months in the zone;
      iii) no routine vaccination against AHS has been carried out during the past 12 months in the zone;
   b) and that vaccinated equids were imported into the zone in accordance with Chapter 12.1.

10. Recovery of status
    Member Countries applying for recovery of status should comply with the provisions of Article 12.1.6. of the Terrestrial Code and provide detailed information as specified in sections 4.a), 4.b), 4.c) and 6. and highlight any measures introduced to prevent a recurrence of the infection under Section 7 of this questionnaire.
Article 1.6.8.

Questionnaires on PPR

Please address concisely the following topics. National regulations and laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction
   a) Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to PPR dissemination. Countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of disease. Provide a map identifying the factors above.
   b) Livestock industry. Provide a general description of the livestock industry in the country.

2. Veterinary system
   a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to PPR.
   b) Veterinary Services. Provide documentation on the compliance of the Veterinary Service of the country with the provisions of Chapters 3.1. and 3.2. of the Terrestrial Code and 1.1.3. of the Terrestrial Manual and describe how the Veterinary Services supervise and control all PPR related activities. Provide maps and tables wherever possible.
   c) Role of farmers, industry and other relevant groups in PPR surveillance and control (include a description of training and awareness programmes on PPR).
   d) Role of private veterinary profession in PPR surveillance and control.

3. PPR eradication
   a) History. Provide a description of the PPR history in the country, date of first detection, epidemiological patterns, origin of infection, date of eradication (date of last case), lineage(s) present if available.
   b) Strategy. Describe how PPR was controlled and eradicated (e.g. stamping-out policy, modified stamping-out policy, zoning), provide time frame for eradication.
   c) Vaccines and vaccination. Was PPR vaccine ever used? If so, when was the last vaccination carried out? What species were vaccinated?
   d) Legislation, organisation and implementation of the PPR eradication campaign. Provide a description of the organisational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.
   e) Animal identification and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of animal identification, herd or flock registration and traceability. How are animal movements controlled in the country? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and related paths of movement.

4. PPR diagnosis
   Provide evidence that a system is in place for the rapid confirmation of a suspected outbreak i.e. that the provisions in Chapters 1.1.2., 1.1.3. and 2.7.11. of the Terrestrial Manual are applied. In particular, the following points should be addressed:
   a) Is PPR laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results.
b) Provide an overview of the PPR approved laboratories in the country, in particular to address the following points:
   i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the laboratory system.
   ii) Give details of participation in inter-laboratory validation tests (ring tests).
   iii) Is live virus handled?
   iv) Biosecurity measures applied.
   v) Details of the type of tests undertaken.

5. PPR surveillance

Provide documentary evidence that surveillance for PPR in the country complies with the provisions of Articles 14.8.27. to 14.8.33. of the Terrestrial Code and Chapter 2.7.11. of the Terrestrial Manual. In particular, the following points should be addressed:

a) Clinical suspicion. What are the criteria for raising a suspicion of PPR? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what disincentives for failure to report? Provide a summary table indicating, for the past two years, the number of suspected cases, the number of samples tested for PPR virus, species, type of sample, testing method(s) and results (including differential diagnosis). In particular, provide evidence of compliance with the provisions of Articles 14.8.27. to 14.8.33. of the Terrestrial Code.

b) Serological surveillance. Are serological surveys conducted? If so, provide detailed information on the survey design in accordance with Articles 14.8.27. to 14.8.33. of the Terrestrial Code. Are wildlife susceptible species included in serological surveys? If not, explain the rationale. Provide a summary table indicating, for the past two years, the number of samples tested for PPR virus, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted surveillance and numbers of animals examined and samples tested. Provide details on the methods applied for monitoring the performance of the surveillance system including indicators.

c) Domestic small ruminant demographics and economics. What is the population by species and production systems? How many herds or flocks of each species are in the country? How are they distributed (e.g. herd or flock density)? Provide tables and maps as appropriate.

d) Wildlife demographics. What susceptible species are present in the country? Provide estimates of population sizes and geographic distribution.

e) Slaughterhouses/abattoirs and markets. Where are the major domestic small ruminant marketing or collection centres? What are the patterns of domestic small ruminant movement within the country? How are the animals transported and handled during these transactions?

6. PPR prevention

a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries that should be taken into account (e.g. distance from the border to susceptible herds, flocks or animals in the neighbouring country)? Describe coordination, collaboration and information sharing activities with neighbouring countries.

b) Import control procedures

From what countries or zones does the country authorise the import of sheep and goats and susceptible wildlife or their products? What criteria are applied to approve such countries or zones? What controls are applied on entry of such animals and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported sheep and goats and susceptible wildlife required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of sheep and goats and susceptible wildlife and their products for the past two years, specifying country or zone of origin, species and volume.

c) Provide a map with the number and location of ports, airports and land crossings. Is the service responsible for import controls part of the government services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central Veterinary Services. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

d) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country or their final destination, concerning the import and follow-up of the following:
   i) small ruminants,
ii) genetic material (semen and embryos),
iii) animal products,
iv) veterinary medicinal products, i.e. biologics.

e) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning
a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed outbreaks of PPR.
b) Is quarantine imposed on premises with suspected cases, pending final diagnosis? What other procedures are followed regarding suspected cases?
c) In the event of a PPR outbreak:
   i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;
   ii) describe the actions taken to control the disease situation in and around any holdings found to be infected with PPR;
   iii) indicate the control or eradication procedures (e.g. vaccination, stamping-out policy, modified stamping-out policy, etc.) that would be taken;
   iv) describe the procedures used to confirm that an outbreak has been successfully controlled and the disease eradicated, including any restrictions on restocking;
   v) give details and prescribed timetable of any compensation made available to owners when animals are slaughtered for disease control or eradication purposes.

8. Compliance with the Terrestrial Code
The Delegate of the Member Country must submit documentary evidence that the provisions of Article 14.8.3. or point 1 of Article 1.4.6. (historical freedom) of the Terrestrial Code have been properly implemented and supervised.

9. Recovery of status
Member Countries applying for recovery of status should comply with the provisions of Article 14.8.7. of the Terrestrial Code and provide detailed information as specified in Sections 3.a, 3.b, 3.c and 5.b of this questionnaire. Information in relation to other sections need only be supplied if relevant.

PPR FREE ZONE
Report of a Member Country which applies for recognition of status, under Chapter 14.8. of the Terrestrial Code, as a PPR free zone

Please address concisely the following topics. National regulations and laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction
   a) Geographical factors. Provide a general description of the country and the zone including physical, geographical and other factors that are relevant to PPR dissemination, countries or zones sharing common borders and other countries or zones that although may not be adjacent share a link for the potential introduction of disease. The boundaries of the zone must be clearly defined, including a protection zone if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the zone.
   b) Livestock industry. Provide a general description of the livestock industry in the country and the zone.

2. Veterinary system
   a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to PPR.
   b) Veterinary Services. Provide documentation on the compliance of the Veterinary Service of the country with the provisions of Chapters 3.1. and 3.2. of the Terrestrial Code and Chapter 1.1.3. of the Terrestrial Manual
and describe how the Veterinary Services supervise and control all PPR related activities. Provide maps and tables wherever possible.

c) Role of farmers, industry and other relevant groups in PPR surveillance and control (include a description of training and awareness programmes on PPR).

d) Role of private veterinary profession in PPR surveillance and control.

3. PPR eradication

a) History. Provide a description of the PPR history in the country and zone, date of first detection, epidemiological patterns, origin of infection, date of eradication (date of last case), lineage(s) present if available.

b) Strategy. Describe how PPR was controlled and eradicated in the zone (e.g. stamping-out policy, modified stamping-out policy, zoning), provide time frame for eradication.

c) Vaccines and vaccination. Was PPR vaccine ever used? If so, when was the last vaccination carried out? What species were vaccinated?

d) Legislation, organisation and implementation of the PPR eradication campaign. Provide a description of the organisational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.

e) Animal identification and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of animal identification, herd or flock registration and traceability. How are animal movements controlled in and between zones of the same or different status? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and related paths of movement.

4. PPR diagnosis

Provide evidence that a system is in place for the rapid confirmation of a suspected outbreak i.e. that the provisions in Chapters 1.1.2., 1.1.3. and 2.7.11. of the Terrestrial Manual are applied. In particular, the following points should be addressed:

a) Is PPR laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results.

b) Provide an overview of the PPR approved laboratories in the country, in particular to address the following points:

   i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the laboratory system.

   ii) Give details of participation in inter-laboratory validation tests (ring tests).

   iii) Is live virus handled?

   iv) Biosecurity measures applied.

   v) Details of the type of tests undertaken.

5. PPR surveillance

Provide documentary evidence that surveillance for PPR in the zone complies with the provisions of Articles 14.8.27. to 14.8.33. of the Terrestrial Code and Chapter 2.7.11. of the Terrestrial Manual. In particular, the following points should be addressed:

a) Clinical suspicion. What are the criteria for raising a suspicion of PPR? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what disincentives for failure to report? Provide a summary table indicating, for the past two years, the number of suspected cases, the number of samples tested for PPR virus, species, type of sample, testing method(s) and results (including differential diagnosis). In particular, provide evidence of compliance with the provisions of Articles 14.8.27. to 14.8.33. of the Terrestrial Code.

b) Serological surveillance. Are serological surveys conducted? If so, provide detailed information on the survey design in accordance with Articles 14.8.27. to 14.8.33. of the Terrestrial Code. Are wildlife susceptible species included in serological surveys? If not, explain the rationale. Provide a summary table indicating, for the past two years, the number of samples tested for PPR virus, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted surveillance and numbers of animals examined and samples tested. Provide details on the methods applied for monitoring the performance of the surveillance system including indicators.
c) Domestic small ruminant demographics and economics. What is the population by species and production systems? How many herds or flocks of each species are in the country and the zone? How are they distributed (e.g. herd or flock density)? Provide tables and maps as appropriate.

d) Wildlife demographics. What susceptible species are present in the country and the zone? Provide estimates of population sizes and geographic distribution.

e) Slaughterhouses/abattoirs and markets. Where are the major domestic small ruminant marketing or collection centres? What are the patterns of domestic small ruminant movement within the country? How are the animals transported and handled during these transactions?

6. PPR prevention

a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries and zones that should be taken into account (e.g. distance from the border to susceptible herds, flocks or animals in the neighbouring country)? Describe coordination, collaboration and information sharing activities with neighbouring countries and zones.

If the PPR free zone is situated in a PPR infected country or borders an infected country or zone, describe the animal health measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers.

b) Import control procedures

From what countries or zones does the country authorise the import of sheep and goats and susceptible wildlife or their products into a free zone? What criteria are applied to approve such countries or zones? What controls are applied on entry of such animals and products, and subsequent internal movement? What import conditions and test procedures are required? What other procedures are used? Provide summary statistics of imports of sheep and goats and susceptible wildlife and their products for the past two years, specifying country or zone of origin, species and volume.

c) Provide a map with the number and location of ports, airports and land crossings. Is the service responsible for import controls part of the government services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central Veterinary Services. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

d) Describe the regulations, procedures, type and frequency of checks at the point of entry into the zone or their final destination, concerning the import and follow-up of the following:

i) small ruminants,

ii) genetic material (semen and embryos);

iii) animal products,

iv) veterinary medicinal products, i.e. biologics.

e) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed outbreaks of PPR.

b) Is quarantine imposed on premises with suspected cases, pending final diagnosis? What other procedures are followed regarding suspected cases?

c) In the event of a PPR outbreak:

i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;

ii) describe the actions taken to control the disease situation in and around any holdings found to be infected with PPR;

iii) indicate the control or eradication procedures (e.g. vaccination, stamping-out policy, modified stamping-out policy, etc.) that would be taken;

iv) describe the procedures used to confirm that an outbreak has been successfully controlled and the disease eradicated, including any restrictions on restocking;

v) give details and prescribed timetable of any compensation made available to owners when animals are slaughtered for disease control or eradication purposes.
8. Compliance with the *Terrestrial Code*

The Delegate of the Member Country must submit documentary evidence that the provisions of Article 14.8.3. or point 1 of Article 1.4.6. (historical freedom) of the *Terrestrial Code* have been properly implemented and supervised.

9. Recovery of status

Member Countries applying for recovery of status should comply with the provisions of Article 14.8.7. of the *Terrestrial Code* and provide detailed information as specified in Sections 3.a), 3.b), 3.c) and 5.b) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

**Article 1.6.9.**

**Questionnaire on CSF**

Please address concisely the following topics. National regulations and laws and Veterinary Authority directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. **Introduction**
   a) Geographical factors. Provide a general description of the country or zone including physical, geographical and other factors that are relevant to CSF dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of disease. The boundaries of the country or zone must be clearly defined, including a protection zone if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the country or zone.
   b) Pig industry. Provide a general description of the domestic and captive wild pig industry in the country or zone.

2. **Veterinary system**
   a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to CSF.
   b) Veterinary Services. Provide documentation on the compliance of the Veterinary Service of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and Chapter 1.1.3. of the *Terrestrial Manual* and describe how the Veterinary Services supervise and control all CSF related activities. Provide maps and tables wherever possible.
   c) Role of farmers, industry and other relevant governmental and non-governmental organisations in CSF surveillance and control (include a description of training and awareness programmes on CSF).
   d) Role of private veterinary profession in CSF surveillance and control.

3. **CSF eradication**
   a) History. Provide a description of the CSF history in the country and zone, date of first detection, temporal and spatial distribution, origin of infection, date of last case in the country or zone.
   b) Strategy. Describe how CSF was controlled and eradicated in the country or zone (e.g. stamping-out policy, modified stamping-out policy, zoning), provide time frame for eradication.
   c) Vaccines and vaccination. Was CSF vaccine ever used? If so, of what type and when was the last vaccination carried out? If DIVA vaccine has been used, provide details of the differential tests.
   d) Legislation, organisation and implementation of the CSF eradication campaign. Provide a description of the organisational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.
   e) Animal identification and movement control. Are pigs identified (individually or at a group level)? Provide a description of the criteria and methods for animal identification, herd registration and traceability for all sectors.
Chapter 1.6.- Procedures for self declaration and for official recognition by the OIE

of pig production including free-ranging pig management systems. How are pig movements controlled in different sectors in the country or zone, or between zones of the same or different status?

4. CSF diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.1, 1.1.2., 1.1.3., and 2.8.3. of the Terrestrial Manual are applied. In particular, the following points should be addressed:

a) Is CSF laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results.

b) Provide an overview of the CSF approved laboratories, in particular to address the following points:
   i) Procedures for the official accreditation of laboratories. Give details of formal quality management systems, such as Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the laboratory system.
   ii) Give details of participation in inter-laboratory validation tests (ring tests).
   iii) Is live virus handled?
   iv) Biosecurity and biosafety measures applied.
   v) Details of the type of tests undertaken.

5. CSF surveillance

Provide documentary evidence that surveillance for CSF in the country or zone complies with the provisions of Articles 15.2.26. to 15.2.32. of the Terrestrial Code and Chapter 2.8.3. of the Terrestrial Manual. In particular, the following points should be addressed:

a) Clinical suspicion. What are the criteria for raising a suspicion of CSF? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past 12 months, the number of suspected cases, the number of samples tested for CSFV, type of sample, testing method(s) and results (including differential diagnosis).

b) Serological and virological surveillance. Are serological or virological surveys conducted? If so, provide detailed information on the survey design (confidence level, sample size, stratification). How frequently are they conducted? Are wild and feral pigs included in surveillance? For both serological and virological surveillance provide a summary table indicating, for the past 12 months, the number of samples tested for CSFV, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted surveillance and numbers of pigs examined and samples tested. Provide details on the methods applied for monitoring the performance of the surveillance system including indicators.

c) Domestic and captive wild pig populations and production. What is the pig population? Provide a description of the different production systems present in the country and zone(s) and production figures in each sector. How many herds are in the country and zone(s)? How are they distributed (e.g. herd density, etc.)? Provide tables and maps as appropriate.

d) Wild and feral pig populations. Provide estimates of population sizes, geographic distribution and, if available, population trends in the country and zone(s).

e) Slaughterhouses and markets. Where are the major pig marketing or collection centres? What are the patterns of pig movement within the country or zone, and between zone(s) of the same or different status? How are the pigs sourced, transported and handled during these transactions? Is any surveillance carried out at slaughterhouses? Provide data on the number of pigs slaughtered and inspected during the past twelve months.

6. CSF prevention

a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries or zones that should be taken into account (e.g. size, distance from adjacent border to affected herds or wild and feral pig populations)? Describe coordination, collaboration and information sharing activities with neighbouring countries. Are protection zones in place? If so, provide details on the measures that are applied (e.g. vaccination, intensified surveillance, pig density control), and provide a geo-referenced map of the zone(s).

b) Import control procedures

From what countries or zones does the country authorize the import of pigs or their products? What criteria are applied to approve such countries or zones? What controls are applied on entry of such pigs and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported pigs required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits
and health certificates required? What other procedures are used? Provide summary statistics of imports of pigs and their products for the past twelve months, specifying country or zone of origin and volume.

i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central Veterinary Services. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past twelve months, of the quantity disposed of. Is swill feeding of pigs allowed in the country? If so, provide details on any heat inactivation procedures that are applied.

iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country or their final destination, concerning the import and follow-up of the following:
   - pigs,
   - genetic material (semen and embryos),
   - fresh meat, pig products and by-products,
   - veterinary medicinal products (i.e. biologics).

iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

   a) What are the measures in place to prevent contact between domestic and captive wild pigs, and wild and feral pig populations?
   b) If DIVA vaccine is used as part of risk mitigation, provide details of the vaccine and the differential tests.
   c) Describe the procedures applied to ensure disinfection of vehicles and equipment, including verification methods.
   d) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed outbreaks of CSF.
   e) Is quarantine imposed on premises with suspected cases, pending final diagnosis? What other procedures are followed regarding suspected cases?
   f) In the event of a CSF outbreak:
      i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;
      ii) describe the actions taken to control the disease situation in and around any holdings found to be infected with CSF;
      iii) indicate the control and eradication procedures (e.g. policies on emergency vaccination, stamping-out policy, partial slaughter, etc.) that would be taken. Provide details of any vaccine supply scheme and stocks. If DIVA vaccines may be used, also include details on the differential test. Include details on carcass disposal, logistics and methods;
      iv) describe the procedures used to confirm that an outbreak has been successfully controlled or eradicated, including any restrictions on restocking;
      v) give details of any compensation payments when pigs are slaughtered for disease control and eradication purposes and the prescribed timetable for payments.

8. Compliance with the Terrestrial Code

   In addition to the documentary evidence that the provisions of Articles 15.2.2. and 15.2.3. are properly implemented and supervised, the Delegate of the Member Country must submit a declaration indicating:
   a) there has been no outbreak of CSF or evidence of CSFV infection in domestic and captive wild pigs in the country or zone during the past 12 months;
   b) no vaccination against CSF has been carried out in domestic and captive wild pigs in the country or zone during the past 12 months; or, if vaccination is carried out, vaccinated and infected pigs can be distinguished by a means validated according to Chapter 2.8.3. of the Terrestrial Manual;
   c) imported pigs and pig commodities comply with the relevant requirements in Chapter 15.2.
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9. Recovery of free status

Member Countries applying for recovery of free status of a country or zone should comply with the provisions of Article 15.2.6. of the Terrestrial Code and provide detailed information as specified in sections 3.a), 3.b), 3.c), 5.b) and 7 of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Article 1.6.10.

Questionnaire on FMD

Please address concisely the following topics. National laws, regulations and Veterinary Authority directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction
   a) Provide a general description of geographical factors in the country and zones, including physical, geographical and other factors that are relevant to FMD dissemination, countries or zones sharing common borders and other countries or zones that, although not adjacent, present a risk for the introduction of disease.
   b) If the endorsed plan is gradually implemented to specific parts of the country, the boundaries of the zone(s) should be clearly defined, including the protection zone, if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the zone(s).
   c) Provide a general description of the livestock industry in the country and any zones.

2. Veterinary system
   a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to the FMD control programme.
   b) Veterinary Services. Provide documentation on the compliance of the Veterinary Services of the country with the provisions of Chapters 3.1. and 3.2. of the Terrestrial Code and 1.1.3. of the Terrestrial Manual and describe how the Veterinary Services supervise and control all FMD related activities in the country and any zones. Provide maps and tables wherever possible.
   c) Provide a description on the involvement and the participation of industry, producers, farmers, including subsistence and small scale producers, community animal health workers and the role of the private veterinary profession in FMD surveillance and control. Include a description of training and awareness programmes on FMD.
   d) Provide information on any OIE PVS evaluation of the country and follow-up steps within the PVS Pathway.

3. FMD control
   a) Provide a description of the FMD history in the country and any zones, including date of first detection, origin of infection, date of implementation of the control programme in the country and any zones, and types and subtypes of the FMD virus present.
   b) Describe the general epidemiology of FMD in the country and the surrounding countries or zones highlighting the current knowledge and gaps.
   c) Describe how FMD is controlled in the country or any zones.
   d) Provide a description of the legislation, organisation and implementation of the FMD control programme. Indicate if detailed operational guidelines exist and give a brief summary.
   e) Provide information on what types of vaccines are used and which species are vaccinated. Provide information on the licensing process of the vaccines used. Describe the vaccination programme in the country and in any zones, including records kept, and provide evidence to show its effectiveness, such as vaccination coverage, population immunity, etc. Provide details on the studies carried out to determine the population immunity, including the study design.
   f) Provide a description of the methods of animal identification (at the individual or group level), herd registration and traceability; and how the movements of animals and products are assessed and controlled, including
movement of infected animals to slaughter. Describe the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and related paths of movement. Describe measures to prevent introduction of the virus from neighbouring countries or zones and through trade.

4. FMD surveillance

Provide documentary evidence on whether surveillance for FMD in the country complies with the provisions of Articles 8.6.42. to 8.6.47. and Article 8.6.49. of the Terrestrial Code and Chapter 2.1.5. of the Terrestrial Manual. In particular, the following points should be addressed:

a) Describe the criteria for raising a suspicion of FMD and the procedure to notify (by whom and to whom) and what penalties are involved for failure to report.

b) Describe how clinical surveillance is conducted, including which levels of the livestock production system are included in clinical surveillance, such as farms, markets, fairs, slaughterhouse, check points, etc. Provide criteria for selection of populations for targeted surveillance and numbers of animals examined and samples tested in diagnostic laboratories. Provide details on the methods applied for monitoring the performance of the surveillance system including indicators. Explain whether serological and virological surveys are conducted and, if so, how frequently and for what purpose.

c) Provide a summary table indicating, for at least the past two years, the number of samples tested for FMD and FMDV, species, type of sample, testing method(s) and results (including differential diagnosis). Provide procedural details on follow-up actions taken on suspicious and positive results.

d) Provide information on livestock demographics and economics, including the susceptible animal population by species and production systems in the country and the zone. Identify how many herds, flocks, etc. of each susceptible species are in the country and how they are distributed, such as herd density, etc. Provide tables and maps as appropriate.

e) Provide information on the demographics and migration patterns of FMD susceptible wildlife species, including which susceptible species are present in the country and any zones. Provide estimates of population sizes and geographic distribution. Identify whether susceptible wildlife are included in surveillance. Identify the measures in place to prevent contact between domestic and susceptible wildlife.

f) Identify the livestock slaughter, marketing and collection centres. Provide information on the patterns of livestock movement within the country, including how animals are transported and handled during these transactions.

5. FMD laboratory diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. of the Terrestrial Manual are applied. In particular, the following points should be addressed:

a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of laboratories approved by the competent authority to diagnose FMD. If not, provide the name(s) of and the arrangements with the laboratory(ies) to which samples are sent to, the follow-up procedures and the time frame for obtaining results. If applicable, indicate the laboratory(ies) where samples originating from any zone are diagnosed. Is there regular submission of samples from the country or zone to a laboratory that carries out diagnosis and further characterisation of strains in accordance with the standards and methods described in the Terrestrial Manual?

b) Provide an overview of the FMD approved laboratories, in particular to address the following points:

i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the laboratory system.

ii) Give details on participation in inter-laboratory validation tests (ring tests).

iii) Is live virus handled?

iv) Biosecurity measures applied.

v) Details of the type of tests undertaken.

6. FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country. In particular provide details on:

a) Coordination with neighbouring countries, trading partners and other countries within the same region. Identify relevant factors about the adjacent countries and zones that should be taken into account such as size, distance from adjacent borders to affected herds or animals, surveillance carried in adjacent countries. Describe coordination, collaboration and information sharing activities with neighbouring countries and zones. Describe the measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the propagation of the agent within the country or zone and through trade.
b) What measures are taken to limit access of susceptible domestic, *feral* and *wild* animals to waste products of animal origin? Are there controls in place for the feeding of swill containing animal products to pigs? If so provide information on the extent of the practice, and describe controls and *surveillance* measures.

c) Provide information on countries or zones from which the country authorises the import of susceptible *animals* or their products into the country or zone. Describe the criteria applied to approve such countries or zones, the controls applied on entry of such *animals* and products, and subsequent internal movement. Describe the import conditions and test procedures required. Advise whether import of *animals* of susceptible species are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and health certificates are required. Describe any other procedures used. Provide summary statistics on imports of susceptible *animals* and their products for at least the past two years, specifying country or zone of origin, the species and the number or volume.

i) Provide a map with the number and location of ports, airports and land crossings. Advise whether the service responsible for import controls is part of the official services, or if it is an independent body. If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

ii) Provide a description on the methods used for the safe disposal of waste food from international traffic, who is responsible to supervise this and provide a summary, for the past two years, of the quantity disposed of.

iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and their final destination, concerning the import and follow up of the following:

- *animals*,
- genetic material (semen and embryos),
- animal products,
- *veterinary medicinal products*, i.e. biologics,
- other livestock related goods potentially contaminated with FMDV including bedding, litter and feeds.

iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports, if available.

7. **Control measures and emergency response**

a) Give details of any written guidelines, including emergency response plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of FMD.

b) Advise whether quarantine is imposed on premises with suspicious cases, pending final diagnosis and any other procedures followed in respect of suspicious cases.

c) In the event of an FMD *outbreak*:

i) provide a detailed description of procedures that are followed in case of an *outbreak* including forward and backward tracing;

ii) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;

iii) describe the actions taken to control the disease situation in and around any holdings found to be infected with FMD;

iv) indicate the control or eradication procedures, such as *vaccination*, *stamping-out policy*, partial *slaughter* or *vaccination*, movement control, control of *wildlife*, pastured livestock and livestock as pets, control of the livestock waste, campaign to promote awareness of farmers, etc. that would be taken;

v) describe the procedures used to confirm that an *outbreak* has been successfully controlled or eradicated, including any restrictions on restocking;

vi) give details of any compensation payments made available to farmers, etc. when *animals* are slaughtered for disease control or eradication purposes and their prescribed timetable.

8. **Official control programme for FMD submitted for OIE endorsement**

Submit a detailed plan on the measures, in addition to those described in point 3, for the control and eventual eradication of FMD in the Member Country, including:

a) objectives,

b) expected status to be achieved,

c) timelines of the control programme,

d) performance indicators, including methods for measurement and verification,
e) description of the funding for the control programme and annual budgets for its duration,
f) details, if applicable, on a proposed timeline for the transition to the use of vaccines, which are fully compliant
with in the Terrestrial Manual in order to enable demonstration of absence of virus circulation.

9. Recovery of official endorsement of the national FMD control programme

Member Countries applying for recovery of the official endorsement of the national FMD control programme should
provide updated information in compliance with the provisions of Article 8.6.48. of the Terrestrial Code.

Article 1.6.11.

Questionnaire on PPR

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Please address concisely the following topics. National laws, regulations and Veterinary Authority directives may be
referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

   a) Provide a general description of geographical factors in the country and any defined zones, including physical,
geographical and other factors that are relevant to PPR dissemination, countries or zones sharing common
borders and other countries or zones that, although not adjacent, present a risk for the introduction of disease.
   b) If the endorsed plan is being gradually implemented to specific parts of the country, the boundaries of the
zone(s) should be clearly defined, including the protection zone, if applied. Provide a digitalised,
geo-referenced map with a precise text description of the geographical boundaries of the zone(s).
   c) Provide a general description of the livestock industry in the country and any zones.

2. Veterinary system

   a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to the PPR control
   programme.
   b) Veterinary Services. Provide documentation on the compliance of the Veterinary Services of the country with
   the provisions of Chapters 3.1. and 3.2. of the Terrestrial Code and 1.1.3. of the Terrestrial Manual and
describe how the Veterinary Services supervise and control all PPR related activities in the country and any
zones. Provide maps and tables wherever possible.
   c) Provide a description on the involvement and the participation of industry, producers, farmers, including
subsistence and small scale producers, community animal health workers and the role of the private
veterinary profession in PPR surveillance and control. Include a description of training and awareness
programmes on PPR.
   d) Provide information on any OIE PVS evaluation of the country and follow-up steps within the PVS Pathway.

3. PPR control

   a) Provide a description of the PPR history in the country and any zones, including date of first detection, origin
   of infection, date of implementation of the control programme in the country and any zones, and any
   information available on lineages of the PPR virus present.
   b) Describe the general epidemiology of PPR in the country and the surrounding countries or zones highlighting
   the current knowledge and gaps.
   c) Describe how PPR is controlled in the country or any zones.
   d) Provide a description of the legislation, organisation and implementation of the PPR control programme.
   Indicate if detailed operational guidelines exist and give a brief summary.
   e) Provide information on the vaccine and if it is certified (If yes please provide the name of the certifying
   institution/body). Describe the vaccination programme in the country and in any zones, including records kept,
   and provide evidence to show its effectiveness, such as vaccination coverage, population immunity, etc.
   Provide details on the studies carried out to determine the population immunity, including the study design.
f) Provide a description of the methods of animal identification (at the individual or group level), herd registration and traceability; and how the movements of animals are assessed and controlled, including movement of infected animals to slaughter. Describe the effectiveness of animal identification and movement controls. Describe measures to prevent introduction of the virus from neighbouring countries or zones and through trade.

4. PPR surveillance

Provide documentary evidence on whether surveillance for PPR in the country complies with the provisions of Articles 14.8.27. to 14.8.33. of the Terrestrial Code and Chapter 2.7.11. of the Terrestrial Manual. In particular, the following points should be addressed:

a) Describe the criteria for raising a suspicion of PPR and the procedure to notify (by whom and to whom) and what penalties are involved for failure to report.

b) Describe how clinical surveillance is conducted, including which levels of the livestock production system are included in clinical surveillance, such as farms, markets, fairs, slaughterhouses, check points, etc. Provide criteria for selection of populations for targeted surveillance and numbers of animals examined and samples tested in diagnostic laboratories. Provide details on the methods applied for monitoring the performance of the surveillance system including indicators. Explain whether serological and virological surveys are conducted and, if so, how frequently and for what purpose.

c) Provide a summary table indicating, for at least the past two years, the number of samples tested for PPR diagnosis, species, type of sample, testing method(s) and results (including differential diagnosis). Provide procedural details on follow-up actions taken on suspicious and positive results.

d) Provide information on small ruminant demographics and economics, including the production systems in the country and the zone. Identify how many herds, flocks, etc. of each small ruminant species are in the country and how they are distributed, such as herd density, etc. Provide tables and maps as appropriate.

e) Identify the livestock slaughter, marketing and collection centres. Provide information on the patterns of livestock movement within the country, including how animals are transported and handled during these transactions.

5. PPR laboratory diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.7.11. of the Terrestrial Manual are applied. In particular, the following points should be addressed:

a) Is PPR laboratory diagnosis carried out in the country? If so, provide a list of laboratories approved by the Competent Authority to diagnose PPR. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results. If applicable, indicate the laboratory(ies) where samples originating from any zone are diagnosed. Is there regular submission of samples from the country or zone to a laboratory that carries out diagnosis and further characterisation of strains in accordance with the standards and methods described in the Terrestrial Manual?

b) Provide an overview of the approved laboratory(ies) where PPR diagnosis is carried out, in particular to address the following points:
   i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the laboratory system.
   ii) Give details on participation in inter-laboratory validation tests (ring tests).
   iii) Is live virus handled?
   iv) Biosafety measures applied.
   v) Details of the type of tests undertaken.

6. PPR prevention

Describe the procedures in place to prevent the introduction of PPR into the country. In particular provide details on:

a) Coordination with neighbouring countries, trading partners and other countries within the same region. Identify relevant factors about the adjacent countries and zones that should be taken into account such as size, distance from adjacent borders to affected herds or animals, surveillance carried out in adjacent countries. Describe coordination, collaboration and information sharing activities with neighbouring countries and zones. Describe the measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the propagation of the agent within the country or zone and through trade.

b) Provide information on countries or zones from which the country authorises the import of sheep and goats and susceptible wildlife or their products into the country or zone. Describe the criteria applied to approve such countries or zones, the controls applied on entry of such animals, and subsequent internal movement.
Describe the import conditions and test procedures required. Advise whether imported sheep and goats and susceptible *wildlife* are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and health certificates are required.

c) Describe any other procedures used. Provide summary statistics on imports of sheep and goats and susceptible *wildlife* and their products for at least the past two years, specifying country or zone of origin, the species and the number.

i) Provide a map with the number and location of ports, airports and land crossings. Advise whether the service responsible for import controls is part of the official services, or if it is an independent body. If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

ii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and their final destination, concerning the import and follow up of the following:

- animals,
- genetic material (semen and embryos).

iii) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports, if available.

7. **Control measures and emergency response**

a) Give details of any written guidelines, including emergency response plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of PPR.

b) Advise whether quarantine is imposed on premises with suspicious cases, pending final diagnosis and any other procedures followed in respect of suspected cases.

c) In the event of a PPR outbreak:

i) provide a detailed description of procedures that are followed in case of an *outbreak* including forward and backward tracing;

ii) indicate the sampling and testing procedures used to identify and confirm presence of PPR virus;

iii) describe the actions taken to control the disease situation in and around any holdings found to be infected with PPR virus;

iv) indicate the control or eradication procedures, such as *vaccination*, *stamping-out policy*, partial *slaughter*, movement control, pastured sheep and goats, campaign to promote awareness of farmers, etc. that would be taken;

v) describe the procedures used to confirm that an *outbreak* has been successfully controlled or eradicated, including any restrictions on restocking;

vi) give details of any compensation payments made available to farmers, etc. when *animals* are slaughtered for *disease* control or eradication purposes and their prescribed timetable.

8. **Official control programme for PPR submitted for OIE endorsement**

Submit a detailed plan on the measures, in addition to those described in point 3, for the control and eventual eradication of PPR in the Member Country, including:

a) objectives,

b) timelines of the control programme,

c) performance indicators, including methods for measurement and verification,

d) details, if applicable, on a proposed timeline for the transition to the cessation of *vaccination* in order to enable demonstration of absence of virus circulation.

9. **Recovery of official endorsement of the national PPR control programme**

Member Countries applying for recovery of the official endorsement of the national PPR control programme should provide updated information in compliance with the provisions of Article 14.8.34. of the *Terrestrial Code*. 
SECTION 2.
RISK ANALYSIS

CHAPTER 2.1.
IMPORT RISK ANALYSIS

Article 2.1.1.

Introduction

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

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

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

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

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

Fig. 1. The four components of risk analysis

The risk assessment is the component of the analysis which estimates the risks associated with a hazard. Risk assessments may be qualitative or quantitative. For many diseases, particularly for those diseases listed in this Terrestrial Code where there are well developed internationally agreed standards, there is broad agreement concerning the likely risks. In such cases it is more likely that a qualitative assessment is all that is required. Qualitative assessment does not require mathematical modelling skills to carry out and so is often the type of assessment used for routine decision making. No single method of import risk assessment has proven applicable in all situations, and different methods may be appropriate in different circumstances.
Chapter 2.1.- Import risk analysis

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

**Article 2.1.2.**

**Hazard identification**

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

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

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

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

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

**Article 2.1.3.**

**Principles of risk assessment**

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

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

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

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

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

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

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

**Article 2.1.4.**

**Risk assessment steps**

1. **Entry assessment**

   Entry assessment consists of describing the biological pathway(s) necessary for an importation activity to introduce pathogenic agents into a particular environment, and estimating the probability of that complete process occurring, either qualitatively (in words) or quantitatively (as a numerical estimate). The entry assessment describes the probability of the ‘entry’ of each of the potential *hazards* (the pathogenic agents) under each specified set of
conditions with respect to amounts and timing, and how these might change as a result of various actions, events or measures. Examples of the kind of inputs that may be required in the entry assessment are:

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

b) **Country factors**
   - incidence or prevalence
   - evaluation of Veterinary Services, surveillance and control programmes and zoning and compartmentalisation systems of the exporting country.

c) **Commodity factors**
   - quantity of commodity to be imported
   - ease of contamination
   - effect of processing
   - effect of storage and transport.

If the entry assessment demonstrates no significant risk, the risk assessment does not need to continue.

2. **Exposure assessment**

Exposure assessment consists of describing the biological pathway(s) necessary for exposure of animals and humans in the importing country to the hazards (in this case the pathogenic agents) from a given risk source, and estimating the probability of the exposure(s) occurring, either qualitatively (in words) or quantitatively (as a numerical estimate).

The probability of exposure to the identified hazards is estimated for specified exposure conditions with respect to amounts, timing, frequency, duration of exposure, routes of exposure, such as ingestion, inhalation or insect bite, and the number, species and other characteristics of the animal and human populations exposed. Examples of the kind of inputs that may be required in the exposure assessment are:

a) **Biological factors**
   - properties of the agent.

b) **Country factors**
   - presence of potential vectors
   - human and animal demographics
   - customs and cultural practices
   - geographical and environmental characteristics.

c) **Commodity factors**
   - quantity of commodity to be imported
   - intended use of the imported animals or products
   - disposal practices.

If the exposure assessment demonstrates no significant risk, the risk assessment may conclude at this step.

3. **Consequence assessment**

Consequence assessment consists of describing the relationship between specified exposures to a biological agent and the consequences of those exposures. A causal process should exist by which exposures produce adverse health or environmental consequences, which may in turn lead to socio-economic consequences. The consequence assessment describes the potential consequences of a given exposure and estimates the probability of them occurring. This estimate may be either qualitative (in words) or quantitative (a numerical estimate). Examples of consequences include:

a) **Direct consequences**
   - animal infection, disease and production losses
   - public health consequences.

b) **Indirect consequences**
   - surveillance and control costs
   - compensation costs
   - potential trade losses
Chapter 2.1.- Import risk analysis

4. Risk estimation

Risk estimation consists of integrating the results from the entry assessment, exposure assessment, and consequence assessment to produce overall measures of risks associated with the hazards identified at the outset. Thus risk estimation takes into account the whole of the risk pathway from hazard identified to unwanted outcome.

For a quantitative assessment, the final outputs may include:
- estimated numbers of herds, flocks, animals or people likely to experience health impacts of various degrees of severity over time;
- probability distributions, confidence intervals, and other means for expressing the uncertainties in these estimates;
- portrayal of the variance of all model inputs;
- a sensitivity analysis to rank the inputs as to their contribution to the variance of the risk estimation output;
- analysis of the dependence and correlation between model inputs.

Article 2.1.5.

Principles of risk management

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

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

Article 2.1.6.

Risk management components

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

2) Option evaluation - the process of identifying, evaluating the efficacy and feasibility of, and selecting measures to reduce the risk associated with an importation in order to bring it into line with the Member Countries appropriate level of protection. The efficacy is the degree to which an option reduces the likelihood or magnitude of adverse health and economic consequences. Evaluating the efficacy of the options selected is an iterative process that involves their incorporation into the risk assessment and then comparing the resulting level of risk with that considered acceptable. The evaluation for feasibility normally focuses on technical, operational and economic factors affecting the implementation of the risk management options.

3) Implementation - the process of following through with the risk management decision and ensuring that the risk management measures are in place.

4) Monitoring and review - the ongoing process by which the risk management measures are continuously audited to ensure that they are achieving the results intended.

Article 2.1.7.

Principles of risk communication

1) Risk communication is the process by which information and opinions regarding hazards and risks are gathered from potentially affected and interested parties during a risk analysis, and by which the results of the risk assessment and proposed risk management measures are communicated to the decision-makers and interested parties in the importing and exporting countries. It is a multidimensional and iterative process and should ideally begin at the start of the risk analysis process and continue throughout.

2) A risk communication strategy should be put in place at the start of each risk analysis.

3) The communication of the risk should be an open, interactive, iterative and transparent exchange of information that may continue after the decision on importation.
4) The principal participants in *risk communication* include the authorities in the *exporting country* and other stakeholders such as domestic and foreign industry groups, domestic livestock producers and consumer groups.

5) The assumptions and uncertainty in the model, model inputs and the *risk* estimates of the *risk assessment* should be communicated.

6) Peer review is a component of *risk communication* in order to obtain scientific critique and to ensure that the data, information, methods and assumptions are the best available.
SECTION 3.

QUALITY OF VETERINARY SERVICES

CHAPTER 3.1.

VETERINARY SERVICES

Article 3.1.1.

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

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

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

These fundamental principles are presented in Article 3.1.2. Other factors affecting quality are described in Volume I of the Terrestrial Code (notification, principles of certification, etc.).

The quality of Veterinary Services, including veterinary legislation, can be measured through an evaluation, whose general principles are described in Article 3.1.3. and in Article 3.1.4.

Recommendations on the evaluation of Veterinary Services, including veterinary legislation, are described in Chapter 3.2.

A procedure for evaluating Veterinary Services by OIE experts, on a voluntary basis, is described in Article 3.1.5.

Article 3.1.2.

Fundamental principles of quality

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

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

2. Independence
   Care should be taken to ensure that Veterinary Services' personnel are free from any commercial, financial, hierarchical, political or other pressures which might affect their judgement or decisions.
3. Impartiality
The Veterinary Services should be impartial. In particular, all the parties affected by their activities have a right to expect their services to be delivered under reasonable and non-discriminatory conditions.

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

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

6. Veterinary legislation
Veterinary legislation is prerequisite to support good governance and provide the legal framework for all key activities of the Veterinary Services.

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

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

7. General organisation
The Veterinary Services should be able to demonstrate by means of appropriate legislation, sufficient financial resources and effective organisation that they are in a position to have control of the establishment and application of animal health and animal welfare measures, and of international veterinary certification activities.

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

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

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

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

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

a) programming and management of activities, including international veterinary certification activities;
b) prevention, control and notification of disease outbreaks;
c) risk analysis, epidemiological surveillance and zoning;
d) inspection and sampling techniques;
e) diagnostic tests for animal diseases;
f) preparation, production, registration and control of biological products for use in the diagnosis or prevention of diseases;
g) border controls and import regulations;
h) disinfection and disinfestation;
i) treatments intended to destroy, if appropriate, pathogens in animal products.

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

10. Information, complaints and appeals

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

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

11. Documentation

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

12. Self-evaluation

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

A procedure for evaluating Veterinary Services by OIE experts, on a voluntary basis, is described in Article 3.1.5.

13. Communication

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

14. Human and financial resources

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

Article 3.1.3.

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

Any evaluation of Veterinary Services should be conducted having regard to the OIE recommendations on the evaluation of Veterinary Services presented in Chapter 3.2.

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

Article 3.1.4.

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

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

The evaluation process should take into account the fundamental principles and other factors of quality laid down in Article 3.1.1. and in Article 3.1.2. It should also take into consideration the specific circumstances regarding quality, as described in Article 3.1.1., prevailing in the countries concerned.

The outcome of the evaluation conducted by a Member Country should be provided in writing as soon as possible, and in any case within four months of receipt of the relevant information, to the Member Country which has undergone the evaluation. The evaluation report should detail any findings which affect trade prospects. The Member Country which conducts the evaluation should clarify in detail any points of the evaluation on request.
In the event of a dispute between two Member Countries over the conduct or the conclusions of the evaluation of the Veterinary Services, the matter should be dealt with having regard to the procedures set out in Article 5.3.8.

Article 3.1.5.

Evaluation facilitated by OIE experts under the auspices of the OIE

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

The World Assembly of OIE Delegates endorses a list of approved experts to facilitate the evaluation process.

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

The expert(s) facilitate(s) the evaluation of the Veterinary Services of the Member Country based on the provisions in Chapter 3.2., using the OIE Tool for the Evaluation of Performance of Veterinary Services (OIE PVS Tool).

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

The report is submitted to the Director General of the OIE and, with the consent of the Member Country, published by the OIE.
CHAPTER 3.2.

EVALUATION OF VETERINARY SERVICES

Article 3.2.1.

General considerations

1) Evaluation of Veterinary Services is an important element in the risk analysis process which countries may legitimately use in their policy formulations directly applying to animal health and sanitary controls of international trade in animals, animal-derived products, animal genetic material and animal feedstuffs.

Any evaluation should be carried out with due regard for Chapter 3.1.

2) In order to ensure that objectivity is maximised in the evaluation process, it is essential for some standards of discipline to be applied. The OIE has developed these recommendations which can be practically applied to the evaluation of Veterinary Services. These are relevant for evaluation of the Veterinary Services of one country by those of another country for the purposes of risk analysis in international trade. The recommendations are also applicable for evaluation by a country of its own Veterinary Services – the process known as self-evaluation – and for periodic re-evaluation. These recommendations should be used by OIE experts when facilitating an evaluation under the auspices of the OIE, following a request of a Member Country. In applying these recommendations on the evaluation, the OIE Tool for the Evaluation of Performance of Veterinary Services (OIE PVS Tool) should be used.

In carrying out a risk analysis prior to deciding the sanitary or zoosanitary conditions for the importation of a commodity, an importing country is justified in regarding its evaluation of the Veterinary Services of the exporting country as critical.

3) The purpose of evaluation may be either to assist a national authority in the decision-making process regarding priorities to be given to its own Veterinary Services (self-evaluation) or to assist the process of risk analysis in international trade in animals and animal-derived products to which official sanitary or zoosanitary controls apply.

4) In both situations, the evaluation should demonstrate that the Veterinary Services have the capability for effective control of the sanitary and zoosanitary status of animals and animal products. Key elements to be covered in this process include adequacy of resources, management capability, legislative and administrative infrastructures, independence in the exercise of official functions and history of performance, including disease reporting.

5) Good governance is the key to competence, integrity and confidence in organisations. Mutual confidence between relevant official Veterinary Services of trading partner countries contributes fundamentally to stability in international trade in animals and animal-related products. In this situation, scrutiny is directed more at the exporting country than at the importing country.

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

7) An importing country has a right of assurance that information on sanitary or zoosanitary situations provided by the Veterinary Services of an exporting country is objective, meaningful and correct. Furthermore, the Veterinary Services of the importing country are entitled to expect validity in the veterinary certification of export.

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

9) As the veterinary statutory body is not a part of the Veterinary Services, an evaluation of that body should be carried out to ensure that the registration or licensing of veterinarians and authorisation of veterinary para-professionals is included.
Chapter 3.2.- Evaluation of Veterinary Services

Article 3.2.2.

Scope

1) In the evaluation of Veterinary Services, the following items may be considered, depending on the purpose of the evaluation:
   - organisation, structure and authority of the Veterinary Services;
   - human resources;
   - material (including financial) resources;
   - veterinary legislation, regulatory frameworks and functional capabilities;
   - animal health, animal welfare and veterinary public health controls;
   - formal quality systems including quality policy;
   - performance assessment and audit programmes;
   - participation in OIE activities and compliance with Member Countries’ obligations.

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

3) Article 3.2.14. outlines appropriate information requirements for:
   - self-evaluation by the Veterinary Authority which perceives a need to prepare information for national or international purposes;
   - evaluation by a prospective or actual importing country of the Veterinary Services of a prospective or actual exporting country;
   - verification or re-verification of an evaluation in the course of a visit to the exporting country by the importing country;
   - evaluation by third parties such as OIE PVS experts or regional organisations.

Article 3.2.3.

Evaluation criteria for the organisational structure of the Veterinary Services

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

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

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

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

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

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

7) Similarly, where the Veterinary Authority has arrangements with other providers of relevant services such as universities, laboratories, information services, etc., these arrangements should also be described. For the
Chapter 3.2.- Evaluation of Veterinary Services

pursposes of evaluation, it is appropriate to expect that the organisational and functional standards that apply to the Veterinary Authority should also apply to the service providers.

Article 3.2.4.

Evaluation criteria for quality systems

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

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

Article 3.2.5.

Evaluation criteria for human resources

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

2) In addition to raw quantitative data on this resource base, the functions of the various categories of personnel in the Veterinary Services should be described in detail. This is necessary for analysis and estimation of the appropriateness of the application of qualified skills to the tasks undertaken by the Veterinary Services and may be relevant, for example, to the roles of veterinarians and veterinary para-professionals in field services. In this case, the evaluation should provide assurances that disease monitoring is being conducted by a sufficient number of qualified, experienced field veterinarians who are directly involved in farm visits; there should not be an over-reliance on veterinary para-professionals for this task.

3) Analysis of these data can be used to estimate the potential of the Veterinary Services to have reliable knowledge of the state of animal health in the country and to support an optimal level of animal disease control programmes. A large population of private veterinarians would not provide the Veterinary Services with an effective epizootiological information base without legislative (e.g. compulsory reporting of notifiable diseases) and administrative (e.g. official animal health surveillance and reporting systems) mechanisms in place.

4) These data should be assessed in close conjunction with the other information described in this chapter. For example, a large field staff (veterinarians and veterinary para-professionals) need fixed, mobile and budgetary resources for animal health activities in the livestock farming territory of the country. If deficiencies are evident, there would be reason to challenge the validity of epizootiological information.

Article 3.2.6.

Evaluation criteria for material resources

1. Financial

Actual yearly budgetary information regarding the Veterinary Services should be available and should include the details set out in the model questionnaire outlined in Article 3.2.14. Information is required on conditions of service for veterinary staff (including salaries and incentives), and should provide a comparison with the private sector and perhaps with other professionals. Information should also be available on non-government sources of revenue available to veterinarians in their official responsibilities.
2. Administrative
   a) Accommodation

   The Veterinary Services should be accommodated in premises suitable for efficient performance of their functions. The component parts of the Veterinary Services should be located as closely as possible to each other at the central level, and in the regions where they are represented, in order to facilitate efficient internal communication and function.

   b) Communications

   The Veterinary Services should be able to demonstrate that they have reliable access to effective communications systems, especially for animal health surveillance and control programmes. Inadequate communications systems within the field services components of these programmes or between outlying offices and headquarters, or between the Veterinary Services and other relevant administrative and professional services, signify an inherent weakness in these programmes. Adequate communications systems between laboratories and between field and laboratory components of the Veterinary Services should also be demonstrated.

   Examples of types of communications which should be routinely available on an adequate country-wide basis are national postal, freight and telephone networks. Rapid courier services, facsimile and electronic data interchange systems such as e-mail and Internet services are examples of useful communication services which, if available, can supplement or replace the others. A means for rapid international communication should be available to the Veterinary Authority, to permit reporting of changes in national disease status consistent with OIE recommendations and to allow bilateral contact on urgent matters with counterpart Veterinary Authorities in trading-partner countries.

   c) Transport systems

   The availability of sufficient reliable transport facilities is essential for the performance of many functions of Veterinary Services. This applies particularly to the field services components of animal health activities such as emergency response visits. Otherwise, the Veterinary Services cannot assure counterpart services in other countries that they are in control of the animal health situation within the country.

   Appropriate means of transport are also vital for the satisfactory receipt of samples to be tested at veterinary laboratories, for inspection of imports and exports, and for the performance of animals and animal product inspection in outlying production or processing establishments.

3. Technical

   Details available on laboratories should include resources data, programmes under way as well as those recently completed and review reports on the role or functions of the laboratory. Information as described in the model questionnaire should be used in the evaluation of laboratory services.

   a) Cold chain for laboratory samples and veterinary medicines

   Adequate refrigeration and freezing systems should be available and should be used throughout the country to provide suitable low temperature protection for laboratory samples in transit or awaiting analysis, as well as veterinary medical products such as vaccines when these are required for use in animal disease control programmes. If these assurances cannot be given, it may be valid to discount many types of test results, as well as the effectiveness of certain disease control programmes and the export inspection system in the country undergoing evaluation.

   b) Diagnostic laboratories

   Analysis of the laboratory service component of Veterinary Services, which would include official governmental laboratories and other laboratories authorised by the Veterinary Services for specified purposes, is an essential element of the evaluation process. The quality of the veterinary diagnostic laboratories of a country underpins the whole control and certification processes of the zoosanitary or sanitary status of exported animals and animal products, and therefore these laboratories should be subject to rigid quality assurance procedures and should use international quality assurance programmes (wherever available) for standardising test methodologies and testing proficiency. An example is the use of International Standard Sera for standardising reagents.

   In countries where there is more than one diagnostic laboratory for a given pathogen, the designation of a National Reference Laboratory for that pathogen may contribute to the quality of analysis performed by the diagnostic laboratories.

   Quality of analysis is equally important to the testing performed on individual export consignments as to the broader ongoing testing regimes which are used to determine the animal health and veterinary public health profiles of the country and to support its disease control programmes. For the purposes of evaluation, veterinary diagnostic laboratories include those which are concerned with either animal health or veterinary public health activities. The Veterinary Services should approve and designate these laboratories for such purposes and have them audited regularly.
c) Research

The scope of animal disease and veterinary public health problems in the country concerned, the stages reached in the controls which address those problems and their relative importance can be measured to some degree by analysis of information on government priorities and programmes for research in animal health. This information should be accessible for evaluation purposes.

Article 3.2.7.

Legislation and functional capabilities

1. Animal health, animal welfare and veterinary public health

The Veterinary Authority should be able to demonstrate that it has the capacity, supported by appropriate legislation, to exercise control over all animal health matters. These controls should include, where appropriate, compulsory notification of prescribed animal diseases, inspection, movement controls through systems which provide adequate traceability, registration of facilities, quarantine of infected premises or areas, testing, treatment, destruction of infected animals or contaminated materials, controls over the use of veterinary medicines, etc. The scope of the legislative controls should include domestic animals and their reproductive material, animal products, wildlife as it relates to the transmission of diseases to humans and domestic animals, and other products subject to veterinary inspection. Arrangements should exist for co-operation with the Veterinary Authorities of the neighbouring countries for the control of animal diseases in border areas and for establishing linkages to recognise and regulate transboundary activities. Within the structure of Veterinary Services, there should be appropriately qualified personnel whose responsibilities include animal welfare. Information on the veterinary public health legislation covering the production of products of animal origin for national consumption may be also considered in the evaluation.

2. Export and import inspection

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

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

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

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

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

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

Security in the export certification process, including electronic documentation transfer, is important. A system of independent compliance review is desirable, to safeguard against fraud in certification by officials and by private individuals or corporations. The certifying veterinarian should have no conflict of interest in the commercial aspects of the animals or animal product being certified and be independent from the commercial parties.
Article 3.2.8.

Animal health controls

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

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

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

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

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

Article 3.2.9.

Veterinary public health controls

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

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

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

4. Veterinary medicines

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

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

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

5. Integration between animal health controls and veterinary public health

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

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

Article 3.2.10.

Performance assessment and audit programmes

1. Strategic plans

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

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

2. Performance assessment

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

3. Compliance

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

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

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

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

4. Veterinary Services administration
a) Annual reports
   Official government annual reports should be published, which provide information on the organisation and
   structure, budget, activities and contemporary performance of the Veterinary Services. Current and
   retrospective copies of such reports should be available to counterpart Services in other countries, especially
   trade partners.

b) Reports of government review bodies
   The reports of any periodic or ad hoc government reviews of Veterinary Services or of particular functions or
   roles of the Veterinary Services should be considered in the evaluation process. Details of action taken as a
   consequence of the review should also be accessible.

c) Reports of special committees of enquiry or independent review bodies
   Recent reports on the Veterinary Services or elements of their role or function, and details of any subsequent
   implementation of recommendations contained in these reports should be available. The Veterinary Services
   concerned should recognise that the provision of such information need not be detrimental to the evaluation
   outcome; in fact, it may demonstrate evidence of an effective audit and response programme. The supplying
   of such information can reinforce a commitment to transparency.

d) In-service training and development programme for staff
   In order to maintain a progressive approach to meeting the needs and challenges of the changing domestic
   and international role of Veterinary Services, the national administration should have in place an organised
   programme which provides appropriate training across a range of subjects for relevant staff. This programme
   should include participation in scientific meetings of animal health organisations. Such a programme should
   be used in assessing the effectiveness of the Services.

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

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

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

Article 3.2.11.

Participation in OIE activities

Questions on a country's adherence to its obligations as a member of the OIE are relevant to an evaluation of the
Veterinary Services of the country. Self-acknowledged inability or repeated failure of a Member Country to fulfil reporting
obligations to the OIE will detract from the overall outcome of the evaluation. Such countries, as well as non-member
countries, will need to provide extensive information regarding their Veterinary Services and sanitary or zoosanitary
status for evaluation purposes.
Chapter 3.2. - Evaluation of Veterinary Services

Article 3.2.12.

Evaluation of the veterinary statutory body

1. **Scope**

   In the evaluation of the veterinary statutory body, the following items may be considered, depending on the purpose of the evaluation:

   a) objectives and functions;
   b) legislative basis for the veterinary statutory body, including autonomy and functional capacity;
   c) the composition of the veterinary statutory body, including the organisation represented in it;
   d) accountability and transparency of decision-making;
   e) sources and management of funding;
   f) administration of training programmes and continuing professional development for veterinarians and veterinary para-professionals.

2. **Evaluation of objectives and functions**

   The policy and the objectives of the veterinary statutory body, including details of its power and functions, should be defined, notably with regard to:

   a) the licensing or registration of veterinarians and veterinary para-professionals to perform the activities of veterinary medicine/science;
   b) the minimum standards of education (initial and continuing) required for degrees, diplomas and certificates entitling the holders thereof to be registered or licensed as veterinarians and veterinary para-professionals;
   c) the standards of professional conduct and competence of veterinarians and veterinary para-professionals and ensuring that these standards are met.

3. **Evaluation of legislative basis, autonomy and functional capacity**

   The veterinary statutory body should be able to demonstrate that it has the capacity, supported by appropriate legislation, to exercise and enforce control over all veterinarians and veterinary para-professionals subject to its authority. These controls should include, where appropriate, compulsory licensing or registration, participation in the definition of minimum standards of education (initial and continuing) for the recognition of degrees, diplomas and certificates by the Competent Authority, setting standards of professional conduct and competence, investigating complaints and the application of disciplinary procedures.

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

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

4. **Evaluation of the composition of the veterinary statutory body**

   Detailed descriptions of the composition, rules and conditions for membership, including duration of appointment and representation of interested third parties, public and private, should be available.

5. **Evaluation of accountability and transparency of decision-making**

   Detailed information should be available on disciplinary procedures regarding the conducting of enquiries into professional misconduct, transparency of decision-making, publication of findings, sentences and mechanisms for appeal.

   Additional information regarding the publication at regular intervals of activity reports, lists of registered or licensed persons including deletions and additions should also be taken into consideration.

6. **Evaluation of financial sources and financial management**

   Information regarding income and expenditure, including fee structure(s) for the licensing or registration of persons should be available.

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

   Documentary evidence should be available to demonstrate compliance with initial and continuing education requirements, including with OIE recommendations.
8. Evaluation of mechanisms for coordination between Veterinary Authority and veterinary statutory body

The exact mechanisms will vary according to the national governance systems.

Article 3.2.13.

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

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

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

Article 3.2.14.

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

1. Organisation and structure of Veterinary Services
   a) National Veterinary Authority
      Organisational chart including numbers, positions and numbers of vacancies.
   b) Sub-national components of the Veterinary Authority
      Organisational charts including numbers, positions and number of vacancies.
   c) Other providers of veterinary services
      Description of any linkage with other providers of veterinary services.

2. National information on human resources
   a) Veterinarians
      i) Total numbers of veterinarians registered or licensed by the Veterinary statutory body of the country.
      ii) Numbers of:
          – full time government veterinarians: national and sub-national;
          – part time government veterinarians: national and sub-national;
          – private veterinarians authorised by the Veterinary Services to perform official veterinary functions [Describe accreditation standards, responsibilities and limitations applying to these private veterinarians.];
          – other veterinarians.
      iii) Animal health:
          Numbers associated with farm livestock sector on a majority time basis in a veterinary capacity, by geographical area [Show categories and numbers to differentiate staff involved in field service, laboratory, administration, import and export and other functions, as applicable.]:
          – full time government veterinarians: national and sub-national;
          – part time government veterinarians: national and sub-national;
          – other veterinarians.
iv) Veterinary public health:
Numbers employed in food inspection on a majority time basis, by commodity:

- full time government veterinarians: national and sub-national;
- part time government veterinarians: national and sub-national;
- other veterinarians.

v) Numbers of veterinarians relative to certain national indices:
- per total human population;
- per farm livestock population, by geographical area;
- per livestock farming unit, by geographical area.

vi) Veterinary education:
- number of veterinary schools;
- length of veterinary course (years);
- curriculum addressing the minimum competencies of day 1 veterinary graduates and the post-graduate and continuing education topics to assure the delivery of quality veterinary services, as described in the relevant chapter(s) of the Terrestrial Code;
- international recognition of veterinary degree.

vii) Veterinary professional associations.

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

c) Veterinary para-professionals employed by the Veterinary Services

i) Animal health:
- Categories and numbers involved with farm livestock on a majority time basis:
  - by geographical area;
  - proportional to numbers of field Veterinary Officers in the Veterinary Services, by geographical area.
- Education or training details.

ii) Veterinary public health:
- Categories and numbers involved in food inspection on a majority time basis:
  - meat inspection: export meat establishments with an export function and domestic meat establishments (no export function);
  - dairy inspection;
  - other foods.
- Numbers in import and export inspection.
- Education or training details.

d) Support personnel
Numbers directly available to Veterinary Services per sector (administration, communication, transport).

e) Descriptive summary of the functions of the various categories of staff mentioned above

f) Veterinary, veterinary para-professionals, livestock owner, farmer and other relevant associations

g) Additional information or comments.

3. Financial management information

a) Total budgetary allocations to the Veterinary Authority for the current and past two fiscal years:

i) for the national Veterinary Authority;
ii) for each of any sub-national components of the Veterinary Authority;
iii) for other relevant government-funded institutions.

b) Sources of the budgetary allocations and amount:

i) government budget;
ii) sub-national authorities;
iii) taxes and fines;
iv) grants;
v) private services.

c) Proportional allocations of the amounts in a) above for operational activities and for the programme components of Veterinary Services.

d) Total allocation proportionate of national public sector budget. [*This data may be necessary for comparative assessment with other countries which should take into account the contexts of the importance of the livestock sector to the national economy and of the animal health status of the country.*]

e) Actual and proportional contribution of animal production to gross domestic product.

4. Administration details

a) Accommodation
Summary of the numbers and distribution of official administrative centres of the Veterinary Services (national and sub-national) in the country.

b) Communications
Summary of the forms of communication systems available to the Veterinary Services on a nation-wide and local area bases.

c) Transport
i) Itemised numbers of types of functional transport available on a full-time basis for the Veterinary Services. In addition provide details of transport means available part-time.

ii) Details of annual funds available for maintenance and replacement of motor vehicles.

5. Laboratory services

a) Diagnostic laboratories (laboratories engaged primarily in diagnosis)
i) Descriptive summary of the organisational structure and role of the government veterinary laboratory service in particular its relevance to the field Veterinary Services.

ii) Numbers of veterinary diagnostic laboratories operating in the country:
  – government operated laboratories;
  – private laboratories authorised by veterinary authority for the purposes of supporting official or officially-endorsed animal health control or public health testing and monitoring programmes and import and export testing.

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

iv) Human and financial resources allocated to the government veterinary laboratories, including staff numbers, graduate and post-graduate qualifications and opportunities for further training.

v) List of diagnostic methodologies available against major diseases of farm livestock (including poultry).

vi) List of related National Reference Laboratories, if any.

vii) Details of collaboration with external laboratories including international reference laboratories and details on numbers of samples submitted.

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

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

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

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

xii) Strategic and operational plans for the official veterinary laboratory service (if available).

b) Research laboratories (laboratories engaged primarily in research)
i) Numbers of veterinary research laboratories operating in the country:
  – government operated laboratories;
  – private laboratories involved in full time research directly related to animal health and veterinary public health matters involving production animal species.

ii) Summary of human and financial resources allocated by government to veterinary research.

iii) Published programmes of future government sponsored veterinary research.

iv) Annual reports of the government research laboratories.
6. **Veterinary legislation, regulations and functional capabilities**

   a) Animal health and veterinary public health

   i) Assessment of the adequacy and implementation of relevant legislation (national or sub-national) concerning the following:
   - animal and veterinary public health controls at national frontiers;
   - control of endemic animal diseases, including zoonoses;
   - emergency powers for control of exotic disease outbreaks, including zoonoses;
   - inspection and registration of facilities;
   - animal feeding;
   - veterinary public health controls of the production, processing, storage and marketing of meat for domestic consumption;
   - veterinary public health controls of the production, processing, storage and marketing of fish, dairy products and other food of animal origin for domestic consumption;
   - registration and use of veterinary pharmaceutical products including vaccines;
   - animal welfare.

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

   b) Export and import inspection

   i) Assessment of the adequacy and implementation of relevant national legislation concerning:
   - veterinary public health controls of the production, processing, storage and transportation of meat for export;
   - veterinary public health controls of production, processing, storage and marketing of fish, dairy products and other food of animal origin for export;
   - animal health and veterinary public health controls of the export and import of animals, animal genetic material, animal products, animal feedstuffs and other products subject to veterinary inspection;
   - animal health controls of the importation, use and bio-containment of organisms which are aetiological agents of animal diseases, and of pathological material;
   - animal health controls of importation of veterinary biological products including vaccines;
   - administrative powers available to Veterinary Services for inspection and registration of facilities for veterinary control purposes (if not included under other legislation mentioned above);
   - documentation and compliance.

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

7. **Animal health and veterinary public health controls**

   a) Animal health

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

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

   iii) Description and relevant data of current official control programmes including:
   - epidemiological surveillance or monitoring programmes;
   - officially approved industry administered control or eradication programmes for specific diseases.

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

   v) Recent history of animal disease status:
   - animal diseases eradicated nationally or from defined sub-national zones in the last ten years;
   - animal diseases of which the prevalence has been controlled to a low level in the last ten years;
   - animal diseases introduced to the country or to previously free sub national regions in the last ten years;
   - emerging diseases in the last ten years;
   - animal diseases of which the prevalence has increased in the last ten years.
b) Veterinary public health
   i) Food hygiene
      - Annual national slaughter statistics for the past three years according to official data by species of *animals* (bovine, ovine, porcine, caprine, *poultry*, farmed game, wild game, equine, other).
      - Estimate of total annual slaughterings which occur but are not recorded under official statistics.
      - Proportion of total national slaughter which occurs in registered export establishments, by category of *animal*.
      - Proportion of total national slaughter which occurs under veterinary control, by category of *animal*.
      - Numbers of commercial fresh meat establishments in the country which are registered for export by the Veterinary Authority:
        - slaughterhouses (indicate species of *animals*);
        - cutting or packing plants (indicate meat type);
        - meat processing establishments (indicate meat type);
        - cold stores.
      - Numbers of commercial fresh meat establishments in the country approved by other importing countries which operate international assessment inspection programmes associated with approval procedures.
      - Numbers of commercial fresh meat establishments under direct public health control of the Veterinary Services (including details of category and numbers of inspection staff associated with these premises).
      - Description of the veterinary public health programme related to production and processing of animal products for human consumption (including fresh meat, poultry meat, meat products, game meat, dairy products, fish, fishery products, molluscs and crustaceans and other foods of animal origin) especially including details applying to exports of these commodities.
      - Descriptive summary of the roles and relationships of other official organisations in public health programmes for the products listed above if the Veterinary Authority does not have responsibility for those programmes which apply to national production destined to domestic consumption or exports of the commodities concerned.
   ii) Zoonoses
      - Descriptive summary of the numbers and functions of staff of the Veterinary Authority involved primarily with monitoring and control of zoonotic diseases.
      - Descriptive summary of the role and relationships of other official organisations involved in monitoring and control of zoonoses to be provided if the Veterinary Authority does not have these responsibilities.
   iii) Chemical residue testing programmes
      - Descriptive summary of national surveillance and monitoring programmes for environmental and chemical residues and contaminants applied to animal-derived foodstuffs, *animals* and animal feedstuffs.
      - Role and function in these programmes of the Veterinary Authority and other Veterinary Services to be described in summary form.
      - Descriptive summary of the analytical methodologies used and their consistency with internationally recognised standards.
   iv) Veterinary medicines
      - Descriptive summary of the administrative and technical controls involving registration, supply and use of veterinary pharmaceutical products especially including biological products. This summary should include a focus on veterinary public health considerations relating to the use of these products in food-producing *animals*.
      - Role and function in these programmes of the Veterinary Authority and other Veterinary Services to be described in summary form.

8. Quality systems
   a) Accreditation
      Details and evidence of any current, formal accreditation by external agencies of the Veterinary Services of any components thereof.
b) Quality manuals
   Documented details of the quality manuals and standards which describe the accredited quality systems of the Veterinary Services.

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

9. Performance assessment and audit programmes
   a) Strategic plans and review
      i) Descriptive summary and copies of strategic and operational plans of the Veterinary Services organisation.
      ii) Descriptive summary of corporate performance assessment programmes which relate to the strategic and operational plans - copies of recent review reports.

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

d) Other reports
   i) Copies of reports of official reviews into the function or role of the Veterinary Services which have been conducted within the past three years.
   ii) Descriptive summary (and copy of reports if available) of subsequent action taken on recommendations made in these reviews.

   e) Training
      i) Descriptive summary of in-service and development programmes provided by the Veterinary Services (or their parent Ministries) for relevant staff.
      ii) Summary descriptions of training courses and duration.
      iii) Details of staff numbers (and their function) who participated in these training courses in the last three years.

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

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

10. Membership of the OIE
    State if country is a member of the OIE and period of membership.
CHAPTER 3.3.

COMMUNICATION

Article 3.3.1.

General considerations

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

The recognition of communication as a discipline of the Veterinary Services and its incorporation within it is critical for their operations. The integration of veterinary and communication expertise is essential for effective communication.

Communication should be an integral part of all the activities of the Veterinary Services including animal health (surveillance, early detection and rapid response, prevention and control), animal welfare and veterinary public health (food safety, zoonoses) and veterinary medicine.

Objectives of this chapter on communication for the Veterinary Services are to provide guidance for the development of a communication system, strategic and operational communication plans and elements to assess their quality.

Article 3.3.2.

Principles of communication

1) Veterinary Services should have the authority and capability to communicate on matters within their mandate.
2) Veterinary and communication expertises should be combined.
3) Communication should be targeted and follow the fundamental criteria of transparency, consistency, timeliness, balance, accuracy, honesty and empathy and respect the fundamental principles of quality of Veterinary Services (Article 3.1.2.).
4) Communication should be a continuous process.
5) Veterinary Services should have oversight of planning, implementing, monitoring, evaluating and revising their strategic and operational communication plans.

Article 3.3.3.

Definitions

Communication: means the discipline of informing, guiding and motivating individual, institutional and public groups, ideally on the basis of interactive exchanges, about any issue under the competence of the Veterinary Services.

Crisis: means a situation of great threat, difficulty or uncertainty when issues under the competence of the Veterinary Services require immediate action.

Crisis communication: means the process of communicating information as accurately as possible, albeit potentially incomplete, within time constraints in the event of a crisis.

Outbreak communication: means the process of communicating in the event of an outbreak. Outbreak communication includes notification.
**Article 3.3.4.**

**Communication system**

In addition to the Principles of Communication the following elements should be used in conjunction with Chapter 3.1., when planning, implementing and assessing a communication system:

1. **Organisational chart** indicating a direct link between the communication personnel and the Veterinary Authority, through the chain of command, such as dedicated communication unit or communication officer.

2. **Human resources**
   a) Identified and accessible official communication focal point
   b) Job descriptions of communication personnel identifying roles and responsibilities
   c) Sufficient number of qualified personnel with knowledge, skills, attitude and abilities relevant to communication
   d) Continuous training and education on communication provided to communication personnel.

3. **Financial and physical resources**
   a) Clearly identified budget for communication that provides adequate funding
   b) Provision or access to appropriate material resources in order to carry out roles and responsibilities: suitable premises or accommodation that is adequately equipped with sufficient office and technical equipment, including information technology and access to the Internet.

4. **Management of the communication system**
   a) Roles and responsibilities of the communication personnel
      i) Report to the Veterinary Authority
      ii) Engage in decision-making process by providing guidance and expertise on communication issues to the Veterinary Services
      iii) Be responsible for the planning, implementation and evaluation of the strategic and operational plans for communication and relevant standard operating procedures
      iv) Function as contact point on communication issues for the Veterinary Services
      v) Provide and coordinate continuous education on communication for the Veterinary Services.
   b) **Strategic plan for communication**
      A well-designed strategic plan for communication should support the Veterinary Services strategic plan and have management support and commitment. The strategic plan for communication should address all high level organization-wide long-term communication objectives.
      
      A strategic plan for communication should be monitored, periodically reviewed and should identify measurable performance objectives and techniques to assess the effectiveness of communication.
      
      The strategic plan for communication should consider the different types of communication: routine communication, risk communication, outbreak communication and crisis communication, to allow individuals, affected or interested parties, an entire community or the general public to make best possible decisions and be informed of policy decisions and their rationale.
      
      The key outcomes in effectively implementing a strategic plan for communication are increased knowledge and awareness of issues by the public and stakeholders, higher understanding of the role of the Veterinary Services, higher visibility of and improved trust and credibility in the Veterinary Services. These will enhance understanding or acceptance of policy decisions and subsequent change of perception, attitude or behaviour.
c) Operational plans for communication
Operational plans for communication should be based on the assessment of specific issues and should identify specific objectives and target audiences such as staff, partners, stakeholders, media and the general public.
Each operational plan for communication should consist of a well-planned series of activities using different techniques, tools, messages and channels to achieve intended objectives and utilizing available resources within a specific timeframe.
CHAPTER 3.4.

VETERINARY LEGISLATION

Article 3.4.1.

Introduction and objective

Good governance is a recognised global public good and is of critical importance to Member Countries. Legislation is a key element in achieving good governance.

Veterinary legislation should, at a minimum, provide a basis for Competent Authorities to meet their obligations as defined in the Terrestrial Code and the relevant recommendations of the Codex Alimentarius Commission. In addition, there is an obligation for World Trade Organization (WTO) Members under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) to notify the WTO of changes in sanitary measures, including changes in legislation that affect trade, and provide relevant information.

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

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

Article 3.4.2.

Definitions

For the purposes of this chapter the following definitions apply:

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

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

Primary legislation: means the legal instruments issued by the legislative body of a Member Country.

Secondary legislation: means the legal instruments issued by the executive body of a Member Country under the authority of primary legislation.

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

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

Article 3.4.3.

General principles

1. Respect for the hierarchy of legislation

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

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

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

3. Transparency

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

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

4. Consultation

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

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

5. Quality of legislation and legal certainty

*Veterinary legislation* should be clear, coherent, stable and transparent and protect citizens against unintended adverse side effects of legal instruments. It should be technically relevant, acceptable to society, able to be effectively implemented and sustainable in technical, financial and administrative terms. A high quality of legislation is essential for achieving legal certainty.

### Article 3.4.4.

**The drafting of veterinary legislation**

*Veterinary legislation* should:

1) be drafted in a manner that establishes clear rights, responsibilities and obligations (i.e. 'normative');
2) be unambiguous, with clear and consistent syntax and vocabulary;
3) be precise, accurate and consistent in the repeated use of the terminology;
4) contain no definitions that create any conflict or ambiguity;
5) include a clear statement of scope and objectives;
6) provide for the application of penalties and sanctions, either criminal or administrative, as appropriate to the situation; and
7) make provision for the financing needed for the execution of all activities of *Competent Authorities*; the financing should be ensured in accordance with the national funding system.

### Article 3.4.5.

**Competent Authorities**

*Competent Authorities* should be legally mandated, capacitated and organised to ensure that all necessary actions are taken quickly and coherently to address animal health, public health and *animal welfare* emergencies effectively.

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

*Competent Authorities* should appoint technically qualified officials to take any actions needed for implementation or verification of compliance with the *veterinary legislation*, respecting the principles of independence and impartiality prescribed in Article 3.1.2.
1. Necessary powers of the Competent Authority
The veterinary legislation should also ensure that:

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

b) while executing their legal mandate, officials are protected against legal action and physical harm for actions carried out in good faith;

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

d) at least the following powers are available through the primary legislation:
   i) access to premises and vehicles for carrying out inspections;
   ii) access to documents;
   iii) taking samples;
   iv) retention (setting aside) of animals and goods, pending a decision on final disposition;
   v) seizure of animals, products and food of animal origin;
   vi) suspension of one or more activities of an inspected establishment;
   vii) temporary, partial or complete closure of inspected establishments; and
   viii) suspension or withdrawal of authorisations or approvals.

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

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

For this purpose, the veterinary legislation should:

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

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

c) define the procedures for making delegation;

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

e) define the conditions of withdrawals of delegations.

Article 3.4.6.

Veterinarians and veterinary para-professionals

1. Veterinary medicine/science
In order to ensure quality in the conduct of veterinary medicine/science, the veterinary legislation should:

a) define the prerogatives of veterinarians and of the various categories of veterinary para-professionals that are recognised by the Member Country;

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

c) prescribe the conditions for recognition of the qualifications for veterinarians and veterinary para-professionals;

d) define the conditions to perform the activities of veterinary medicine/science; and

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

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

a) describe the general system of control in terms of the political, administrative and geographic configuration of the country;
Chapter 3.4.- Veterinary legislation

b) describe the various categories of veterinary para-professionals recognised by the Member Country according to its needs, notably in animal health and food safety, and for each category, prescribe its training, qualifications, tasks and extent of supervision;

c) prescribe the powers to deal with conduct and competence issues, including licensing requirements, that apply to veterinarians and veterinary para-professionals;

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

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

Article 3.4.7.

Laboratories in the veterinary domain

1. Facilities

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

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

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

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

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

2. Reagents

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

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

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

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

Article 3.4.8.

Health provisions relating to animal production

1. Identification and traceability

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

2. Animal markets and other gatherings

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

a) registration of animal markets and other animal gatherings;

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

c) provision for veterinary checks.

3. Animal reproduction

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

4. Animal feed

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

a) standards for the production, composition and quality control of animal feed;
b) registration and, if necessary, approval of establishments and the provision of health requirements for relevant operations; and

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

5. Animal by-products

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

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

b) rules for collection, processing, use and disposal of animal by-products;

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

d) rules to be followed by animal owners.

6. Disinfection

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

Article 3.4.9.

Animal diseases

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

1. Surveillance

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

2. Disease prevention and control

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

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

i) administrative and logistic organisation;

ii) exceptional powers of the Competent Authority; and

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

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

3. Emerging diseases

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

Article 3.4.10.

Animal welfare

1. General provisions

Veterinary legislation should provide a basis for actions to address the animal welfare related requirements in Section 7.

To this end, the legislation should contain, as a minimum, a legal definition of cruelty as an offence, and provisions for direct intervention of the Competent Authority in the case of neglect by animal keepers.
2. Stray dogs and other free-roaming animals

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

**Article 3.4.11.**

**Veterinary medicines and biologicals**

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

1. **General measures**

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

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

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

2. **Raw materials for use in veterinary medicines and biologicals**

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

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

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

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

3. **Authorisation of veterinary medicines and biologicals**

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

b) Special provisions should be made for:

i) medicated feed;

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

iii) emergencies and temporary situations.

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

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

i) describe the role of the relevant Competent Authorities; and

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

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

4. **Quality of veterinary medicines and biologicals**

**Veterinary legislation** should address the following elements:

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

b) conditions for the conduct of trials;

c) qualifications of experts involved in trials; and

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

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

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

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

c) good manufacturing practices as appropriate;

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

e) mechanisms for traceability and recall.

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

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

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

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

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

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

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

f) reporting on adverse effects to the Competent Authority.

Article 3.4.12.

Human food production chain

Veterinary legislation should provide a basis for actions to safeguard the human food production chain through controls at all critical steps, consistent with national food safety standards. The role of the Veterinary Services in food safety is described in Chapter 6.1.

1. General provisions

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

a) controls over all stages of the production, processing and distribution of food of animal origin;

b) recording all significant animal and public health events that occur during primary production;

c) giving operators of food production premises the primary responsibility for compliance with food safety requirements, including traceability established by the Competent Authority;

d) inspection for compliance with food standards, where this is relevant to health or safety;

e) inspection of premises;

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

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

2. Products of animal origin intended for human consumption

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

a) arrangements for inspection and audit;

b) the conduct of inspection and audit;

c) health standards; and

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

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

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

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

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

b) the use of risk-based management procedures; and

c) prior authorisation of operations that are likely to constitute a significant risk to human or animal health.
Chapter 3.4.- Veterinary legislation

Article 3.4.13.

Import and export procedures and veterinary certification

Veterinary legislation should provide a basis for actions to address the elements relating to import and export procedures and veterinary certification referred to in Section 5.
CHAPTER 4.1.

GENERAL PRINCIPLES ON IDENTIFICATION AND TRACEABILITY OF LIVE ANIMALS

Article 4.1.1.

1) *Animal identification* and *animal traceability* are tools for addressing animal health (including zoonoses) and food safety issues. These tools may significantly improve the effectiveness of activities such as: the management of disease outbreaks and food safety incidents, vaccination programmes, herd/flock husbandry, zoning/compartmentalisation, surveillance, early response and notification systems, animal movement controls, inspection, certification, fair practices in trade and the utilisation of veterinary drugs, feed and pesticides at farm level.

2) There is a strong relationship between animal identification and the traceability of animals and products of animal origin.

3) *Animal traceability* and traceability of products of animal origin should have the capability to be linked to achieve traceability throughout the animal production and food chain taking into account relevant OIE and Codex Alimentarius standards.

4) The objective(s) of animal identification and animal traceability for a particular country, zone or compartment and the approach used should be clearly defined following an assessment of the risks to be addressed and a consideration of the factors listed below. They should be defined through consultation between the Veterinary Authority and relevant sectors/stakeholders prior to implementation, and periodically reviewed.

5) There are various factors which may determine the system chosen for animal identification and animal traceability. Factors such as the outcomes of the risk assessment, the animal and public health situation (including zoonoses) and related programmes, animal population parameters (such as species and breeds, numbers and distribution), types of production, animal movement patterns, available technologies, trade in animals and animal products, cost/benefit analysis and other economic, geographical and environmental considerations, and cultural aspects, should be taken into account when designing the system.

6) Animal identification and animal traceability should be under the responsibility of the Veterinary Authority. It is recognised that other Authorities may have jurisdiction over other aspects of the food chain, including the traceability of food.

7) The Veterinary Authority, with relevant governmental agencies and in consultation with the private sector, should establish a legal framework for the implementation and enforcement of animal identification and animal traceability in the country. In order to facilitate compatibility and consistency, relevant international standards and obligations should be taken into account. This legal framework should include elements such as the objectives, scope, organisational arrangements including the choice of technologies used for identification and registration, obligations of all the parties involved including third parties implementing traceability systems, confidentiality, accessibility issues and the efficient exchange of information.

8) Whatever the specific objectives of the chosen animal identification system and animal traceability, there is a series of common basic factors, and these must be considered before implementation, such as the legal framework, procedures, the Competent Authority, identification of establishments/owners, animal identification and animal movements.
Chapter 4.1.- General principles on identification and traceability of live animals

9) The equivalent outcomes based on performance criteria rather than identical systems based on design criteria should be the basis for comparison of animal identification systems and animal traceability.
CHAPTER 4.2.
DESIGN AND IMPLEMENTATION OF IDENTIFICATION SYSTEMS TO ACHIEVE ANIMAL TRACEABILITY

Article 4.2.1.

Introduction and objectives

These recommendations are based on the general principles presented in Article 4.1.1. The recommendations outline for Member Countries the basic elements that need to be taken into account in the design and implementation of an animal identification system to achieve animal traceability. Whatever animal identification system the country adopts, it should comply with relevant OIE standards, including Chapters 5.10. to 5.12. for animals and animal products intended for export. Each country should design a programme in accordance with the scope and relevant performance criteria to ensure that the desired animal traceability outcomes can be achieved.

Article 4.2.2.

Definitions

For the purpose of this chapter:

Desired outcomes: describe the overall goals of a programme and are usually expressed in qualitative terms, e.g. ‘to help ensure that animals and/or animal products are safe and suitable for use’. Safety and suitability for use could be defined in terms such as animal health, food safety, trade and aspects of animal husbandry.

Performance criteria: are specifications for performance of a programme and are usually expressed in quantitative terms, such as ‘all animals can be traced to the establishment of birth within 48 hours of an enquiry’.

Reporting: means advising the Veterinary Authority and other partner organisations as appropriate in accordance with the procedures listed in the programme.

Scope: specifies the targeted species, population and/or production/trade sector within a defined area (country, zone) or compartment that is the subject of the identification and traceability programme.

Transhumance: periodic/seasonal movements of animals between different pastures within or between countries.

Article 4.2.3.

Key elements of the animal identification system

1. Desired outcomes

Desired outcomes should be defined through consultation between the Veterinary Authority and interested parties, which should include those in the animal production and processing chain, private sector veterinarians, scientific research organisations and other public and private organisations. Desired outcomes may be defined in terms of any or all of the following:

a) animal health (e.g. disease surveillance and notification; detection and control of disease; vaccination programmes);

b) public health (e.g. surveillance and control of zoonotic diseases and food safety);

c) management of emergencies e.g. natural catastrophies or man-made events;

d) trade (support for inspection and certification activities of Veterinary Services, as described in Chapters 5.10. to 5.12. which reproduce model international veterinary certificates);

e) aspects of animal husbandry such as animal performance, and genetic data.
2. **Scope**

Scope should also be defined through consultation between the Veterinary Authority and other parties, as discussed above. The scope of animal identification systems is often based on the definition of a species and sector, to take account of particular characteristics of the farming systems e.g. pigs in pork export production; poultry in a defined compartment; cattle within a defined FMD free zone. Different systems will be appropriate according to the production systems used in countries and the nature of their industries and trade.

3. **Performance criteria**

Performance criteria are also designed in consultation with other parties, as discussed above. The performance criteria depend on the desired outcomes and scope of the programme. They are usually described in quantitative terms according to the epidemiology of the disease. For example, some countries consider it necessary to trace susceptible animals within 24–48 hours when dealing with highly contagious diseases such as FMD and avian influenza. For food safety, animal tracing to support investigation of incidents may also be urgent. For chronic animal diseases that are not zoonoses, it may be considered appropriate that animals can be traced over a longer period.

4. **Preliminary studies**

In designing animal identification systems it is useful to conduct preliminary studies, which should take into account:

a) animal populations, species, distribution, herd management,

b) farming and industry structures, production and location,

c) animal health,

d) public health,

e) trade issues,

f) aspects of animal husbandry,

g) zoning and compartmentalisation,

h) animal movement patterns (including transhumance),

i) information management and communication,

j) availability of resources (human and financial),

k) social and cultural aspects,

l) stakeholder knowledge of the issues and expectations,

m) gaps between current enabling legislation and what is needed long term,

n) international experience,

o) national experience,

p) available technology options,

q) existing identification system(s),

r) expected benefits from the animal identification systems and animal traceability and to whom they accrue,

s) issues pertaining to data ownership and access rights,

t) reporting requirements.

Pilot projects may form part of the preliminary study to test the animal identification system and animal traceability and to gather information for the design and the implementation of the programme.

Economic analysis may consider costs, benefits, funding mechanisms and sustainability.

5. **Design of the programme**

a) **General provisions**

The programme should be designed in consultation with the stakeholders to facilitate the implementation of the animal identification system and animal traceability. It should take into account the scope, performance criteria and desired outcomes as well as the results of any preliminary study.

All the specified documentation should be standardised as to format, content and context.

To protect and enhance the integrity of the system, procedures should be incorporated into the design of the programme to prevent, detect and correct errors e.g. use of algorithms to prevent duplication of identification numbers and to ensure plausibility of data.

b) **Means of animal identification**

The choice of a physical animal or group identifier should consider elements such as the durability, human resources, species and age of the animals to be identified, required period of identification, cultural aspects, animal welfare, technology, compatibility and relevant standards, farming practices, production systems,
animal population, climatic conditions, resistance to tampering, trade considerations, cost, and retention and readability of the identification method.

The Veterinary Authority is responsible for approving the materials and equipment chosen, to ensure that these means of animal identification comply with technical and field performance specifications, and for the supervision of their distribution. The Veterinary Authority is also responsible for ensuring that identifiers are unique and are used in accordance with the requirements of the animal identification system.

The Veterinary Authority should establish procedures for animal identification and animal traceability including:

i) the establishment of birth, and time period within which an animal is born;

ii) when animals are introduced into an establishment;

iii) when an animal loses its identification or the identifier becomes unusable;

iv) arrangements and rules for the destruction and/or reuse of identifiers;

v) penalties for the tampering and/or removal of official animal identification devices.

Where group identification without a physical identifier is adequate, documentation should be created specifying at least the number of animals in the group, the species, the date of identification, the person legally responsible for the animals and/or establishment. This documentation constitutes a unique group identifier and it should be updated to be traceable if there are any changes.

Where all animals in the group are physically identified with a group identifier, documentation should also specify the unique group identifier.

c) Registration

Procedures need to be incorporated into the design of the programme in order to ensure that relevant events and information are registered in a timely and accurate manner.

Depending on the scope, performance criteria and desired outcomes, records as described below should specify, at least, the species, the unique animal or group identifier, the date of the event, the identifier of the establishment, and any establishment used in transit. The movement record may also include a description of the means of transport and the identification of the vehicle/vessel.

Establishments/owners or responsible keepers

Establishments where animals are kept should be identified and registered, including at least their physical location (such as geographical coordinates or street address), the type of establishment and the species kept. The register should include the name of the person legally responsible for the animals at the establishment.

The types of establishments that may need to be registered include holdings (farms), assembly centres (e.g. agriculture shows and fairs, sporting events, transit centres, breeding centres), markets, abattoirs, rendering plants, dead stock collection points, transhumance areas, centres for necropsy and diagnosis, research centres, zoos, border posts, quarantine stations.

In cases where the registration of establishments is not applicable e.g. some transhumance systems, the animal owner, the owner’s place of residence and the species kept should be recorded.

Animals

Animal identification and species should be registered for each establishment/owner. Other relevant information about the animals at each establishment/owner may also be recorded (e.g. date of birth, production category, sex, breed, number of animals of each species, animal identification of the parents).

iii) Other events

The registration of animal movements is necessary to achieve animal traceability. When an animal is introduced into or leaves an establishment, these events constitute a movement.

Some countries classify birth, slaughter and death of the animal as movements. When establishments are not registered as part of the animal identification system, ownership and location changes constitute a movement record.

The information registered should include the date of the movement, the establishment from which the animal or group of animals was dispatched, the number of animals moved, the destination establishment, and any establishment used in transit. The movement record may also include a description of the means of transport and the identification of the vehicle/vessel.

Procedures should be in place to maintain animal traceability during transport and when animals arrive at and leave an establishment.

The following events may also be registered:

– birth, slaughter and death of the animal (when not classified as a movement),
– attachment of the unique identifier to an animal,
– change of owner or keeper regardless of change of establishment,
Chapter 4.2.- Design and implementation of identification systems to achieve animal traceability

- observation of an animal on an establishment (testing, health investigation, health certification, etc.),
- animal imported: a record of the animal identification from the exporting country should be kept and linked with the animal identification assigned in the importing country,
- animal exported: a record of the animal identification from the exporting country should be provided to the Veterinary Authority in the importing country,
- animal identifier lost or replaced,
- animal missing (lost, stolen, etc.),
- animal identifier retired (at slaughter, following loss of the identifier or death of the animal on a farm, at diagnostic laboratories, etc.).

d) Documentation
Documentation requirements should be clearly defined and standardised, according to the scope, performance criteria and desired outcomes and supported by the legal framework.

e) Reporting
Depending on the scope, performance criteria and desired outcomes, relevant information (such as animal identification, movement, events, changes in numbers of livestock, establishments) should be reported to the Veterinary Authority by the person responsible for the animals.

f) Information system
An information system should be designed according to the scope, performance criteria and desired outcomes. This may be paper based or electronic. The system should provide for the collection, compilation, storage and retrieval of information on matters relevant to registration. The following considerations are important:
- have the potential for linkage to traceability in the other parts of the food chain;
- minimize duplication;
- relevant components, including databases, should be compatible;
- confidentiality of data;
- appropriate safeguards to prevent the loss of data, including a system for backing up the data.

The Veterinary Authority should have access to this information system as appropriate to meet the scope, performance criteria and desired outcomes.

g) Laboratories
The results of diagnostic tests should record the animal identifier or the group identifier, the date of sample was taken from the animal and the establishment where the sample was collected.

h) Abattoirs, rendering plants, dead stock collection points, markets and assembly centres
Abattoirs, rendering plants, dead stock collection points, markets and assembly centres should document arrangements for the maintenance of animal identification and animal traceability in compliance with the legal framework.

These establishments are critical points for control of animal health and food safety.

Animal identification should be recorded on documents accompanying samples collected for analysis.

The components of the animal identification system operating within abattoirs should complement and be compatible with arrangements for tracking animal products throughout the food chain. At an abattoir, animal identification should be maintained during the processing of the animal’s carcass until the carcass is deemed fit for human consumption.

The animal identification and the establishment from which the animal was dispatched should be registered by the abattoir, rendering plant and dead stock collection points.

Abattoirs, rendering plants and dead stock collection points should ensure that identifiers are collected and disposed of according to the procedures established and regulated within the legal framework. These procedures should minimize the risk of unauthorized reuse and, if appropriate, should establish arrangements and rules for the reuse of identifiers.

Reporting of movement by abattoirs, rendering plants and dead stock collection points should occur according to the scope, performance criteria and desired outcomes and the legal framework.

i) Penalties
Different levels and types of penalties should be defined in the programme and supported by the legal framework.
6. Legal framework

The Veterinary Authority, with other relevant governmental agencies and in consultation with stakeholders, should establish a legal framework for the implementation and enforcement of animal identification system and animal traceability in the country. The structure of this framework will vary from country to country.

Animal identification, animal traceability and animal movement should be under the responsibility of the Veterinary Authority.

This legal framework should address:

a) desired outcomes and scope;

b) obligations of the Veterinary Authority and other parties;

c) organisational arrangements, including the choice of technologies and methods used for the animal identification system and animal traceability;

d) management of animal movement;

e) confidentiality of data;

f) data access / accessibility;

g) checking, verification, inspection and penalties;

h) where relevant, funding mechanisms;

i) where relevant, arrangements to support a pilot project.

7. Implementation

a) Action plan

For implementing the animal identification system, an action plan should be prepared specifying the timetable and including the milestones and performance indicators, the human and financial resources, and checking, enforcement and verification arrangements.

The following activities should be addressed in the action plan:

i) Communication

The scope, performance criteria, desired outcomes, responsibilities, movement and registration requirements and sanctions need to be communicated to all parties.

Communication strategies need to be targeted to the audience, taking into account elements such as the level of literacy (including technology literacy) and spoken languages.

ii) Training programmes

It is desirable to implement training programmes to assist the Veterinary Services and other parties.

iii) Technical support

Technical support should be provided to address practical problems.

b) Checking and verification

Checking activities should start at the beginning of the implementation to detect, prevent and correct errors and to provide feedback on programme design.

Verification should begin after a preliminary period as determined by the Veterinary Authority in order to determine compliance with the legal framework and operational requirements.

c) Auditing

Auditing should be carried out under the authority of the Veterinary Authority to detect any problems with the animal identification system and animal traceability and to identify possible improvements.

d) Review

The programme should be subject to periodic review, taking into account the results of checking, verification and auditing activities.
CHAPTER 4.3.

ZONING AND COMPARTMENTALISATION

Article 4.3.1.

Introduction

For the purposes of the Terrestrial Code, ‘zoning’ and ‘regionalisation’ have the same meaning.

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

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

A particular application of the concept of zoning is the establishment of a containment zone. In the event of limited outbreaks of a specified disease within an otherwise free country or zone, a single containment zone, which includes all cases, can be established for the purpose of minimizing the impact on the entire country or zone.

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

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

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

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

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

Article 4.3.2.

General considerations

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

The procedures used to establish and maintain the distinct animal health status of a zone or compartment will depend on the epidemiology of the disease, in particular the presence and role of susceptible wildlife species, and environmental factors, as well as on the application of biosecurity measures.

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

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

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

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

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

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

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

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

Article 4.3.3.

Principles for defining and establishing a zone or compartment, including protection and containment zones

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

1) The extent of a zone and its geographical limits should be established by the Veterinary Authority on the basis of natural, artificial and/or legal boundaries, and made public through official channels.

2) A protection zone may be established to preserve the health status of animals in a free country or zone, from adjacent countries or zones of different animal health status. Measures should be implemented based on the epidemiology of the disease under consideration to prevent introduction of the pathogenic agent and to ensure early detection.

These measures should include intensified movement control and surveillance and may include:

a) animal identification and animal traceability to ensure that animals in the protection zone are clearly distinguishable from other populations;

b) vaccination of all or at risk susceptible animals;

c) testing and/or vaccination of animals moved;

d) specific procedures for sample handling, sending and testing;
e) enhanced biosecurity including cleansing – disinfection procedures for transport means, and possible compulsory routes;

f) specific surveillance of susceptible wildlife species and relevant vectors;

g) awareness campaigns to the public or targeted at breeders, traders, hunters, veterinarians.

The application of these measures can be in the entire free zone or in a defined area within and/or outside the free zone.

3) In the event of limited outbreaks in a country or zone previously free of a disease, a containment zone may be established for the purposes of trade. Establishment of a containment zone should be based on a rapid response including:

a) appropriate standstill of movement of animals and other commodities upon notification of suspicion of the specified disease and the demonstration that the outbreaks are contained within this zone through epidemiological investigation (trace-back, trace-forward) after confirmation of infection. The primary outbreak has been identified and investigations on the likely source of the outbreak have been carried out and all cases shown to be epidemiologically linked.

b) A stamping-out policy or another effective control strategy aimed at eradicating the disease should be applied and the susceptible animal population within the containment zones should be clearly identifiable as belonging to the containment zone. Increased passive and targeted surveillance in accordance with Chapter 1.4. in the rest of the country or zone should be carried out and has not detected any evidence of infection.

c) Measures consistent with the disease-specific chapter should be in place to prevent spread of the infection from the containment zone to the rest of the country or zone, including ongoing surveillance in the containment zone.

d) For the effective establishment of a containment zone, it is necessary to demonstrate that there have been no new cases in the containment zone within a minimum of two incubation periods from the last detected case.

e) 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, once the containment zone is clearly established, irrespective of the provisions of the disease-specific chapter.

f) 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.

g) The recovery of the free status of the containment zone should follow the provisions of the disease-specific chapter.

4) The factors defining a compartment should be established by the Veterinary Authority on the basis of relevant criteria such as management and husbandry practices related to biosecurity, and made public through official channels.

5) Animals and herds belonging to such subpopulations need to be recognisable as such through a clear epidemiological separation from other animals and all things presenting a disease risk. For a zone or compartment, the Veterinary Authority should document in detail the measures taken to ensure the identification of the subpopulation and the establishment and maintenance of its health status through a biosecurity plan. The measures used to establish and maintain the distinct animal health status of a zone or compartment should be appropriate to the particular circumstances, and will depend on the epidemiology of the disease, environmental factors, the health status of animals in adjacent areas, applicable biosecurity measures (including movement controls, use of natural and artificial boundaries, the spatial separation of animals, and commercial management and husbandry practices), and surveillance.

6) Relevant animals within the zone or compartment should be identified in such a way that their movements are traceable. Depending on the system of production, identification may be done at the herd, flock lot or individual animal level. Relevant animal movements into and out of the zone or compartment should be well documented and controlled. The existence of a valid animal identification system is a prerequisite to assess the integrity of the zone or compartment.

7) For a compartment, the biosecurity plan should describe the partnership between the relevant industry and the Veterinary Authority, and their respective responsibilities. It should also describe the routine operating procedures to provide clear evidence that the surveillance conducted, the live animal identification and traceability system, and the management practices are adequate to meet the definition of the compartment. In addition to information on animal movement controls, the plan should include herd or flock production records, feed sources, surveillance results, birth and death records, visitor logbook, morbidity and mortality history, medications, vaccinations, documentation of training of relevant personnel and any other criteria necessary for evaluation of risk mitigation. The information required may vary according to the species and disease(s) under consideration. The biosecurity
plan should also describe how the measures will be audited to ensure that the *risks* are regularly re-assessed and the measures adjusted accordingly.
CHAPTER 4.4.

APPLICATION OF COMPARTMENTALISATION

Article 4.4.1.

Introduction and objectives

The recommendations in this chapter provide a structured framework for the application and recognition of compartments within countries or zones, based on the provisions of Chapter 4.3. with the objective to facilitate trade in animals and products of animal origin and as a tool for disease management.

Establishing and maintaining a disease free status throughout the country should be the final goal for Member Countries. However, establishing and maintaining a disease free status for an entire country may be difficult, especially in the case of diseases that can easily cross international boundaries. For many diseases, Member Countries have traditionally applied the concept of zoning to establish and maintain an animal subpopulation with a different animal health status within national boundaries.

The essential difference between zoning and compartmentalisation is that the recognition of zones is based on geographical boundaries whereas the recognition of compartments is based on management practices and biosecurity. However, spatial considerations and good management practices play a role in the application of both concepts.

Compartmentalisation is not a new concept for Veterinary Services; in fact, it has been applied for a long time in many disease control programmes that are based on the concept of disease free herds/flocks.

The fundamental requirement for compartmentalisation is the implementation and documentation of management and biosecurity measures to create a functional separation of subpopulations.

For example, an animal production operation in an infected country or zone might have biosecurity measures and management practices that result in negligible risk from diseases or agents. The concept of a compartment extends the application of a ‘risk boundary’ beyond that of a geographical interface and considers all epidemiological factors that can help to create an effective disease-specific separation between subpopulations.

In disease free countries or zones, compartments preferably should be defined prior to the occurrence of a disease outbreak. In the event of an outbreak or in infected countries or zones, compartmentalisation may be used to facilitate trade.

For the purpose of international trade, compartments should be under the responsibility of the Veterinary Authority in the country. For the purposes of this chapter, compliance by Member Countries with Chapters 1.1. and 3.1. is an essential prerequisite.

Article 4.4.2.

Principles for defining a compartment

A compartment may be established with respect of a specific disease or diseases. A compartment should be clearly defined, indicating the location of all its components including establishments, as well as related functional units (such as feed mills, slaughterhouses, rendering plants, etc.), their interrelationships and their contribution to an epidemiological separation between the animals in a compartment and subpopulations with a different health status. The definition of compartment may revolve around disease-specific epidemiological factors, animal production systems, biosecurity practices infrastructural factors and surveillance.

Article 4.4.3.

Separation of a compartment from potential sources of infection

The management of a compartment should provide to the Veterinary Authority documented evidence on the following:
1. **Physical or spatial factors that affect the status of biosecurity in a compartment**

While a compartment is primarily based on management and biosecurity measures, a review of geographical factors is needed to ensure that the functional boundary provides adequate separation of a compartment from adjacent animal populations with a different health status. The following factors should be taken into consideration in conjunction with biosecurity measures and, in some instances, may alter the degree of confidence achieved by general biosecurity and surveillance measures:

a) disease status in adjacent areas and in areas epidemiologically linked to the compartment;

b) location, disease status and biosecurity of the nearest epidemiological units or other epidemiologically relevant premises. Consideration should be given to the distance and physical separation from:
   i) flocks or herds with a different health status in close proximity to the compartment, including wildlife and their migratory routes;
   ii) slaughterhouses, rendering plants or feed mills;
   iii) markets, fairs, agricultural shows, sporting events, zoos, circuses and other points of animal concentration.

2. **Infrastructural factors**

Structural aspects of the establishments within a compartment contribute to the effectiveness of its biosecurity. Consideration should be given to:

a) fencing or other effective means of physical separation;

b) facilities for people entry including access control, changing area and showers;

c) vehicle access including washing and disinfection procedures;

d) unloading and loading facilities;

e) isolation facilities for introduced animals;

f) facilities for the introduction of material and equipment;

g) infrastructure to store feed and veterinary products;

h) disposal of carcasses, manure and waste;

i) water supply;

j) measures to prevent exposure to living mechanical or biological vectors such as insects, rodents and wild birds;

k) air supply;

l) feed supply/source.

More detailed recommendations for certain establishments can be found in Sections 4 and 6.

3. **Biosecurity plan**

The integrity of the compartment relies on effective biosecurity. The management of the compartment should develop, implement and monitor a comprehensive biosecurity plan.

The biosecurity plan should describe in detail:

a) potential pathways for introduction and spread into the compartment of the agents for which the compartment was defined, including animal movements, rodents, fauna, aerosols, arthropods, vehicles, people, biological products, equipment, fomites, feed, waterways, drainage or other means. Consideration should also be given to the survivability of the agent in the environment;

b) the critical control points for each pathway;

c) measures to mitigate exposure for each critical control point;

d) standard operating procedures including:
   i) implementation, maintenance, monitoring of the measures,
   ii) application of corrective actions,
   iii) verification of the process,
   iv) record keeping;

e) contingency plan addressing any potential future changes in the risk factors;

f) reporting procedures to the Veterinary Authority;

g) the programme for educating and training workers to ensure that all persons involved are knowledgeable and informed on biosecurity principles and practices;
h) the surveillance programme in place.

In any case, sufficient evidence should be submitted to assess the efficacy of the biosecurity plan in accordance with the level of risk for each identified pathway. This evidence should be structured in line with the principles of Hazard Analysis and Critical Control Point (HACCP). The biosecurity risk of all operations of the compartment should be regularly re-assessed and documented at least on a yearly basis. Based on the outcome of the assessment, concrete and documented mitigation steps should be taken to reduce the likelihood of introduction of the disease agent into the compartment.

4. Traceability system

A prerequisite for assessing the integrity of a compartment is the existence of a valid traceability system. All animals within a compartment should be individually identified and registered in such a way that their history and movements can be documented and audited. In cases where individual identification may not be feasible, such as broilers and day-old chicks, the Veterinary Authority should provide sufficient assurance of traceability.

All animal movements into and out of the compartment should be recorded at the compartment level, and when needed, based on a risk assessment, certified by the Veterinary Authority. Movements within the compartment need not be certified but should be recorded at the compartment level.

Article 4.4.4.

Documentation

Documentation should provide clear evidence that the biosecurity, surveillance, traceability and management practices defined for a compartment are effectively and consistently applied. In addition to animal movement information, the necessary documentation should include herd or flock production records, feed sources, laboratory tests, birth and death records, the visitor logbook, morbidity history, medication and vaccination records, biosecurity plans, training documentation and any other criteria necessary for the evaluation of disease exclusion.

The historical status of a compartment for the disease(s) for which it was defined should be documented and demonstrate compliance with the requirements for freedom in the relevant Terrestrial Code chapter.

In addition, a compartment seeking recognition should submit to the Veterinary Authority a baseline animal health report indicating the presence or absence of listed diseases for the animal species of interest to the compartment according to Article 1.2.3. This report should be regularly updated to reflect the current animal health situation of the compartment.

Vaccination records including the type of vaccine and frequency of administration should be available to enable interpretation of surveillance data.

The time period for which all records should be kept may vary according to the species and disease(s) for which the compartment was defined.

All relevant information should be recorded in a transparent manner and be easily accessible so as to be auditable by the Veterinary Authority.

Article 4.4.5.

Surveillance for the agent or disease

The surveillance system should comply with Chapter 1.4. on Surveillance and the specific recommendations for surveillance for the disease(s) for which the compartment was defined, if available.

If there is an increased risk of exposure to the agent for which the compartment has been defined, the sensitivity of the internal and external surveillance system should be reviewed and, where necessary, increased. At the same time, biosecurity measures in place should be reassessed and increased if necessary.

1. Internal surveillance

Surveillance should involve the collection and analysis of disease/infection data so that the Veterinary Authority can certify that the animal subpopulation contained in all the establishments comply with the defined status of that compartment. A surveillance system that is able to ensure early detection in the event that the agent enters a subpopulation is essential. Depending on the disease(s) for which the compartment was defined, different surveillance strategies may be applied to achieve the desired confidence in disease freedom.
Chapter 4.4.- Application of compartmentalisation

2. External surveillance

The biosecurity measures applied in a compartment should be appropriate to the level of exposure of the compartment. External surveillance will help identify a significant change in the level of exposure for the identified pathways for disease introduction into the compartment.

An appropriate combination of active and passive surveillance is necessary to achieve the goals described above. Based on the recommendations of Chapter 1.4., targeted surveillance based on an assessment of risk factors may be the most efficient surveillance approach. Targeted surveillance should in particular include epidemiological units in close proximity to the compartment or those that have a potential epidemiological link with it.

Article 4.4.6.

Diagnostic capabilities and procedures

Officially-designated laboratory facilities complying with the OIE standards for quality assurance, as defined in Chapter 1.1.3. of the Terrestrial Manual, should be available for sample testing. All laboratory tests and procedures should comply with the recommendations of the laboratory for the specific disease. Each laboratory that conducts testing should have systematic procedures in place for rapid reporting of disease results to the Veterinary Authority. Where appropriate, results should be confirmed by an OIE Reference Laboratory.

Article 4.4.7.

Emergency response and notification

Early detection, diagnosis and notification of disease are critical to minimize the consequences of outbreaks.

In the event of suspicion of occurrence of the disease for which the compartment was defined, the free status of the compartment should be immediately suspended. If confirmed, the status of the compartment should be immediately revoked and importing countries should be notified following the provisions of Article 5.3.7.

In case of an occurrence of any infectious disease not present according to the baseline animal health report of the compartment referred to in Article 4.4.4., the management of the compartment should notify the Veterinary Authority, and initiate a review to determine whether there has been a breach in the biosecurity measures. If a significant breach in biosecurity, even in the absence of outbreak, is detected, export certification as a free compartment should be suspended. Disease free status of the compartment may only be reinstated after the compartment has adopted the necessary measures to re-establish the original biosecurity level and the Veterinary Authority re-approves the status of the compartment.

In the event of a compartment being at risk from a change, in the surrounding area, in the disease situation for which the compartment was defined, the Veterinary Authority should re-evaluate without delay the status of the compartment and consider whether any additional biosecurity measures are needed to ensure that the integrity of the compartment is maintained.

Article 4.4.8.

Supervision and control of a compartment

The authority, organisation, and infrastructure of the Veterinary Services, including laboratories, should be clearly documented in accordance with Chapter 3.2., to provide confidence in the integrity of the compartment.

The Veterinary Authority has the final authority in granting, suspending and revoking the status of a compartment. The Veterinary Authority should continuously supervise compliance with all the requirements critical to the maintenance of the compartment status described in this chapter and ensure that all the information is readily accessible to the importing countries. Any significant change should be notified to the importing country.
CHAPTER 4.5.

GENERAL HYGIENE IN SEMEN COLLECTION AND PROCESSING CENTRES

Article 4.5.1.

General considerations

Observation of the recommendations described in the articles below will very significantly reduce the likelihood of the semen being contaminated with common micro-organisms some of which are potentially pathogenic.

Article 4.5.2.

Conditions applicable to artificial insemination centres

1) The artificial insemination centre is comprised of:
   a) animal accommodation areas (including one isolation facility for sick animals) and a semen collection room, these two premises hereon designated as semen collection facilities; accommodation areas should be species specific where relevant;
   b) a semen laboratory and semen storage areas;
   c) administration offices;
   d) a pre-entry isolation facility which is not compulsory in case of horses.
2) The centre should be under the direct supervision and control of a centre veterinarian.
3) Only animals associated with semen production should be permitted to enter the centre. Other species of livestock may exceptionally be resident on the centre, provided that they are kept physically apart from these animals.
4) Donors and teasers on the centre should be adequately isolated from farm livestock on adjacent land or buildings for instance by natural or artificial means.
5) The entry of visitors should be strictly controlled. Personnel at a centre should be technically competent and observe high standards of personal hygiene to preclude the introduction of pathogenic organisms. Protective clothing and footwear for use only on the centre should be provided.
6) Individual semen containers and storage rooms should be capable of being disinfected.
7) The centre should be officially approved by the Veterinary Authority.
8) The centre should be under the supervision and control of the Veterinary Services which will be responsible for regular audits, at an interval of no more than 12 months, of protocols, procedures and records on the health and welfare of the animals in the centre and on the hygienic production, storage and dispatch of semen.

Article 4.5.3.

Conditions applicable to semen collection facilities

1) The semen collection facilities should include separate and distinct areas for accommodating resident animals, for semen collection, for feed storage, for manure storage, and for the isolation of animals suspected of being infected.
2) Only animals associated with semen production should be permitted to enter the semen collection facilities. Other species of animals may be resident at the centre, if necessary for the movement or handling of the donors and teasers or for security, but contact with the donors and teasers should be minimised. All animals resident at the semen collection facilities should meet the minimum health requirements for donors.
3) The donors and teasers should be adequately isolated to prevent the transmission of diseases from farm livestock and other animals. Measures should be in place to prevent the entry of wild animals susceptible to ruminant and swine diseases transmissible via semen.
4) Personnel at the centre should be technically competent and observe high standards of personal hygiene to preclude the introduction of pathogenic organisms. Special protective clothing and footwear for use only at the semen collection facilities should be provided and worn at all times inside.
5) Visitors to the semen collection facilities should be kept to a minimum, and visits should be subject to formal authorisation and control. Equipment for use with the livestock should be dedicated to the semen collection facilities or disinfected prior to entry. All equipment and tools brought on to the premises should be examined and treated if necessary to ensure that they cannot introduce disease.

6) Vehicles used for transport of animals to and from the semen collection facilities should not be allowed to enter the facilities.

7) The semen collection area should be cleaned daily after collection. The animals' accommodation should be kept clean.

8) Fodder introduction and manure removal should be done in a manner which poses no significant animal health risk.

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Conditions applicable to semen laboratories

1) The semen laboratory should be physically separated from the semen collection facilities, and include separate areas for artificial vagina cleaning and preparation, semen evaluation and processing, semen pre-storage and storage. Entry to the laboratory should be prohibited to unauthorised personnel.

2) The laboratory personnel should be technically competent and observe high standards of personal hygiene to preclude the introduction of pathogenic organisms during semen evaluation, processing and storage.

3) Visitors to the laboratory should be kept to a minimum, and visits should be subject to formal authorisation and control.

4) The laboratory should be constructed with materials that permit effective cleaning and disinfection.

5) The laboratory should be regularly cleaned. Work surfaces for semen evaluation and processing should be cleaned and disinfected at the end of each workday.

6) The laboratory should be treated against rodents and insects on a regular basis as needed to control these pests.

7) The storage rooms and individual semen containers should be easy to clean and disinfect.

8) Only semen collected from donors having a health status equivalent to or better than the donors at the semen collection facilities should be processed in the laboratory.

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Conditions applicable to the management of bulls, rams, bucks and boars

The objective is to keep the animals in a satisfactory state of cleanliness, particularly of the lower thorax and abdomen.

1) Whether on pasture or housed, the animal should be kept under hygienic conditions. If housed, the litter should be kept clean and renewed as often as necessary.

2) The coat of the animal should be kept clean.

3) For bulls, the tuft of hairs at the preputial orifice, which is often soiled, should be cut to about 2 cm. The hair should not be removed altogether, because of its protective role. If cut too short, irritation of the preputial mucosa may result because these hairs aid the drainage of urine.

4) The animal should be brushed regularly, and where necessary on the day before semen collection, paying special attention to the underside of the abdomen.

5) In the event of obvious soiling, there should be careful cleaning, with soap or a detergent, of the preputial orifice and the adjoining areas, followed by thorough rinsing and drying.

6) When the animal is brought into the collection area, the technician should make sure that it is clean, and that it is not carrying any excessive litter or particles of feed on its body or its hooves.
CHAPTER 4.6.

COLLECTION AND PROCESSING OF BOVINE, SMALL RUMINANT AND PORCINE SEMEN

Article 4.6.1.

General considerations

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

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

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

Artificial insemination centres should comply with recommendations in Chapter 4.5.

Standards for diagnostic tests are described in the Terrestrial Manual.

Article 4.6.2.

Conditions applicable to testing of bulls and teaser animals

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

1. Prior to entering pre-entry isolation facility

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

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

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

   c) Bovine viral diarrhoea (BVD)

      The animals should be subjected to:

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

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

   d) Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis

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

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

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

   e) Bluetongue

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

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

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

   a) Bovine brucellosis

      The animals should be subjected to a serological test with negative results.
b) BVD
   i) The animals should be subjected to a virus isolation test or a test for virus antigen, with negative results. Only when all the animals in pre-entry isolation have had negative results, may the animals enter the semen collection facilities.
   ii) All animals should be subjected to a serological test to determine the presence or absence of BVD antibodies.
   iii) Only if no seroconversion occurs in the animals which tested seronegative before entry into the pre-entry isolation facility, may any animal (seronegative or seropositive) be allowed entry into the semen collection facilities.
   iv) If seroconversion occurs, all the animals that remain seronegative should be kept in pre-entry isolation until there is no more seroconversion in the group for a period of three weeks. Serologically positive animals may be allowed entry into the semen collection facilities.

c) Campylobacter fetus subsp. venerealis
   i) Animals less than six months old or kept since that age only in a single sex group prior to pre-entry isolation should be tested once on a preputial specimen, with a negative result.
   ii) Animals aged six months or older that could have had contact with females prior to pre-entry isolation should be tested three times at weekly intervals on a preputial specimen, with a negative result in each case.

d) Tritrichomonas foetus
   i) Animals less than six months old or kept since that age only in a single sex group prior to pre-entry isolation, should be tested once on a preputial specimen, with a negative result.
   ii) Animals aged six months or older that could have had contact with females prior to pre-entry isolation should be tested three times at weekly intervals on a preputial specimen, with a negative result in each case.

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

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

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

a) Bovine brucellosis
b) Bovine tuberculosis
c) BVD
   Animals negative to previous serological tests should be retested to confirm absence of antibodies. Should an animal become serologically positive, every ejaculate of that animal collected since the last negative test should be either discarded or tested for virus with negative results.

d) Campylobacter fetus subsp. venerealis
   i) A preputial specimen should be tested.
   ii) Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a lay off of more than six months should be tested not more than 30 days prior to resuming production.

e) Bluetongue
   The animals should comply with the provisions referred to in Article 8.3.10. or Article 8.3.11.

f) Tritrichomonas foetus
   i) A preputial specimen should be cultured.
   ii) Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a lay off of more than six months should be tested not more than 30 days prior to resuming production.
g) IBR/IPV

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

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

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

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

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

Article 4.6.3.

Conditions applicable to testing of rams/bucks and teaser animals

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

1. Prior to entering pre-entry isolation facility

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

   a) Caprine and ovine brucellosis – Article 14.1.6.
   b) Ovine epididymitis – Article 14.7.3.
   c) Contagious agalactia – Points 1 and 2 of Article 14.3.1.
   d) Peste des petits ruminants – Points 1, 2 or 4 of Article 14.8.10.
   e) Contagious caprine pleuropneumonia – Article 14.4.7., depending on the CCPP status of the country or zone of origin of the *animals*.
   f) Paratuberculosis – Free from clinical signs for the past two years.
   g) Scrapie – Comply with Article 14.9.8. if the *animals* do not originate from a scrapie free country or zone as defined in Article 14.9.3.
   h) Maedi-visna – Article 14.6.2.
   i) Caprine arthritis/encephalitis – Article 14.2.2. in the case of goats.
   j) Bluetongue

   The *animals* should comply with Articles 8.3.7. or 8.3.8., depending on the bluetongue status of the country or zone of origin of the *animals*.
   k) Tuberculosis – In the case of goats, a single or comparative tuberculin test, with negative results.

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

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

   a) Caprine and ovine brucellosis – Point 1 c) of Article 14.1.8.
   b) Ovine epididymitis – Point 1 d) of Article 14.7.4.
   c) Maedi-visna and caprine arthritis/encephalitis – Test on *animals*.
   d) Bluetongue

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

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

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

   a) caprine and ovine brucellosis;
   b) ovine epididymitis;
c) Maedi-visna and caprine arthritis/encephalitis;
d) tuberculosis (for goats only);
e) bluetongue.

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

Article 4.6.4.

Conditions applicable to testing of boars

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

1. Prior to entering pre-entry isolation facility

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

a) Porcine brucellosis – Article 15.3.3.
b) Foot and mouth disease – Articles 8.6.12., 8.6.13. or 8.6.14.
c) Aujeszky’s disease – Article 8.2.9. or Article 8.2.10.
d) Transmissible gastroenteritis – Article 15.5.2.
e) Swine vesicular disease – Article 15.4.5. or Article 15.4.7.
f) African swine fever – Article 15.1.5. or Article 15.1.6.
g) Classical swine fever – Article 15.2.7. or Article 15.2.8.
h) Porcine reproductive and respiratory syndrome – Test complying with the standards in the Terrestrial Manual.

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

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

a) Porcine brucellosis – Article 15.3.5.
b) Foot and mouth disease – Articles 8.6.15., 8.6.16., 8.6.17. or 8.6.18.
c) Aujeszky’s disease – Articles 8.2.13., 8.2.14. or 8.2.15.
d) Transmissible gastroenteritis – Article 15.5.4.
e) Swine vesicular disease – Article 15.4.9. or Article 15.4.10.
f) African swine fever – Article 15.1.8. or Article 15.1.9.
g) Classical swine fever – Article 15.2.10. or Article 15.2.11.

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

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

a) Porcine brucellosis – Article 15.3.5.
b) Foot and mouth disease – Articles 8.6.15., 8.6.16., 8.6.17. or 8.6.18.
c) Aujeszky’s disease – Articles 8.2.13., 8.2.14. or 8.2.15.
d) Transmissible gastroenteritis – Article 15.5.4.
e) Swine vesicular disease – Article 15.4.9. or Article 15.4.10.
f) African swine fever – Article 15.1.8. or Article 15.1.9.
g) Classical swine fever – Article 15.2.10. or Article 15.2.11.
Article 4.6.5.

General considerations for hygienic collection and handling of semen

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

Article 4.6.6.

Conditions applicable to the collection of semen

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

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

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

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

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

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

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

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

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

Article 4.6.7.

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

1. Diluents
   a) All receptacles used should have been sterilised.
   b) Buffer solutions employed in diluents prepared on the premises should be sterilized by filtration (0.22 µm) or by autoclaving (121°C for 30 minutes) or be prepared using sterile water before adding egg yolk (if applicable) or equivalent additive and antibiotics.
   c) If the constituents of a diluent are supplied in commercially available powder form, the water used should have been distilled or demineralised, sterilized (121°C for 30 minutes or equivalent), stored correctly and allowed to cool before use.
   d) Whenever milk, egg yolk or any other animal protein is used in preparing the semen diluent, the product should be free of pathogens or sterilised; milk heat-treated at 92°C for 3–5 minutes, eggs from SPF flocks when available. When egg yolk is used, it should be separated from eggs using aseptic techniques. Alternatively, commercial egg yolk prepared for human consumption or egg yolk treated by, for example, pasteurisation or irradiation to reduce bacterial contamination, may be used. Other additives should also be sterilized before use.
   e) Diluent should not be stored for more than 72 hours at +5°C before use. A longer storage period is permissible for storage at -20°C. Storage vessels should be stoppered.
Chapter 4.6.- Collection and processing of bovine, small ruminant and porcine semen

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

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

2. Procedure for dilution and packing
   a) The tube containing freshly collected semen should be sealed as soon as possible after collection, and kept sealed until processed.
   b) After dilution and during refrigeration, the semen should also be kept in a stoppered container.
   c) During the course of filling receptacles for dispatch (such as insemination straws), the receptacles and other disposable items should be used immediately after being unpacked. Materials for repeated use should be disinfected with alcohol, ethylene oxide, steam or other approved disinfection techniques.
   d) If sealing powder is used, care should be taken to avoid its being contaminated.

3. Conditions applicable to the storage and identification of frozen semen

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

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

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

4. Sperm sorting

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

Semen straws containing sex-sorted sperm should be permanently identified as such.
CHAPTER 4.7.

COLLECTION AND PROCESSING OF IN VIVO DERIVED EMBRYOS FROM LIVESTOCK AND EQUIDS

Article 4.7.1.

Aims of control

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

Article 4.7.2.

Conditions applicable to the embryo collection team

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

1) The team should be approved by the Competent Authority.
2) The team should be supervised by a team veterinarian.
3) The team veterinarian is responsible for all team operations which include verification of donor health status, sanitary handling and surgery of donors and disinfection and hygienic procedures.
4) Team personnel should be adequately trained in the techniques and principles of disease control. High standards of hygiene should be practiced to preclude the introduction of infection.
5) The collection team should have adequate facilities and equipment for:
   a) collecting embryos;
   b) processing and treatment of embryos at a permanent site or mobile laboratory;
   c) storing embryos.
   These facilities need not necessarily be at the same location.
6) The embryo collection team should keep a record of its activities, which should be maintained for inspection by the Veterinary Authority for a period of at least two years after the embryos have been exported.
7) The embryo collection team should be subjected to regular inspection at least once a year by an Official Veterinarian to ensure compliance with procedures for the sanitary collection, processing and storage of embryos.

Article 4.7.3.

Conditions applicable to processing laboratories

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

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

Additionally:

1) The processing laboratory should be under the direct supervision of the team veterinarian and be regularly inspected by an Official Veterinarian.
Chapter 4.7.- Collection and processing of in vivo derived embryos from livestock and equids

While embryos for export are being handled prior to their storage in ampoules, vials or straws, no embryos of a lesser health status should be processed.

The processing laboratory should be protected against rodents and insects.

The processing laboratory should be constructed with materials which permit its effective cleansing and disinfection. This should be done frequently, and always before and after each occasion on which embryos for export are processed.

2) While embryos for export are being handled prior to their storage in ampoules, vials or straws, no embryos of a lesser health status should be processed.

3) The processing laboratory should be protected against rodents and insects.

4) The processing laboratory should be constructed with materials which permit its effective cleansing and disinfection. This should be done frequently, and always before and after each occasion on which embryos for export are processed.

Article 4.7.4.

Conditions applicable to the introduction of donor animals

1. Donor animals
   a) The Veterinary Authority should have knowledge of, and authority over, the herd/flock from which the donor animals have been sourced.
   b) The donor animals should not be situated in a herd/flock subject to veterinary restrictions for OIE listed disease or pathogens for relevant species (see Chapter 1.2.), other than those that are in International Embryo Transfer Society (IETS) Category 1 for the species of embryos being collected (see Article 4.7.14.).
   c) At the time of collection, the donor animals should be clinically inspected by the team veterinarian, or by a veterinarian responsible to the team veterinarian and certified to be free of clinical signs of diseases.

2. Semen donors
   a) Semen used to inseminate donor animals artificially should have been produced and processed in accordance with the provisions of Chapter 4.6.
   b) When the donor of the semen used to inseminate donor females for embryo production is dead, and when the health status of the semen donor concerning a particular infectious disease or diseases of concern was not known at the time of semen collection, additional tests may be required of the inseminated donor female after embryo collection to verify that these infectious diseases were not transmitted. An alternative may be to test an aliquot of semen from the same collection date.
   c) Where natural service or fresh semen is used, donors should meet the health conditions set out in Chapter 4.6. as appropriate to the species.

Article 4.7.5.

Risk management

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

1) The first phase, which is applicable to diseases not included in Category 1 of the IETS categorisation (Article 4.7.14.), comprises the risk potential for embryo contamination and depends on:
   a) the disease situation in the exporting country or zone;
   b) the health status of the herds or flocks and the donors from which the embryos are collected;
   c) the pathogenic characteristics of the specified disease agents that are of concern to the Veterinary Authority of the importing country.

2) The second phase covers risk mitigation by use of internationally accepted procedures for processing of embryos which are set out in the IETS Manual. These include the following:
   a) The embryos should be washed at least ten times with at least 100–fold dilutions between each wash, and a fresh pipette should be used for transferring the embryos through each wash.
   b) Only embryos from the same donor should be washed together, and no more than ten embryos should be washed at any one time.
   c) Sometimes, for example when inactivation or removal of certain viruses, such as bovine herpesvirus-1 and Aujeszky’s disease virus, is required, the standard washing procedure should be modified to include additional washes with the enzyme trypsin, as described in the IETS Manual.
   d) The zona pellucida of each embryo, after washing, should be examined over its entire surface area at not less than 50X magnification to ensure that it is intact and free of adherent material.
e) All shipments of embryos should be accompanied by a statement signed by the team veterinarian certifying that these embryo processing procedures have been completed.

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

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

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

Article 4.7.6.

Conditions applicable to the collection and storage of embryos

1. Media

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

2. Equipment

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

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

Article 4.7.7.

Optional tests and treatments

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

a) Non-viable embryos and oocytes

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

b) Embryo collection (flushing) fluids

   The collection fluid should be placed in a sterile, closed container and, if there is a large amount, it should be allowed to stand undisturbed for one hour. The supernatant fluid should then be removed and the bottom 10–20 ml, along with accumulated debris, decanted into a sterile bottle. If a filter is used in the collection of embryos and oocytes then any debris that is retained on the filter should be rinsed off into the retained fluid.

c) Washing fluids

   The last four washes of the embryos and oocytes should be pooled according to the IETS Manual.

d) Samples

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

2) When treatment of the viable embryos is modified to include additional washings with the enzyme trypsin (see point 2(c) in Article 4.7.5.), the procedure should be carried out according to the IETS Manual. Enzyme treatment is necessary only when pathogens for which the IETS recommends this additional treatment (such as with trypsin) may be present. It should be noted that such treatment is not always beneficial and it should not be regarded as a general disinfectant. It may also have adverse effects on embryo viability, for instance in the case of equine embryos where the embryonic capsule could be damaged by the enzyme.
Article 4.7.8.

Conditions applicable to the storage and transport of embryos

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

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

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

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

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

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

Article 4.7.9.

Procedure for micromanipulation

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

Article 4.7.10.

Specific conditions applicable to porcine embryos

The herd of origin should be free of clinical signs of swine vesicular disease and brucellosis.

The development of effective cryopreservation methods for the storage of zona pellucida-intact porcine embryos is still at a very early stage.

Article 4.7.11.

Specific conditions applicable to equine embryos

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

Article 4.7.12.

Specific conditions applicable to camelid embryos

South American camelid embryos recovered from the uterine cavity by the conventional non-surgical flushing technique at 6.5 to 7 days post-ovulation are almost invariably at the hatched blastocyst stage, and thus the zona pellucida has already been shed. Since the embryos do not enter the uterus and cannot be recovered before 6.5 to 7 days, it would be unrealistic to stipulate for these species that only zona pellucida-intact embryos can be used in international trade. The development of cryopreservation methods for storage of camelid embryos is still at an early stage, and also that pathogen interaction studies with camelid embryos have not yet been carried out.
Chapter 4.7. - Collection and processing of in vivo derived embryos from livestock and equids

Article 4.7.13.

Specific conditions applicable to cervid embryos

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

Article 4.7.14.

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

Based on the conclusions of the IETS, the following listed diseases and pathogenic agents are categorised into four categories, which applies only to in vivo derived embryos.

1. **Category 1**
   a) Category 1 diseases or pathogenic agents are those for which sufficient evidence has accrued to show that the risk of transmission is negligible provided that the embryos are properly handled between collection and transfer according to the IETS Manual.
   b) The following diseases or pathogenic agents are in category 1:
      - Aujeszky's disease (pigs): trypsin treatment required
      - Bluetongue (cattle)
      - Bovine spongiform encephalopathy (cattle)
      - Brucella abortus (cattle)
      - Enzootic bovine leukosis
      - Foot and mouth disease (cattle)
      - Infectious bovine rhinotracheitis: trypsin treatment required
      - Scrapie (sheep).

2. **Category 2**
   a) Category 2 diseases are those for which substantial evidence has accrued to show that the risk of transmission is negligible provided that the embryos are properly handled between collection and transfer according to the IETS Manual, but for which additional transfers are required to verify existing data.
   b) The following diseases are in category 2:
      - Bluetongue (sheep)
      - Caprine arthritis/encephalitis
      - Classical swine fever.

3. **Category 3**
   a) Category 3 diseases or pathogenic agents are those for which preliminary evidence indicates that the risk of transmission is negligible provided that the embryos are properly handled between collection and transfer according to the IETS Manual, but for which additional in vitro and in vivo experimental data are required to substantiate the preliminary findings.
   b) The following diseases or pathogenic agents are in category 3:
      - Atypical scrapie (not a listed disease)
      - Bovine immunodeficiency virus (not a listed disease)
      - Bovine spongiform encephalopathy (goats) (not a listed disease of goats)
      - Bovine viral diarrhoea virus (cattle)
      - Campylobacter fetus (sheep) (not a listed disease of sheep)
      - Foot and mouth disease (pigs, sheep and goats)
      - Haemophilus somnus (cattle) (not a listed disease)
      - Maedi-visna (sheep)
      - Mycobacterium paratuberculosis (cattle)
      - Neospora caninum (cattle) (not a listed disease)
Chapter 4.7.- Collection and processing of in vivo derived embryos from livestock and equids

– Ovine pulmonary adenomatosis (not a listed disease)
– Porcine reproductive and respiratory disease syndrome (PRRS)
– Rinderpest (cattle)
– Swine vesicular disease.

4. Category 4

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

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

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

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

– African swine fever
– Akabane (cattle) (not a listed disease)
– Bovine anaplasmosis
– Bluetongue (goats)
– Border disease (sheep) (not a listed disease)
– Bovine herpesvirus-4 (not a listed disease)
– Chlamydia psittaci (cattle, sheep)
– Contagious equine metritis
– Enterovirus (cattle, pigs) (not a listed disease)
– Equine rhinopneumonitis
– Equine viral arteritis
– Escherichia coli 09:K99 (cattle) (not a listed disease)
– Leptospira borrelii serovar hardjobovis (cattle) (not a listed disease)
– Leptospira sp. (pigs) (not a listed disease)
– Lumpy skin disease
– Mycobacterium bovis (cattle)
– Mycoplasma spp. (pigs)
– Ovine epididymitis (Brucella ovis)
– Parainfluenza-3 virus (cattle) (not a listed disease)
– Parvovirus (pigs) (not a listed disease)
– Porcine circovirus (type 2) (pigs) (not a listed disease)
– Scrapie (goats)
– Tritrichomonas foetus (cattle)
– Ureaplasma and Mycoplasma spp. (cattle, goats) (not a listed disease)
– Vesicular stomatitis (cattle, pigs).
CHAPTER 4.8.

COLLECTION AND PROCESSING OF
IN VITRO PRODUCED EMBRYOS/OOCYTES
FROM LIVESTOCK AND HORSES

Article 4.8.1.

Aims of control

Production of embryos in vitro involves the collection of oocytes from the ovaries of donors, in vitro maturation and fertilization of the oocytes, then in vitro culture to the morula/blastocyst stage at which they are ready for transfer into recipients. The purpose of official sanitary control of in vitro produced embryos intended for movement internationally is to ensure that specific pathogenic organisms, which could be associated with such embryos, are controlled and transmission of infection to recipient animals and progeny is avoided. The conditions outlined in this chapter are also applicable where the movement of in vitro maturing (IVM) oocytes is intended.

Article 4.8.2.

Conditions applicable to the embryo production team

The embryo production team is a group of competent technicians, including at least one veterinarian, to perform the collection and processing of ovaries/oocytes and the production and storage of in vitro produced embryos. The following conditions should apply:
1) The team should be approved by the Competent Authority.
2) The team should be supervised by a team veterinarian.
3) The team veterinarian is responsible for all team operations which include the hygienic collection of ovaries and oocytes and all other procedures involved in the production of embryos intended for international movement.
4) Team personnel should be adequately trained in the techniques and principles of disease control. High standards of hygiene should be practised to preclude the introduction of infection.
5) The production team should have adequate facilities and equipment for:
   a) collecting ovaries and/or oocytes;
   b) processing of oocytes and production of embryos at a permanent or mobile laboratory;
   c) storing oocytes and/or embryos.
   These facilities need not necessarily be at the same location.
6) The embryo production team should keep a record of its activities, which should be maintained for inspection by the Veterinary Authority for a period of at least two years after the embryos have been exported.
7) The embryo production team should be subjected to regular inspection at least once a year by an Official Veterinarian to ensure compliance with procedures for the sanitary collection and processing of oocytes and the production and storage of embryos.

Article 4.8.3.

Conditions applicable to the processing laboratories

A processing laboratory used by the embryo production team may be mobile or permanent. It may be contiguous with the oocyte recovery area or at a separate location. It is a facility in which oocytes which have been recovered from ovaries are then matured and fertilised, and where the resulting embryos are further cultured in vitro.

Embryos may also be subjected to any required treatments such as washing and storage and quarantine in this laboratory.
Chapter 4.8.- Collection and processing of in vitro produced embryos/oocytes from livestock and horses

Additionally:

1) The laboratory should be under the direct supervision of the team veterinarian and regularly inspected by an Official Veterinarian.

2) While embryos for export are being produced prior to their storage in ampoules, vials or straws, no oocyte/embryo of a lesser health status should be recovered or processed in the same laboratory.

3) The laboratory should be protected against rodents and insects.

4) The processing laboratory should be constructed with materials which permit its effective cleansing and disinfection. This should be done frequently and always before and after each occasion when embryos for export are processed.

Article 4.8.4.

Conditions applicable to donor animals

Oocytes for the in vitro production of embryos are obtained from donors basically in two different ways: individual collection or batch collection. The recommended conditions for these differ.

Individual collection usually involves the aspiration of oocytes from the ovaries of individual live animals on the farm where the animal resides, or at the laboratory. Occasionally oocytes may also be recovered from individual live donors by aspiration from surgically excised ovaries. When oocytes are recovered from individual live animals, the conditions for these donors should resemble those set out in Article 4.7.4.

In these cases the cleaning and sterilisation of equipment (e.g. ultrasound guided probes) is especially important and should be carried out between each donor in accordance with the recommendations in the Manual of the International Embryo Transfer Society (IETS).\(^1\)

Batch collection involves the removal of ovaries from batches of donors slaughtered at a slaughterhouse/abattoir (hereafter ‘abattoir’); these ovaries are then transported to the processing laboratory where the oocytes are recovered from the ovarian follicles by aspiration. Batch collection has the disadvantage that it is usually impractical to relate the ovaries which are transported to the laboratory to the donors which were slaughtered at the abattoir. Nevertheless, it is critical to ensure that only healthy tissues are obtained and that they are removed from the donors and transported to the laboratory in a hygienic manner.

Additionally:

1) The Veterinary Authority should have knowledge of the herd(s)/flock(s) from which the donor animals have been sourced.

2) The donor animals should not originate from herds / flocks that are subject to veterinary restrictions for foot and mouth disease, rinderpest and peste des petits ruminants, and neither should the removal of any tissue or aspiration of oocytes take place in an infected zone, or one that is subject to veterinary restrictions for those diseases.

3) In the case of oocyte recovery from live donors, post-collection surveillance of the donors and donor herd(s)/flock(s) should be conducted based on the recognized incubation periods of the diseases of concern to determine retrospectively the health status of donors.

4) In the case of oocyte recovery from batches of ovaries collected from an abattoir, the abattoir should be officially approved and under the supervision of a veterinarian whose responsibility is to ensure that ante-mortem and post-mortem inspections of potential donor animals are carried out, and to certify them to be free of clinical or pathological signs of the diseases listed in point 2.

5) Donor animals slaughtered at an abattoir should not have been designated for compulsory slaughter for a notifiable disease and should not be slaughtered at the same time as donors from which ovaries and other tissues will be removed.

6) Batches of ovaries and other tissues collected from an abattoir should not be transported to the processing laboratory before confirmation has been obtained that ante- and post-mortem inspection of donors has been satisfactorily completed.

7) Equipment for the removal and transport of ovaries and other tissues should be cleaned and sterilised before use and exclusively used for these purposes.

8) Records of the identities and origins of all donors should be maintained for inspection by the Veterinary Authority for a period of at least two years after the embryos have been exported. While this may be difficult to achieve in the case of batch collection, it is to be expected that the identities of the herds/flocks from which the donors originated will be maintained.
Optional tests and treatments

A supplementary approach for ensuring that in vitro produced embryos do not transmit disease is by testing various materials to confirm the absence of pathogenic organisms listed in point 2 of Article 4.8.4.

Tests may also be used to assess whether quality control procedures being applied in the processing laboratory are of an acceptable standard.

Tests may be carried out on the following materials:
1) non-viable oocytes/embryos from any stage of the in vitro production line from batches intended for export;
2) samples of in vitro maturation medium taken prior to mixing the oocytes with semen for the fertilisation process;
3) samples of embryo culture medium taken immediately prior to embryo storage.

These samples should be stored at 4°C and tested within 24 hours. If this is not possible, then the samples should be stored frozen at minus 70°C or lower.

Additionally:
1) Semen used to fertilise oocytes in vitro should meet the health requirements and standards set out in Chapter 4.6. as appropriate to the species. When the donor of the semen used to fertilise the oocytes is dead, and when the health status of the semen donor concerning a particular infectious disease or diseases of concern was not known at the time of semen collection, additional tests on the spare embryos may be required to verify that these infectious diseases were not transmitted. An alternative may be to test an aliquot of semen from the same collection date.
2) Any biological product of animal origin, including co-culture cells and media constituents, used in oocyte recovery, maturation, fertilisation, culture, washing and storage should be free of living pathogens. Media should be sterilised prior to use by approved methods according to the IETS Manual and handled in such a manner as to ensure that sterility is maintained. Antibiotics should be added to all fluids and media as recommended in the IETS Manual.
3) All equipment used to recover, handle, culture, wash, freeze and store oocytes/embryos should be new or cleaned and sterilised prior to use as recommended in the IETS Manual.

Risk management

With regard to disease transmission, transfer of in vitro produced embryos is a low risk method for moving animal genetic material although the risk is not quite as low as for in vivo derived embryos. It should be noted that categorisation of diseases/disease agents by the IETS, as described for in vivo derived embryos in Article 4.7.14., does not apply in the case of in vitro produced embryos. Irrespective of the animal species, there are three phases in the embryo production and transfer process that determine the final level of risk. These are as follows:
1) the first phase comprises the risk potential for ovary/oocyte/embryo contamination and depends on:
   a) the disease situation in the exporting country and/or zone;
   b) the health status of the herds/flocks and the donors from which the ovaries/oocytes/embryos are collected;
   c) the pathogenic characteristics of the specified disease agents listed in point 2 of Article 4.8.4.;
2) the second phase covers risk mitigation by the use of internationally accepted procedures for the processing of embryos which are set out in the IETS Manual. These include the following:
   a) after the in vitro culture period is finished the embryos should be washed at least ten times with at least 100–fold dilutions between each wash, and a fresh pipette should be used for transferring the embryos through each wash;
   b) only embryos from the same donor (in the case of individual collection) or from the same batch (in the case of batch collection) should be washed together, and no more than ten embryos should be washed at any one time;
   c) sometimes, for example when inactivation or removal of certain viruses (e.g. bovine herpesvirus-1, or Aujeszky’s disease virus) is required, the standard washing procedure should be modified to include additional washes with the enzyme trypsin, as described in the IETS Manual;
   d) the zona pellucida of each embryo, after washing, should be examined over its entire surface area at not less than 50X magnification to ensure that it is intact and free of adherent material;
Chapter 4.8. - Collection and processing of in vitro produced embryos/oocytes from livestock and horses

3) the third phase, which is applicable to diseases listed in point 2 of Article 4.8.4. encompasses the risk reductions resulting from:
   a) post-collection surveillance of the donors and donor herds/flocks based on the recognised incubation periods of the diseases of concern to determine retrospectively the health status of the donors whilst the embryos are stored (in species where effective storage by cryopreservation is possible) in the exporting country. Post-collection surveillance of donors is not, of course, possible in the case of batch collection from an abattoir, although surveillance of the herds/flocks of origin may be possible;
   b) testing of oocytes/embryos, co-culture cells, media and other samples (e.g. blood) (as referred to in Article 4.8.5.) in a laboratory for presence of disease agents.

Article 4.8.7.

Conditions applicable to the storage and transport of embryos

1) Only embryos from the same individual donor or from the same batch collection should be stored together in the same ampoule, vial or straw.
2) The embryos should if possible, depending on the species, be frozen in fresh liquid nitrogen or other cryoprotectant and then stored in fresh cryoprotectant in cleaned and sterilised tanks or containers under strict hygienic conditions at a storage place.
3) Ampoules, vials or straws should be sealed at the time of freezing and should be labelled according to the IETS Manual1.
4) Liquid nitrogen containers should be sealed prior to shipment from the exporting country.
5) Embryos should not be exported until the appropriate veterinary certificates are completed.

Article 4.8.8.

Procedure for micromanipulation

When micromanipulation of the embryos is to be carried out, this should be done after completion of the treatments described in point 2 of Article 4.8.6. and conducted in accordance with Chapter 4.9.

CHAPTER 4.9.

COLLECTION AND PROCESSING OF MICROMANIPULATED EMBRYOS/OOCYTES FROM LIVESTOCK AND HORSES

Article 4.9.1.

Introduction

Neither Chapter 4.7, which recommends official sanitary control measures for the international movement of in vivo derived embryos nor Chapter 4.8, which recommends measures for in vitro produced embryos/in vitro maturing oocytes covers embryos which have been subjected to biopsy, splitting, transgene injection, intracytoplasmic sperm injection (ICSI), nuclear transfer or other interventions which breach the integrity of the zona pellucida. Such embryos/oocytes are those referred to here as having been ‘micromanipulated’.

It should be noted that complete removal of granulosa cells or other adherent material from the outer surface of the zona pellucida of oocytes, zygotes and embryos is necessary prior to micromanipulation to avoid lowering their health status.

Removal of such material from the zona pellucida of immature oocytes can be difficult. However, to bring micromanipulated embryos/oocytes within the scope of the above mentioned chapters, the following conditions should apply.

Article 4.9.2.

1) Prior to any micromanipulation which involves breaching the zona pellucida, all embryos/oocytes should be collected and processed according to the sanitary conditions laid down in Chapter 4.7. (in vivo derived embryos), or produced according to the sanitary conditions laid down in Chapter 4.8. (in vitro produced embryos/oocytes).

2) Responsibility for the embryos/oocytes remains with the embryo collection team (in vivo derived embryos) or with the embryo production team (in vitro produced embryos), and all processing involving micromanipulation should be carried out in an approved processing laboratory under supervision of an approved team veterinarian (see Articles 4.7.2. and 4.7.3., and Articles 4.8.2. and 4.8.3., as appropriate).

3) Donor animals should comply with the conditions laid down in Article 4.7.4. (in vivo derived embryos) or Article 4.8.4. (in vitro produced embryos), whichever is appropriate. Risk management and criteria for testing samples to ensure that embryos are free of pathogenic organisms are laid down in Articles 4.7.5. and Article 4.7.7. and in Articles 4.8.5. and 4.8.6. respectively, and these should be followed.

4) All embryos to be micromanipulated should be washed according to the protocols laid down in the IETS Manual¹ and they should be observed to have an intact zona pellucida before and after washing. Only embryos from the same donor, or, in the case of some in vitro produced embryos, embryos originating from the same batch of ovaries from an abattoir (see Chapter 4.8.), should be washed together at the same time. After washing, but before micromanipulation, the zona pellucida of each embryo should be examined over its entire surface area at not less than 50X magnification and certified to be intact and free of adherent material.

5) If surrogate zonae are used, they should be from the same species and the embryos/oocytes from which they are obtained should be treated in the same manner as if they were in vivo derived or in vitro produced embryos intended for international movement.

Article 4.9.3.

Procedures for micromanipulation

The term ‘micromanipulation’ covers several different procedures and a variety of specialised microsurgical instruments and other equipment may be used. However, from the standpoint of animal health, any cutting, penetrating or breaching of the integrity of the zona pellucida is an action that can alter the health status of an embryo. To maintain health status during and after micromanipulation, the following conditions should apply:
1. **Media**

Any product of animal origin, including co-culture cells and media constituents, used in the collection or production of embryos, oocytes or other cells, and in their micromanipulation, culture, washing and storage should be free of pathogenic micro-organisms (including transmissible spongiform encephalopathy agents, sometimes called prions). All media and solutions should be sterilized by approved methods according to the IETS Manual and handled in such a manner as to ensure that sterility is maintained. Antibiotics should be added to all fluids and media as recommended in the IETS Manual.

2. **Equipment**

Equipment (e.g. microsurgical instruments which have direct contact with embryos) should either be of the single-use type (disposed of after each embryo/oocytes batch) or should be effectively sterilised between embryos/oocytes batch in accordance with recommendations in the IETS Manual.

3. **Nuclei for transplantation (‘nuclear transfer’)**

a) Where it is intended to transplant nuclei derived from pre-hatching stage (i.e. zona pellucida intact) embryos, the parent embryos from which those nuclei are derived should fulfil the conditions of this chapter. Where nuclei derived from other types of donor cell (e.g. post-hatching stage embryos, embryonic, fetal and adult cells, including spermatozoa/spermatids for ICSI) are to be transplanted, the parent embryo, fetus or animal from which those donor cells originate, and the methods whereby they are derived, including cell culture, should comply with the relevant animal health standards recommended elsewhere in this Terrestrial Code and in the Terrestrial Manual.

b) Where it is intended to transplant a nucleus into an intact oocyte (e.g. for ICSI), or into an enucleated oocyte (for nuclear transfer), those oocytes should be collected, cultured and manipulated according to the recommendations in this chapter.

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**Optional tests and treatments**

The importing country may request that tests be carried out on certain samples or that embryos be treated to ensure that specified pathogenic organisms are absent.

1. **Samples**

Samples to be tested may include those referred to in Article 4.7.7. and/or in Article 4.8.5. Where cells other than from zona pellucida-intact embryos (e.g. somatic or sperm cells) are used as donors of nuclei for transplantation, then samples or cultures of those donor cells may also be tested.

2. **Treatments**

Treatments of embryos with the enzyme trypsin or other substances proven to inactivate or remove pathogenic organisms may be requested when pathogens that are not removed by washing may be present. If used, such treatments should also be applied prior to any micromanipulation, and according to the IETS Manual.

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**Conditions applicable to storage, quarantine and transport**

Micromanipulated embryos should be stored, quarantined and transported according to the conditions laid down in Article 4.7.8. or in Article 4.8.7. as appropriate. Veterinary certification documents should identify all micromanipulations, where and when they were carried out.

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CHAPTER 4.10.

COLLECTION AND PROCESSING OF LABORATORY RODENT AND RABBIT EMBRYOS/OVA

Microbial status of laboratory animal colonies

Colonies of the various species and genotypes of laboratory animals are usually kept within specialised premises and their microbial status depends largely on the system whereby the colony was formed and is maintained. In this chapter the microbial status of colonies is considered to be of three main types: 'defined', 'conventional' and 'undefined'. Colonies of defined status are those where, at least initially, the animals are totally free of pathogenic and non-pathogenic micro-organisms (i.e. gnotobiotic), although sometimes a cocktail of known, non-pathogenic micro-organisms has been given subsequently. In either case defined colonies are kept in highly controlled environments in barrier maintained rooms, with strict protocols in place to exclude all potential sources of unwanted microbiological contamination. Colonies of conventional status are those where the animals are kept in closed colonies but where known ('specific') pathogens as well as non-pathogenic micro-organisms may exist. While management protocols for conventional colonies may be less rigid than those for defined colonies, they are designed to control potential sources of microbial contamination. Simple aseptic precautions (e.g. the autoclaving of food and bedding) are taken to ensure that the animals do not become infected with any unwanted microflora. Finally, laboratory animals may be kept in microbiologically undefined colonies which are unrestricted and may include free ranging animals. Details of these different types of colony can be found in the FELASA Report.

The health status of defined and conventional colonies should be confirmed at least quarterly by bacteriological, virological, parasitological, serological and other tests on pre-designated sentinel animals or other representative members of the colony. Older breeding males which have sired multiple litters are often selected for this purpose.

The purpose of official sanitary control of laboratory rodent and rabbit embryos intended for movement internationally is to ensure that specific pathogenic micro-organisms, which could be associated with such embryos, are controlled and transmission of infection to recipient animals, progeny and colonies, is avoided. Requirements for the management of donors and processing of embryos vary depending on the microbial status of the colony, i.e. whether it is defined (including gnotobiotic), conventional, or undefined.

Conditions applicable to the embryo collection team

The embryo collection team is a group of competent technicians including at least one experienced professional to perform the collection, processing and storage of embryos/oocytes.

The following conditions should apply:
1) The team should be supervised by a team professional.
2) The team professional is responsible for all team operations which include verification of colony and donor health status, sanitary handling and surgery of donors, disinfection and hygienic procedures. The team professional should be responsible to the institute veterinarian.
3) The institute veterinarian should be certified or accredited in laboratory animal care and should be specifically approved for the purpose of embryo collection for export. It is the responsibility of the institute veterinarian to ensure that required health profiling procedures appropriate for the colony status are implemented. He/she is responsible for certifying that the embryo handling procedures and laboratory facilities conform to the requirements laid down in this chapter.
4) Team personnel should be adequately trained in the techniques and principles of disease control and in the use of aseptic techniques in embryo handling. The zoonotic potential of specific pathogens affecting the various laboratory animal species should be identified and understood so as to avoid contamination of colonies via human vectors, and vice versa.
5) High standards of hygiene should be practiced to preclude the introduction of infection to the donor animals, colonies, facilities, and equipment. Restrictions should be established to prevent free access of personnel into the embryo collection and handling facilities especially after such personnel have been exposed to other animal facilities.

6) The team should have adequate facilities and equipment for:
   a) collecting embryos;
   b) processing and treatment of embryos at a permanent or mobile laboratory;
   c) storing embryos.

7) It is the responsibility of the institute veterinarian to ensure that complete animal and embryo records, including records of collection, processing and storage of embryos are maintained. Record sheets of the type shown in the IETS Manual for livestock species should be used where applicable, and data such as genotypic identification of the donors, embryo quality grading, morphological stage and should be given. The embryo collection team should keep a record of its activities which should be maintained for inspection by the Veterinary Authority for at least two years after the embryos have been exported.

8) The embryo collection team, if involved in the export of embryos, should be approved by the Competent Authority and be subject to regular inspection by an Official Veterinarian to ensure compliance with procedures for the sanitary collection, processing and storage of embryos.

Article 4.10.3.

Conditions applicable to the processing laboratory

A processing laboratory used by the embryo collection team is a facility in which embryos are recovered from donors (or from their excised reproductive tracts), and from the collection media. Here also the embryos are examined and subjected to any required treatments such as washing, cryopreservation for storage and quarantine pending results of any diagnostic procedures. The processing laboratory may be part of a specifically designed collection and processing unit, or a suitably adapted part of an existing building. It may be on the premises where the donor animals are kept but in this case should be physically separated from animals.

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

Article 4.10.4.

Risk management

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

1) The first phase comprises the risk potential for embryo contamination and depends on:
   a) the disease situation in the exporting country and/or zone;
   b) the microbial status of the colony (i.e. defined, conventional or undefined) and the donors from which the embryos are collected;
   c) the pathogenic characteristics of the specified disease agents that are of concern to the Veterinary Authority of the importing country.

2) The second phase covers risk mitigation by use of internationally accepted procedures for processing of embryos which are set out in the IETS Manual. These include the following:
   a) Depending on microbial status of the colony, the embryos should be washed up to ten times with at least 100-fold dilutions between each wash, with a fresh pipette being used for transferring the embryos through each wash.
Chapter 4.10.- Collection and processing of laboratory rodent and rabbit embryos/ova

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

c) Sometimes, for example when removal of certain viruses (e.g. herpesviruses) is required, the standard washing procedure should be modified to include additional washes with the enzyme trypsin, as described in the IETS Manual2.

d) The zona pellucida of each embryo, after washing, should be examined over its entire surface area at not less than 50X magnification to ensure that it is intact and (apart from the mucin layer in the case of rabbit embryos) free of adherent material.

3) The third phase, which is applicable to diseases of concern to the Veterinary Authority of the importing country, encompasses risk mitigation resulting from:

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

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

Article 4.10.5.

Conditions applicable to the embryo team/institute veterinarian

1) It is the responsibility of the institute veterinarian to ensure that required health testing procedures are implemented to demonstrate microbial status of the colony (i.e. defined, conventional or undefined). Colony microbial status should be reviewed by the institute veterinarian before shipment of the embryos.

2) The veterinarian is responsible for certifying that the embryo handling procedures and laboratory conditions were maintained in accordance with Articles 4.10.2. and 4.10.3.

3) The veterinarian is responsible for the risk management procedures outlined in Article 4.10.4.

4) The veterinarian should authorise all embryo shipments, ensuring that the correct embryo collection records and veterinary certification documents have been completed and are included in the shipments.

Article 4.10.6.

Conditions applicable to donors from animal colonies of different microbial status

It should be noted that the conditions applicable to donor animals vary according to the microbial status of the colony from which they originate, i.e. defined, conventional or undefined.

Sentinel animals in each donor colony of defined and conventional status should be subjected to routine microbial screening, preferably monthly, but at least quarterly. Testing for specific pathogens depends on the animal species and may be influenced by geographical location. Recommendations regarding specific microbial agents to be tested for in different laboratory animal species have been published elsewhere1.

1. Defined microbial status
   a) Microbiologically defined colonies (Article 4.10.1.) represent the cleanest sources of gametes, and the embryos recovered from these animals can be regarded as pathogen free.
   b) Since the male and female donors are pathogen free, dissection of the female reproductive tract and embryo collection procedures should be performed under aseptic laboratory conditions, using a biological safety cabinet if appropriate.
   c) Embryo washed as described in point 2 of Article 4.10.4. is not necessary but it is recommended that embryos are washed two or three times. In each wash, embryos should be gently agitated in the medium.
   d) The embryos should be recorded as coming from a germfree or microbiologically defined, barrier maintained colony, thus indicating that special risk management procedures (Article 4.10.4.) for pathogen removal are not necessary. The need to quarantine the embryo recipients is a matter for the importing institute.

2. Conventional conditions
   a) Colonies of conventional microbial status are usually closed and their health status is routinely monitored (Article 4.10.1.). The animals may have been exposed to various pathogens, resulting in infection, with
positive antibody titres or even active clinical disease, but the pathogen(s) of concern in each individual colony should be well known.

b) Reproductive tracts (uteri, oviducts and/or ovaries) should be removed at a separate site and then taken into the embryo processing laboratory. These procedures should be performed by different technicians or, at the minimum, their protective clothing should be changed between locations. If animals should be handled in the laboratory, the tracts should be dissected out within a biological safety cabinet. This will help protect against the possible shedding of pathogens into the laboratory itself.

c) Once the reproductive tracts have been removed, embryo recovery should be performed under aseptic conditions. Depending on which, if any, pathogens are known to occur in the colony, embryos should be processed according to the risk management procedures, including washing, as described in Article 4.10.4., and in the IETS Manual2.

d) Embryos derived from animals that have positive antibody titres or other evidence of specific pathogens should only be transferred into a new colony via a quarantine system, using microbiologically defined recipient females. Quarantine may also be appropriate if there is any uncertainty about the microbial status of the donor colony or the donors. In situations where the embryos could have been exposed to bacterial infection, they should be cultured in a medium containing appropriate antibiotic for 24 h before cryopreservation, or in the interval between thawing and transfer into recipients.

e) If the recipient institution does decide to quarantine the recipient dam and offspring until their health status is confirmed, the recipients should be tested post-weaning for pathogens of concern, and introduction of offspring into the colony should only take place if the test results are satisfactory.

3. Undefined microbial conditions

a) Embryos from free ranging animals or from colonies of unknown health status require the full range of risk management procedures that are described in Article 4.10.4. and in the IETS Manual2. The procedures resemble those used for embryos of livestock as recommended in Chapters 4.7. and 4.8. of this Terrestrial Code. Ideally, the breeder males and donor females should be separated from other animals and tested 15 days before and on the day of breeding (for males) or at embryo collection (for females). Alternatively, the animals could be incorporated into a conventional colony, where, over time, a health history can be documented to reduce the strict monitoring and embryo handling requirements.

b) Biological safety cabinet should be used for handling donors and reproductive tissues, and for processing embryos.

c) Post-mortem testing of the donor females for diseases or pathogens of concern to the importing country may be appropriate after the embryos/oocytes have been collected. Alternatively if embryos are collected surgically an aliquot of flush fluid from each donor, or a pooled sample, should be tested for the presence of specific pathogens of concern.

d) Embryos should be washed at least ten times in accordance with the protocols in the IETS Manual2 and trypsin treatment should be used if presence of certain pathogenic herpesviruses is of concern.

e) Cryopreserved embryos should be stored in the exporting laboratory until such time as the necessary disease screening of colonies, tissues or fluids is completed and the supporting documents for certification completed and signed by the institute veterinarian.

f) On arrival in the importing country the embryos should be transferred into recipients in a quarantine system. Recipients should be tested at intervals appropriate to recognized incubation periods of the diseases of concern. In addition to testing recipients after transfer, the offspring should be tested at 12 weeks of age and before their introduction into breeding colonies outside the quarantine facility.

Article 4.10.7.

Conditions applicable to the storage and transport of embryos

1) Embryos for export should be frozen in fresh liquid nitrogen and then stored in fresh liquid nitrogen in cleaned and disinfected tanks or containers.

2) The embryos should be stored in sealed sterile ampoules, vials or straws under strict hygienic conditions at a storage place approved by the Veterinary Authority of the exporting country. Only embryos from the same donor should be stored together in the same ampoule, vial or straw.

3) Ampoules, vials or straws should be sealed at the time of freezing (or prior to export where cryopreservation is not possible) and they should be clearly identified according to or similar to the system recommended in the IETS Manual2. Identification should include details of the species/genotype of the donors, microbial status (e.g. defined, conventional or undefined), collection/cryopreservation date, number and developmental stage of the embryos, container number and details of any specialized procedure such as in vitro fertilization, micromanipulation.
4) Liquid nitrogen storage containers should be sealed under the supervision of the Official Veterinarian prior to shipment from the exporting country.

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

Article 4.10.8.

Procedures for in vitro fertilization and micromanipulation

If embryos are to be produced by in vitro fertilization of oocytes, it is advised that the washed sperm should be used so as to minimize the risk of possible pathogen exposure. If embryos are to undergo micromanipulation procedures that involve penetration of the zona pellucida, any required risk management steps (including washing) should be carried out first, as described in Chapter 4.9.


CHAPTER 4.11.

SOMATIC CELL NUCLEAR TRANSFER IN
PRODUCTION LIVESTOCK AND HORSES

Article 4.11.1.

Preface

Following the first meeting of the OIE ad hoc Group on Biotechnology held from 3 to 5 April 2006, the OIE Biological Standards Commission suggested restricting the mandate “to develop recommendations on the animal health risks arising from somatic cell nuclear transfer (SCNT) cloning of production animals, including criteria for assessing the health of embryos and animals derived from such cloning.” The following Articles are a starting point for identifying, characterising and providing a basis for discussion on the animal health risks associated with SCNT cloning technology.

Article 4.11.2.

Overview

At the first meeting of the ad hoc Group on Biotechnology, it was recommended that the Subgroup on Reproductive Animal Biotechnologies should draft recommendations on risk analysis, based on the life-cycle approach, for biotechnology-derived animals. The definition of ‘Reproductive Animal Biotechnology’ was proposed as “the generation of animals through the use of assisted reproductive technologies, which range from artificial insemination through to technologies involving a significant in-vitro component, such as in vitro fertilisation, embryo transfer, embryo splitting and including asexual reproduction such as nuclear transfer”. The following recommendations are restricted to SCNT and are based on a risk analysis approach to biotechnology-derived animals categorised according to the life-cycle approach consisting of: i) embryos, ii) recipients, iii) offspring, and iv) progeny of animal clones.

Article 4.11.3.

Scope

These recommendations address animal health aspects of production animals derived from some reproductive biotechnologies.

Recognising the mandate of the OIE and the suggestion of the OIE Biological Standards Commission, it is the recommendation of the ad hoc Group on Biotechnology to identify risk analysis parameters for animal health and their implication for environmental safety and food and feed safety. These recommendations will focus initially on the scientific basis for the risk assessment aspects, prevention measures and guidance for production livestock and horses derived from SCNT cloning. This is without prejudice to the addition of any relevant issue at a later stage. At present, these recommendations include the following:

- identification of animal health risks and recommendations for management of those risks in embryos, recipients, animal clones and progeny of clones;
- risk and prevention measures related with SCNT cloning technology;
- some welfare issues related to animal health.

Recognising further that the following issues have been discussed or may be addressed by other bodies or instruments, or that they may be addressed at a later stage by the OIE, the document does not address:

- safety and nutritional aspects of food derived from assisted reproductive technologies, for example transgenics (addressed by Codex);
- risks related to the environmental release of animal clones;
- risks related to transgenic animals that have not involved SCNT or other cloning technology;
- non-reproductive animal biotechnologies;
– risks related to animals produced for xenotransplantation or organ donors;
– technologies related to stem cells;
– risks related to aquatic animal health, including fish clones;
– risks related to other terrestrial animals, such as wild mammals and non-mammals, including avian species and insects.

Article 4.11.4.

Background: risk analysis – general principles

1) Risk analysis in general includes hazard identification, risk assessment, risk management and risk communication. The risk assessment is the component of the analysis that estimates the risks associated with a hazard (see Chapter 2.1.). These principles are routinely used by regulators in making decisions about experimental or commercial releases. These analyses can then be used to determine whether the outcomes require management or regulation. Risk management is the process by which risk managers evaluate alternative actions or policies in response to the result(s) of the risk assessment taking into consideration the various social, economic, and legal considerations that form the environment in which such activities occur.

2) For animal diseases, particularly those listed in the Terrestrial Code, there is broad agreement concerning the likely risks and risks can be qualitative or quantitative (see Chapter 2.1.). In disease scenarios it is more likely that a qualitative risk assessment is all that is required. Qualitative assessments do not require mathematical modelling to carry out routine decision-making. Quantitative or semi-quantitative risk assessments assign magnitudes to the risks in numerical (e.g. 1/1,000,000) or descriptive (high/medium/low) terms.

3) In the context of animal cloning, two broad categories of risk assessments are considered: absolute risk assessment and comparative risk assessments. Absolute risk assessments characterise risk independent of a comparator (e.g. the likelihood of an animal transmitting a specific livestock disease). A comparative risk assessment (or relative risk assessment) puts the risk in the context of a comparator. For example the degree to which an animal produced by one reproductive technology can transmit a particular disease to another animal of the same species compared with the degree to which a similar animal produced by another reproductive technology transmits the same disease to another animal of same species.

4) Regardless of the methodology used, hazard identification is an early step in all science-based risk assessments. In the context of assessing the risks associated with animal cloning (SCNT) and starting with the embryo and moving on through animal clone development and subsequent progeny, it is important to be clear at this juncture that only a comparative semi-quantitative risk assessment can be completed. A systematic, absolute, quantitative risk assessment of potential risks is difficult, due to the relative newness of the technology, and the variability in outcomes among laboratories and species cloned. Furthermore, with the technology of SCNT there is no introduced hazard from the insertion of novel genes (which may potentially happen in transgenesis). Thus, to analyse what factors contribute to animal health risks, the existing baseline must be analysed.

5) In short, the specific points where the risk assessment needs to be focused need to be identified. As illustrated in the accompanying diagram – the focus is to look at the basics of creating an embryo – using current terminology, starting from the selection of donor of oocyte and the cells to the creation of an embryo by the cloning methodology. The second phase will focus on the recipient of the embryo clone and the animal health and care considerations for the animals. The actual embryo clone that is born as an offspring is the third part of the paradigm that needs clear recommendations for assessment, and the next generation, either the progeny of the animal clone (which is a result of normal sexual reproduction) or animals produced by recloning (clones of clones) is the fourth and final stage.

Article 4.11.5.

Managing animal health risks associated with embryos

Embryo production by in vitro techniques has been applied for many years. Although the additional steps involved in cloning add a new dimension to this procedure, many of the risks associated with SCNT have previously been identified
Chapter 4.11. - Somatic cell nuclear transfer in production livestock and horses

for established animal reproductive biotechnologies (see Chapter 4.8.). An analysis of SCNT methodology allows the procedural details to be categorised into:

1) Oocytes (obtained from the abattoir, recovered from trans-vaginal ultrasound-guided procedures or by laparotomy procedures)

Ovaries which are collected at an abattoir should be collected, transported and processed according to the recommendations laid down in Chapter 4.8.

The primary risks are associated with the health status of the animal from which the ovaries are harvested and the quality of the oocytes.

2) Donor cells (cells obtained from animals chosen to be cloned – by biopsy, harvesting at slaughter or after death)

Currently there are no specific new risks identified with SCNT cloning. There is a proposed risk related to activation of endogenous retroviruses during cell transfer procedures, however, this may be more theoretical than practical. In some current experimental procedures, the donor cell may be treated with chemicals to modify its composition, for example cell cycle inhibitors or chromatin modifiers.

3) In vitro culture of reconstructed embryos (procedure used to fuse the donor and recipient material and to culture the reconstructed embryo)

4) Risks associated with the method of fusing donor cells with enucleated recipient oocytes and with culture conditions.

In addition, the practitioner should ensure that the clone pregnancy is compatible to the surrogate dam’s breed, anatomy and physiology.

1. Oocytes

The laboratory or the producer should establish a detailed record of ovaries – their origin, health of the animal from which the ovaries are obtained, details of any systemic lesion on the animal and proper herd data. This is particularly useful where the pooling of ovaries may provide cross-contamination of ovarian tissue.

Follicular fluids may carry various infectious agents like bovine viral diarrhoea virus (BVDV) and can contaminate pooled follicular fluid from healthy animals. Furthermore, the technique for collecting oocytes, such as aspiration or slicing of the ovarian follicles, determines the extent of blood contamination or extraneous material. A representative sample to demonstrate the absence of infectious biological material should be done with each pooled batch.

Oocytes are matured as cumulus oocyte complexes (COCs) and then matured in most instances in the culture/maturation media. Care and efforts should be taken to carefully select and mature the oocytes from the pools that are morphologically good; also the media used should have been quality tested. Use of serum or protein components from an undefined or untested source should be avoided. Addition of proper and safe antibiotics in the culture media to control opportunistic bacteria should be encouraged.

Use of proper sanitary and disinfection procedures is of utmost importance and should be emphasised in any in vitro fertilisation (IVF) laboratory. Proper handling and following sanitary protocols during the maturation and further culture of embryos should be encouraged.

2. Donor cells

In order to minimise risks:

- Donor cells should be properly harvested from the animal and cultured under proper sanitary conditions using good laboratory practices.

- When applicable, the passaging of the cells used for the cloning procedure should be documented and at different stage sampling may be warranted to look at the chromosomal component of the cell lines. If possible, procedures should be in place for regular sampling of the cells for morphological and other characteristics.

- Master cell lines (to be used for cloning at a later stage) should be stored under conditions found to be optimal for maintaining viability. Freedom from extraneous agents should be established by testing for bacteria, fungi, mycoplasmas or viruses, using appropriate tests (see Manual of the International Embryo Transfer Society [IETS]).
3. Cloning procedures/reconstruction
The cloning procedure that employs the use of chemicals or other reagents should be carefully evaluated, in terms
of the quality of embryos and overall efficiency.

During the fusion of recipient and donor material by chemical or physical means care and control should be
employed. The optimisation of the procedure based on the laboratory protocols or published reports should be
determined to avoid early embryonic mortalities.

If co-culture of the cell is used for the culture procedure after reconstruction of embryos, proper screening of the
co-culture cells should be done. A sample of each batch may be tested for the bacterial, fungal, mycoplasmal or
viral component.

Embryos should be cultured and harvested for an appropriate time and stage to transfer them or to cryo-preserve
them for later use. Proper procedures based on the international standards (IETS Codes of Practice) for washing
and preservation of the embryos should be followed.

Care should be taken with regard to grading the embryos before transfer (see Chapters 4.7. and 4.8.).

Article 4.11.6.

Managing animal health risks related to the recipients (surrogate dams)

1. Animal health risks to the surrogate dams
Currently, when compared with in vitro produced embryos, SCNT has a higher rate of pregnancy failure and, in
some species, placental abnormalities. Loss due to defects in the embryo or failure to implant in the uterus of the
surrogate dam does not pose a hazard to the dam. Rather, the surrogate dam simply resorbs any embryonic tissue
and returns to cycling. Mid- and late-term spontaneous abortions may be hazardous to surrogates if they are unable
to expel the fetus and its associated membranes. Most abortions in natural service and artificial insemination (AI)
pregnancies in cattle remain undiagnosed due to the expense of laboratory work and the low profit margin in both
the beef and dairy industry. Producers and veterinarians become concerned when the rate of abortion exceeds
3–5 percent in a herd. The same potential impact of external influences should be considered with pregnancy
evaluation with SCNT and other reproductive technologies. Disease, under-nutrition, and severe environmental
conditions are stressors known to interfere with animal fertility and embryo survival. Under these circumstances,
the risk to the pregnancy is directly related to stress factors and not to the technology used.

To date, a species-specific effect has been seen. Abnormalities in clones may result from incomplete
reprogramming of the donor nucleus. Epigenetic reprogramming occurs at different times in embryos in different
species. Many of the abnormalities reported in cattle and sheep pregnancies have not been noted in goats or swine
carrying SCNT clones. The amount of in vitro manipulation of an embryo inversely correlates to the chances for
successful pregnancy outcomes. This has been observed in both SCNT embryos and in vitro produced fertilised
embryos. Unlike other forms of other reproductive technologies SCNT pregnancy losses occur at all stages of
gestation in cattle. Clone pregnancies have been lost during the second and third trimesters and have been
accompanied by reports of hydrops, enlarged umbilicus, and abnormal placentation.

2. Animal health risks posed by the surrogate dam to the clone embryos
No new animal health risks have been identified for the developing clone fetus from the surrogate dam compared
with conventional pregnancies. The latter include vertically transmitted diseases and abnormalities due to
metabolic or physiological stress.

With respect to the animal health risks associated with the surrogate dam, it is difficult to document the relative
frequency of early stage losses of SCNT embryos compared with early stage losses of other pregnancies as these
abortions are not typically diagnosed with other reproductive technologies. Additionally, external stressors will
similarly impact SCNT pregnancies.

Veterinarians should monitor the progress of pregnancy as the common gestational anomalies seen in other
assisted reproductive technologies may be exhibited and diagnosed during the physical examination. A database
of commonly encountered problems in clone pregnancies would be useful if available to animal health experts.

– Care should be taken to assess the general health of the recipient dam before selection to carry the embryo
clones. The general health status of the recipient should be determined in terms of freedom from infection and
disease, proper vaccination and follow-up, and, if applicable, proof of earlier uneventful pregnancies, absence of
birthing problems, and proper post-pregnancy recovery.

– Pregnancy loss is greatest with SCNT embryos prior to 60 days’ gestation in cattle. This is similar to the
pattern seen with other reproductive technologies. However, in clones, high pregnancy losses during this time
of placental formation (between 45–60 days) suggest that embryonic death may be a consequence of faulty
placentation. Abnormal placentation may lead to a build up of wastes in the fetus and associated membranes,
or inadequate transfer of nutrients and oxygen from the dam to the fetus. Care should be taken to monitor the recipient dam during pregnancy. Once the pregnancy is established and confirmed, regular veterinary assessments and monitoring of animal health status is desirable up to the birth of the offspring.

- To ensure that the recipient is pregnant and to monitor its health during the first trimester, it is useful to perform ultrasonographic assessments, determine hormonal profiles and assess the general physiological parameters. Based on these profiles, proper attention should be paid to aid in the proper establishment of pregnancy by providing proper husbandry conditions and nutrition.

- The animals should be observed carefully for the signs of labour nearing the time of birth. In some species, one of the more common problems is uterine inertia and the absence of contractions. The absence of contractions may result in prolonged pregnancies with associated sequellae that may require assistance with deliveries.

- A surgical intervention should be decided and should be available for the near term animal if the situation so warrants. Proper procedures should be employed to ascertain the proper handling of the offspring and the surrogate dam.

- Health concerns may arise as a result of surgical procedures, excessive traction, or other complications such as retained fetal membranes. In these cases post-partum care may be necessary.

3. Managing animal health risks of animal clones

The health problems of individual clones can be observed in utero and post-partum. These appear to be the same as observed in other assisted reproductive technologies, but they may be more common in clones. It is important to determine whether the abnormalities are of genetic or epigenetic origin. Large offspring syndrome (LOS), probably in relation to placental abnormalities rather than fetal abnormalities, have been particularly observed in cloned sheep and cattle following suboptimal in vitro handling. These abnormalities are becoming less frequent in small ruminants.

- Appropriate husbandry practices are important to the health of animal clones. Care should be taken to provide colostrums and a clean and hygienic environment, supervision for the first few weeks after birth should be practiced.

- The animal clones must be checked routinely for the most common phenotypic anomalies, such as atresia ani, umbilical hernia, flexor muscle contractions, respiratory or cardiac insufficiency, and failure to suckle. This will allow proper treatment and care of the newborn and increase the survival of the young one.

- To consolidate current understanding of the health status of animal clones, a comprehensive veterinary examination should be performed to monitor the progress of the clone, as unexplained fatalities or fatalities arising from systemic complications have been reported. It is encouraged to follow the health profile of the animals to at least the reproductive maturity stage, and to record the ability to reproduce (fertility index).

- Animal welfare concerns ranging from LOS to serious abnormalities are notable in the debates pertaining to cloning technology. Proper research and peer-reviewed data should be generated. The animal clones should undergo species-specific basic welfare assessments. If welfare concerns are detected at initial screening, a more extensive characterisation of that phenotype should be performed to document the animal welfare concerns.

- Proper monitoring of the animal population during different stages of life from birth to puberty should be documented to address and validate the genomic potential of the animal clones.

4. Managing animal health risks related to sexually reproduced progeny of clones

Presently there is no evidence of an increased health risk if sexual reproduction is used for obtaining progeny. Some data indicate that the reprogramming errors during the cloning process may actually be corrected during the natural mating and reproduction process:

a) Characterisation of the health profile, including health status and data on animal welfare, would consolidate the knowledge of sexually reproduced progeny.

b) Monitoring the reproductive performance of sexually reproduced progeny of clones would be useful to assess their reproductive capacity in comparison with their conventional counterparts.

5. Managing animal health risks associated with re-cloning/clones of clones

Information on recloning is only beginning to appear. It is therefore necessary to follow the approach below:

a) The health profile (health status and data on animal welfare) should be characterised to consolidate the knowledge.

b) The reproductive performance of clones of clones should be monitored to assess the capacity of the animals to perform in comparison with their conventional counterparts.
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Article 4.11.7.

Review

The goal of this chapter is to provide a scientific basis and recommendations on animal health and welfare risks to animals involved in SCNT cloning compared with other assisted reproductive technologies. These recommendations will focus initially on the scientific basis for the risk assessment aspects, prevention measures and guidance for production livestock and horses, derived from SCNT cloning and should be reviewed in light of new scientific information.
CHAPTER 4.12.

DISPOSAL OF DEAD ANIMALS

Article 4.12.1.

Introduction

The mass disposal of dead animals associated with an animal disease outbreak is often subject to intense public and media scrutiny thereby obligating the Veterinary Authority of a Member Country to not only conduct disposal operations within acceptable scientific principles to destroy the causative pathogen but also to address public and environmental concerns.

The recommendations in this chapter are general in nature. The choice of one or more of the recommended methods should be in compliance with relevant local and national legislation and be attainable with the resources available. The recommendations should also be applied in conjunction with the procedures described for the killing of animals in Chapter 7.6.

Strategies for the disposal of dead animals (entire animals or parts thereof) should be prepared well in advance of any emergency. Major issues related to the disposal of dead animals include the number of animals involved, biosecurity concerns over the movement of infected or exposed animals, people and equipment, environmental concerns, and the psychological distress experienced by farmers and animal handlers.

Article 4.12.2.

Regulations and jurisdiction

The legislation regulating animal health and the organisation of the Veterinary Authority should give the Veterinary Services the authority and the legal powers to carry out the activities necessary for the efficient and effective disposal of dead animals. Cooperation between the Veterinary Service and other relevant government bodies is necessary to developing a coherent set of legal measures for the disposal of dead animals in advance of any emergency. In this context the following aspects should be regulated:

1) Powers of Veterinary Services (inspectors, veterinary officers, etc.) to effect controls and direct persons as well as the right of entry to an establishment for the Veterinary Services and associated personnel;
2) movement controls and the authority to make exemptions under certain biosecurity conditions, for example for transport of dead animals to another location for disposal;
3) the obligation on the involved farmer and animal handlers to cooperate with the Veterinary Services;
4) any need to transfer the ownership of animals to the competent authority;
5) the determining of the method and location of disposal, and the necessary equipment and facilities, by the Veterinary Services, in consultation with other involved authorities including national and local governmental organisations competent for the protection of human health and of the environment.

Should the chosen option for the disposal of dead animals be applied near the border of a neighbouring country, the competent authorities of that country should be consulted.

Article 4.12.3.

Preparedness

The mass killing and disposal of animals in the event of a disease outbreak or disposal of animals in the event of natural disasters such as floods, usually should proceed with the minimum delay. The success is determined by the structures, policies and infrastructure established in advance:
Chapter 4.12.- Disposal of dead animals

1. **Relationship with industry**
   A relationship with industry organisations, such as farmer associations, commodity representatives, animal welfare organisations, security services, media and consumer representatives is essential to obtain compliance with animal health policies.

2. **Standard operating procedures**
   Standard operating procedures should be developed (including documented decision-making processes, training of staff).

3. **Financial preparedness**
   Financial preparedness means a compensation or insurance mechanism, an access to emergency funding and an access to personnel through agreements with private veterinarians.

4. **Communication plan**
   Information sharing with officials involved in the outbreak, affected farmers, professional organizations, politicians and the media is essential. A well informed spokesperson should be available at all times to answer enquiries.

5. **Resources**
   The management of resources should address such items as personnel, transport, storage facilities, equipment (such as mobile handling facilities for animals, disinfection equipment), fuel, protective and disposable material and logistical support.

6. **Special equipment**
   Special equipment such as trucks, tractors, bulldozers, and front-end loaders should be available.

**Article 4.12.4.**

**Critical elements**

Critical elements which need to be considered in planning and implementation include:

1. **Timeliness**
   Early detection of new infections, immediate killing of infected animals and rapid removal of the dead animals with inactivation of the pathogen are important. Spread of the pathogen from the dead animals and their surroundings should be blocked as soon and as effectively as possible.

2. **Occupational health and safety**
   Disposal should be organised in such a way that the workers are safeguarded against the risks of handling decomposing dead animals. Special attention should be given to zoonotic aspects. Workers should receive appropriate training and be sufficiently protected against infection with protective clothing, gloves, face masks, effective respirators, goggles, vaccination, and effective anti viral medicines. Workers should also receive regular health checks.

3. **Pathogen inactivation**
   The disposal procedure should be selected to result in inactivation of the pathogen.

4. **Environmental concerns**
   Different methods of the disposal of dead animals have different effects on the environment. For instance, pyre burning will produce smoke and smells; burial might lead to gas and leachate production resulting in potential contamination of air, soil, surface and sub surface water.

5. **Availability of capacity**
   An assessment of capacities of different methods of disposal should be made prior to any emergency. Temporary storage of dead animals in cold stores may relieve a lack of processing capacity.

6. **Adequate funding**
   Adequacy of funding for the options chosen should be ascertained and committed at the earliest possible stage.
7. **Staff resources**

Availability of sufficient and well trained staff resources in particular for extended and/or large operations should be ensured. This is particularly important for technical and inspection personnel who are usually in short supply.

8. **Societal acceptance**

Societal acceptance is an important point in choosing a disposal method.

9. **Acceptance by farmers**

Farmers will be sensitive to the safety measures taken to prevent spread of the disease by disposal method selected and the transport of the dead animals to the disposal site. Adequate compensation of owners for the loss of animals or for burial or burning sites will improve acceptability.

10. **Equipment**

Equipment used in the disposal of dead animals can transfer infection to other premises. The cleaning and disinfection of the outside surfaces of equipment such as cranes, containers and trucks, and the departure of vehicles from the farm should receive special attention. Trucks transporting dead animals should be leak proof.

11. **Scavengers and vectors**

When disposing of dead animals, full attention should be given to preventing scavengers and vectors gaining access to dead animals, which might cause spread of disease.

12. **Economic impact (short and long term including recovery)**

The method of disposal used has a significant bearing on economic impact.

Article 4.12.5.

**Practical considerations**

1. **Selection of disposal site**

Sufficient top soil to cover the site; soil type; water drainage; prevailing wind conditions; easy access to transport; availability of meteorological data; separation from sensitive public sites, and the effect on future use.

2. **Contractors**

Contractors — availability of manpower, materials and equipment including transport vehicles; can they supply in all the needs; exclusive use of vehicles or would they also be used for other purposes (risk of disease transmission); access to available roads; suitable for the purpose to be used.

3. **Logistical preparedness for the appropriate technology**

Availability of fuel; sufficient manual labour available; sites and availability of disinfection tents for personnel; storage and disposal of protective clothing; housing for personnel to minimise the spread of infection; facilities for entry and exit control; availability of electricity for night operations; personal facilities for personnel such as toilets, drinking water; availability of communication – mobile phone reception; protection (e.g. vaccination) of personnel; rendering capacity at rendering plants; arms and ammunition, additional cold storage and holding facilities at rendering plants and abattoirs.

4. **Procedures and policies for disposal of other possibly contaminated products**

Animal products such as litter, manure, wool, eggs and milk; animal feed; non-animal products such as protective clothing.

5. **Wildlife**

Need to minimise the risks posed by wildlife, including by excluding or repelling them from the disposal site.
Chapter 4.12.- Disposal of dead animals

Article 4.12.6.

Recommended methods for the disposal of dead animals

The method(s) chosen should be based on local conditions and the required capacity and speed of outcome and on the conditions required for the inactivation of the causative agent.

Some of the methods below may require on-farm pre-processing prior to transportation of dead animals to central facilities for rendering or incineration. Preprocessing could include the grinding of dead animals which can then be transported in sealed containers, or be subjected to fermentation, composting or freezing.

1. Rendering
   This is a closed system for mechanical and thermal treatment of animal tissues leading to stable, sterilized products, e.g. animal fat and dried animal protein. The technology exists in dedicated facilities. It produces an effective inactivation of all pathogens with the exception of prions where infectivity is reduced. The availability of the capacity should be determined in advance.

2. Incineration in a dedicated facility
   In such a facility, whole dead animals or parts of animals can be completely burned and reduced to ash, often in conjunction with other substances (such as municipal waste, hazardous waste or hospital waste). Effective inactivation of pathogens, including spores, occurs. Fixed facility incineration is wholly contained and has some advantages from the environmental viewpoint as the exhausts may be fitted with afterburner chambers to completely burn hydrocarbon gases and particulate matter from the main combustion chamber.

3. Rendering and incineration
   These may be combined for improved security and to provide additional fuel for furnaces in facilities used for other purposes such as in cement kilns and electricity generation plants.

4. Air curtain incineration
   This process fan-forces a mass of air through a manifold, thereby creating a turbulent environment in which incineration is accelerated up to six times for example in a burn-pit. The equipment can be mobile and, because it can be used on site, there is no requirement for transportation of the animal material. It also produces effective inactivation of pathogens.

5. Pyre burning
   This open system of burning dead animals is a well established procedure that can be conducted on site with no requirement for transportation of animal material. However, it takes an extended period of time and has no way of verifying pathogen inactivation, and there may be particulate dissemination from incomplete combustion. Further, because the process is open to view, there may be a lack of acceptance by the public.

6. Composting
   Composting is a natural biological decomposition process that takes place in the presence of oxygen. In the first phase, the temperature of the compost pile increases, organic materials break down into relatively small compounds, soft tissue decomposes, and bones soften partially. In the second phase, the remaining materials, mainly bones, break down fully to a dark brown or black humus containing primarily non-pathogenic bacteria and plant nutrients. However, some viruses and spore forming bacteria, such as Bacillus anthracis, and other pathogens such as Mycobacterium tuberculosis may survive.

7. Burial
   In this method, whole dead animals are buried and covered by soil. Burial is an established procedure which may be conducted on site. It may not inactivate all pathogens. In some circumstances, dead animals may be disposed of by mounding whereby they are covered by a layer of soil above ground.

8. Biogas production
   This is a closed system of anaerobic fermentation which would require for the disposal of dead animals or their parts prior mechanical and thermal treatment of the input material (such as the liquid product of rendering plants). This process may not inactivate all pathogens.
9. **Alkaline hydrolysis**

This method uses sodium hydroxide or potassium hydroxide to catalyse the hydrolysis of biological material into a sterile aqueous solution consisting of small peptides, amino acids, sugars, and soaps. Heat is applied (150°C) to accelerate the process. The only solid byproducts are the mineral constituents of bones and teeth. This residue (2 percent of the original weight of the animal) is sterile and easily crushed into a powder. The temperature and alkaline conditions of the process destroy the protein coats of viruses and the peptide bonds of prions. Both lipids and nucleic acids are degraded. The process is carried out in an insulated steam-jacketed, stainless steel pressure vessel.

10. **Bio-refining**

Bio-refining is a process of high pressure, high temperature, thermal hydrolysis conducted in a sealed pressurised chamber. The waste material is treated with high-pressure saturated steam at 180°C under a minimum of 10 bar pressure and continuous disruption by mechanical stirring for a period of 40 minutes. The whole procedure, from the loading of the chamber until the discharge from the chamber, occupies approximately 120 minutes. All microbiological agents are inactivated and the infectivity of the infectious agents causing transmissible spongiform encephalopathies is destroyed.

11. **Dead animal disposal at sea**

International Conventions define the conditions to be met for the disposal of dead animals at sea.

**Article 4.12.7.**

**Recommendations for decision-making for the disposal of dead animals**

The disposal of large numbers of dead animals will be expensive. As well, fixed and variable costs will vary with the choice of the disposal method. Each method used will result in indirect costs on the environment, local economies, producers, and the livestock industry. In addition to biosecurity considerations, decision makers need to understand the economic, social, environmental protection and aesthetic impact of various disposal technologies.

A disposal option hierarchy may be incapable of fully capturing and systematizing the relevant dimensions at stake, and decision makers may be forced to consider the least preferred means. It therefore requires a comprehensive understanding of any array of dead animal disposal technologies and should reflect a balance between the scientific, economic, and social issues at stake. Timely slaughter, maintenance of security and prevention of further spread of disease, are the essential considerations in terms of disease control.

The following is an example of a possible process for aiding decision-making by comparing the suitability of various disposal options against factors that are considered important for the specific disposal event in question:

1) Step 1 - Define the factors to be considered. Include all relevant factors and allow enough flexibility to permit modifications for different situations and locations. Examples of possible factors include operator safety, community concerns, international acceptance, transport availability, industry standards, cost effectiveness and speed of resolution. These factors can be modified or changed, as is shown in the following example, to best fit the situation of event involved.

2) Step 2 - Assess the relative importance of the factors by weighting each on their considered importance to addressing the event in question. The sum of all the weightings, regardless of the number of factors, should total 100.

3) Step 3 - Identify and list all disposal options under consideration. Rate each disposal option against each factor and assign a Utility Rating of between 1 to 10 to each comparison. The Utility Rating (U) is a number between 1 and 10 which is allocated according to how well the option achieves the ideal with respect to each factor (eg 1 = the worst possible fit, and 10 = the best fit).

4) Step 4 - For each factor and each disposal option, multiply the Factor Weight (F) x Utility Rating (U) to yield a numeric Balanced Value (V), (eg V = F x U).

5) Step 5 - By adding the Balanced Values to a sum for each disposal option, it is possible to compare the suitability of disposal options by numerically ranking the sums of the Balanced Values for each disposal option. The largest sum would suggest that disposal option is the best balanced choice.

An example of the use of this process follows in Table 1. In this example, rendering achieved the highest sum and would be considered as the best balanced choice and the most suitable disposal option for the factors considered.
<table>
<thead>
<tr>
<th>Method</th>
<th>Rendering</th>
<th>Fixed Incineration</th>
<th>Pyre Burning</th>
<th>Composting</th>
<th>Mass Burial</th>
<th>On-Farm Burial</th>
<th>Commercial Landfill</th>
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<tr>
<td></td>
<td>Weight</td>
<td>Utility</td>
<td>Value</td>
<td>Utility</td>
<td>Value</td>
<td>Utility</td>
<td>Value</td>
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<td>140</td>
<td>4</td>
<td>80</td>
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<td>160</td>
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<tr>
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<td>160</td>
<td>8</td>
<td>160</td>
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<td>150</td>
<td>10</td>
<td>150</td>
<td>8</td>
<td>120</td>
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<td>100</td>
<td>8</td>
<td>80</td>
<td>3</td>
<td>30</td>
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<tr>
<td>Reaction of the Public</td>
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<td>100</td>
<td>7</td>
<td>70</td>
<td>1</td>
<td>10</td>
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<td>5</td>
<td>1</td>
<td>5</td>
<td>8</td>
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<td>25</td>
<td>3</td>
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<td>650</td>
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CHAPTER 4.13.

GENERAL RECOMMENDATIONS ON DISINFECTION AND DISINSECTISATION

Article 4.13.1.

General provisions

Veterinary Authorities are requested to draw up regulations in their respective countries concerning the use of disinfectants and insecticides on the basis of the principles described below:

1) The choice of disinfectants and of procedures for disinfection should be made taking into account the causal agents of infection and the nature of the premises, vehicles and objects which are to be treated.

2) Disinfectants and insecticides should be authorised only after thorough tests have been carried out under field condition.

3) The following should be considered:
   a) few universal disinfectants exist;
   b) whereas hypochlorite, which is very often used, may be regarded as a universal disinfectant, its effectiveness is diminished by prolonged storage and it is therefore necessary to check its activity before use; a concentration of 0.5 percent active chlorine appears necessary for satisfactory disinfection;
   c) no matter what substances are used, disinfection techniques should comprise the following:
      i) thorough soaking of bedding and litter as well as faecal matter with the disinfectant;
      ii) washing and cleaning by careful brushing and scrubbing of the ground, floors and walls;
      iii) then further washing with the disinfectant;
      iv) washing and disinfecting the outside of vehicles; these procedures will be carried out, if possible, with liquids applied under pressure and the washing, disinfecting or destroying of articles used for tying up the animals (ropes, reins, etc.) should not be omitted.

Article 4.13.2.

Pathogen-specific disinfection

1) Foot and mouth disease virus is easily destroyed by a high or low pH but the disinfectants used may be caustic or corrosive in concentrated form.

2) Mycobacteria are very resistant to disinfectants and a high concentration is required to destroy the organisms, as well as prolonged action.

3) Bacillus anthracis
   a) In situations in which manure, dung or bedding may be contaminated with Bacillus anthracis (B. anthracis) spores, the following are recommended:
      i) small volumes by incineration; or
      ii) chemothermal treatment by composting as follows:
         – mix with one of the following at a rate of 1–1.5 litre/m³:
         – 10 percent formaldehyde (approximately 30 percent formalin), or
         – 4 percent gluteraldehyde (pH 8.0–8.5);
         – turn the material after five weeks;
         – leave for a further five weeks.
   [Note: Spontaneous combustion of the composting pile is possible. Also note: Formalin is a dangerous chemical and as such the appropriate personal protective equipment should be used and safety training on the handling of this chemical should be provided.]
b) In situations in which liquid manure (slurry) may be contaminated with B. anthracis spores, disinfection with formalin (35 percent aqueous solution of formaldehyde) with stirring for one hour daily is recommended:
   i) for slurry up to 5 percent dry matter, 50 kg formalin per m³ for 4 days;
   ii) for slurry >5 percent and <10 percent dry matter, 100 kg formalin per m³ for 4 days.
   [Note: Formalin is a dangerous chemical and as such the appropriate personal protective equipment should be used and safety training on the handling of this chemical should be provided.]

c) In situations in which surfaces in animal houses, stables, vehicles, etc. may be contaminated with B. anthracis spores, the following three-step approach is recommended:
   i) a preliminary disinfection should be carried out using one of the following disinfectants at a rate of 1–1.5 litres/m³ for 2 hours;
      – 10 percent formaldehyde (approximately 30 percent formalin); or
      – 4 percent glutaraldehyde (pH 8.0–8.5);
   ii) all surfaces should be washed and scrubbed using ample hot water and, when cleaned and waste water is free from dirt particles, dried;
   iii) a final disinfection step should be carried out using one of the following disinfectants applied at a rate of 0.4 litre/m³ for 2 hours;
      – 10 percent formaldehyde (approximately 30 percent formalin), repeated after one hour; or
      – 4 percent glutaraldehyde (pH 8.0–8.5), repeated after one hour; or
      – 3 percent hydrogen peroxide; or
      – 1 percent peracetic acid, repeated after one hour; or
      – 5–10 percent sodium hypochloride solution.
   [Note: Formaldehyde and glutaraldehyde should not be used at temperatures below 10°C. Hydrogen peroxide and peracetic acid are not suitable in the presence of blood. As with all chemicals the appropriate personal protective equipment should be worn and appropriate safety training should be provided to staff handling dangerous chemicals.]

d) Contaminated rooms which cannot be cleared before cleaning and disinfection can be fumigated to eliminate B. anthracis spores. The following procedure is recommended:
   i) all windows, doors and vents to the outside should be sealed with heavy adhesive tape; and
   ii) for rooms up to 30 m³, 4 litres of water containing 400 ml of concentrated formalin (37 percent w/v formaldehyde) in an electric kettle (with a timing switch to turn it off) should be boiled away and the room left overnight. Room temperature should be >15°C.
   [Note: Formaldehyde fumigation is hazardous and proper respirators should be on hand for operator safety. The effectiveness of the fumigation process should be verified by exposing dried discs of filter paper which have been dipped in a suspension of spores of B. subtilis var. globigii or B. cereus or Sterne vaccine strain of B. anthracis and placed in the room before fumigation is started. At the end of fumigation, the discs should be placed on nutrient agar plates containing 0.1 percent histidine and incubated overnight at 37°C. If fumigation has been effective, there will be no bacterial growth.]
OFFICIAL HEALTH CONTROL
OF BEE DISEASES


Purpose

This chapter is intended to set out guidelines for official health control of bee diseases. These are needed for the control of endemic bee diseases at the country level and to detect incursions of exotic diseases, thereby ensuring safe international trade of bees, bee products and used apicultural equipment. The guidelines are designed to be general in nature and more specific recommendations or requirements are made in chapters on bee diseases.

Article 4.14.2.

Overview

In each country or region, official health control of bee diseases should include:

1) official registration of the apiaries by the Veterinary Authority or other Competent Authority in the whole country or region;
2) an organisation for permanent health surveillance;
3) approval of breeding apiaries for export trade;
4) measures for cleaning, disinfection and disinfestation of apicultural equipment;
5) rules precisely stating the requirements for issuing an international veterinary certificate.

Article 4.14.3.

Official registration of the apiaries by the Veterinary Authority or other Competent Authority in the whole country or region

The registration of apiaries is the first step in developing a regional management plan for bee disease surveillance and control. With knowledge of bee density and location it is possible to design valid sampling schemes, to predict the spread of disease and to design inspection programmes to target areas of high risk.

The official registration of apiary sites should be annual and may provide information such as the presumptive locations of the apiary sites in the next 12 months, the average number of colonies in each apiary site, and the name and address of the principal owner of the bees in the apiary.

The main apiary locations (places where the bee hives are located the longest time in the year) should be registered first, followed as far as possible by the seasonal apiary locations.


Organisation for permanent official sanitary surveillance of apiaries

Veterinary Authorities or other Competent Authorities of countries are requested to regulate the organisation for permanent official sanitary surveillance of apiaries.

Permanent official sanitary surveillance of apiaries should be under the authority of the Veterinary Authority or other Competent Authority and should be performed either by representatives of this Authority or by representatives of an approved organisation, with the possible assistance of bee-keepers specially trained to qualify as 'health inspectors and advisers'.
Chapter 4.14.- Official health control of bee diseases

The official surveillance service thus established should be entrusted with the following tasks:

1) visit apiaries:
   a) annual visits to an appropriate sample of apiaries, based on the estimated risk in the whole country or region, during the most appropriate periods for the detection of diseases;
   b) additional visits to apiaries may be carried out for specific purposes including trade or transfer to other regions, or any other purpose whereby diseases could be spread;

2) collect samples required for the diagnosis of diseases and despatch them to a laboratory; the results of laboratory examinations should be communicated within the shortest delay to the Veterinary Authority or other Competent Authority;

3) apply hygiene measures, comprising, in particular, treatment of colonies of bees, as well as disinfection of the equipment and possibly the destruction of affected or suspect colonies and of the contaminated equipment so as to ensure rapid eradication of any outbreak of a disease.

Article 4.14.5.

Conditions for approval of breeding apiaries for export trade

Veterinary Authorities or other Competent Authorities of exporting countries are requested to regulate the conditions for approval of breeding apiaries for export trade.

The apiaries should:

1) have received, for at least the past two years, visits by a health inspector and adviser, carried out at least once a year using a risk-based approach during the most appropriate periods for detection of listed diseases of bees. During these visits, there should be a systematic examination of at least 10% of the hives containing bees and of the used apicultural equipment (especially stored combs), and the collection of samples to be sent to a laboratory and, depending on the situation of the importing and exporting countries, no positive results were reported to the Veterinary Authorities or other Competent Authorities for the relevant listed disease of bees;

2) be regularly sampled, depending on the epidemiological situation of the importing and exporting countries, and found free from the relevant listed diseases of bees. To achieve this, a statistically valid number of bee colonies should be examined by any method complying with the relevant chapters of the Terrestrial Manual.

Bee-keepers should:

3) immediately notify the Veterinary Authority or other Competent Authority of any suspicion of a listed disease of bees in the breeding apiary and in other epidemiologically linked apiaries;

4) not introduce into the apiary any bee (including pre-imago stages) or used apicultural equipment or product originating from another apiary unless that apiary is recognised by the Veterinary Authority or other Competent Authority to be of equivalent or higher health status or the used apicultural equipment or product has been treated in agreement with a procedure described in the relevant chapters of the Terrestrial Code;

5) apply special breeding and despatch techniques to ensure protection against any outside contamination, especially for the breeding and sending of queen-bees and accompanying bees and to enable retesting in the importing country;

6) collect at least every 30 days, during the breeding and despatch period, appropriate samples to be sent to a laboratory and all the positive results officially reported to the Veterinary Authority or other Competent Authority.


Conditions for sanitation and disinfection or disinfestation of apicultural equipment

Veterinary Authorities or other Competent Authorities of countries are requested to regulate the use of products and means for sanitation and disinfection or disinfestation of apicultural equipment in their own country, taking into account the following recommendations.

1) Any apicultural equipment kept in an establishment which has been recognised as being affected with a contagious disease of bees should be subjected to sanitary measures ensuring the elimination of pathogens.

2) In all cases, these measures comprise the initial cleaning of the equipment, followed by sanitation or disinfection or disinfestation depending on the disease concerned.

3) Any infested or contaminated equipment which cannot be subjected to the above-mentioned measures should be destroyed, preferably by burning.
Chapter 4.14. - Official health control of bee diseases

4) The products and means used for sanitation and disinfection or disinfestation should be accepted as being effective by the Veterinary Authority or other Competent Authority. They should be used in such a manner as to exclude any risk of contaminating the equipment which could eventually affect the health of bees or adulterate the products of the hive.


Preparation of the international veterinary certificate for export

This certificate covers hives containing bees, brood-combs, royal cells, used apicultural equipment and bee products. This document should be prepared in accordance with the model contained in Chapter 5.10. and taking into account the chapters on bee diseases.
CHAPTER 4.15.

HYGIENE PRECAUTIONS, IDENTIFICATION, BLOOD SAMPLING AND VACCINATION

Article 4.15.1.

The use of microchip implanters, needles and syringes in a wide range of routine veterinary procedures relative to identification, blood sampling, vaccination and the injection of medicinal products or devices is now commonplace.

Unsterilised equipment and the use of opened vials of vaccine and medicinal products for different herds should be unacceptable professionally.

The use of unsterilised and contaminated equipment (microchip implanters, needles, syringes, etc.) or products is of special importance for different herds and animals to be exported. It is a requirement, particularly applicable for animals to be exported, that care is taken to ensure the sterility of all equipment and veterinary products associated with the conditions of the export certificate.

These precautions have particular importance for teams of veterinarians and para-veterinarians.

The range of organisms capable of being transmitted includes viruses, bacteria and protozoa. The list of infectious agents transmissible in the context of this chapter continues to expand for all species of animals.
SECTION 5.

TRADE MEASURES, IMPORT/EXPORT PROCEDURES
AND VETERINARY CERTIFICATION

CHAPTER 5.1.

GENERAL OBLIGATIONS RELATED TO
CERTIFICATION

Article 5.1.1.

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

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

These requirements should be included in the model certificates approved by the OIE which are included from Chapters 5.10. to 5.12.

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

The certification requirements should not include conditions for diseases that are not transmitted by the commodity concerned. The certificate should be signed in accordance with the provisions of Chapter 5.2.

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

Article 5.1.2.

Responsibilities of the importing country

1) The import requirements included in the international veterinary certificate should assure that commodities introduced into the importing country comply with the standards of the OIE. Importing countries should restrict their requirements to those necessary to achieve the national appropriate level of protection. If these are stricter than the standards of the OIE, they should be based on an import risk analysis.

2) The international veterinary certificate should not include requirements for the exclusion of pathogens or animal diseases which are present in the importing country and are not subject to any official control programme. The measures imposed on imports to manage the risks posed by a specific pathogen or disease should not require a higher level of protection than that provided by measures applied as part of the official control programme operating within the importing country.
Chapter 5.1. - General obligations related to certification

3) The international veterinary certificate should not include measures against pathogens or diseases which are not OIE listed, unless the importing country has demonstrated through import risk analysis, carried out in accordance with Section 2., that the pathogen or disease poses a significant risk to the importing country.

4) The transmission by the Veterinary Authority of certificates or the communication of import requirements to persons other than the Veterinary Authority of another country, necessitates that copies of these documents are also sent to the Veterinary Authority. This important procedure avoids delays and difficulties which may arise between traders and Veterinary Authorities when the authenticity of the certificates or permits is not established.

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

5) Situations may arise which result in changes to the consignee, identification of the means of transportation, or border post after a certificate is issued. Because these do not change the animal or public health status of the consignment, they should not prevent the acceptance of the certificate.

Article 5.1.3.

Responsibilities of the exporting country

1) An exporting country should, on request, supply the following to importing countries:
   a) information on the animal health situation and national animal health information systems to determine whether that country is free or has zones or compartments free from listed diseases, including the regulations and procedures in force to maintain its free status;
   b) regular and prompt information on the occurrence of notifiable diseases;
   c) details of the country's ability to apply measures to control and prevent the relevant listed diseases;
   d) information on the structure of the Veterinary Services and the authority which they exercise according to Chapters 3.1. and 3.2.;
   e) technical information, particularly on biological tests and vaccines applied in all or part of the national territory.

2) Veterinary Authorities of exporting countries should:
   a) have official procedures for authorisation of certifying veterinarians, defining their functions and duties as well as conditions of oversight and accountability, including possible suspension and termination of the authorisation;
   b) ensure that the relevant instructions and training are provided to certifying veterinarians;
   c) monitor the activities of the certifying veterinarians to verify their integrity and impartiality.

3) The Veterinary Authority of the exporting country is ultimately accountable for veterinary certification used in international trade.

Article 5.1.4.

Responsibilities in case of an incident related to importation

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

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

3) In case of suspicion, on reasonable grounds, that an official certificate may be fraudulent, the Veterinary Authority of the importing country and exporting country should conduct an investigation. Consideration should also be given to notifying any third country(ies) that may have been implicated. All associated consignments should be kept under official control, pending the outcome of the investigation. The Veterinary Authorities of all countries involved should
fully cooperate with the investigation. If the certificate is found to be fraudulent, every effort should be made to identify those responsible so that appropriate action can be taken according to the relevant legislation.
CHAPTER 5.2.

CERTIFICATION PROCEDURES

Article 5.2.1.

Protection of the professional integrity of the certifying veterinarian

Certification should be based on the highest possible ethical standards, the most important of which is that the professional integrity of the certifying veterinarian should be respected and safeguarded according to Chapters 3.1. and 3.2.

It is essential to include in any requirements only those specific statements that can be accurately and honestly signed by a certifying veterinarian. For example, these requirements should not include certification of an area as being free from diseases other than notifiable diseases, or the occurrence of which the signing veterinarian is not necessarily informed about. It is unacceptable to ask for certification for events which will take place after the document is signed when these events are not under the direct control and supervision of the signing veterinarian.

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

The note of guidance referred to in Article 5.1.1. is not only to inform the signing veterinarian but also to safeguard professional integrity.

Article 5.2.2.

Certifying veterinarians

Certifying veterinarian should:

1) be authorised by the Veterinary Authority of the exporting country to sign international veterinary certificates;

2) only certify matters that are within their own knowledge at the time of signing the certificate, or that have been separately attested by another competent party;

3) sign only at the appropriate time certificates that have been completed fully and correctly; where a certificate is signed on the basis of supporting documentation, the certifying veterinarian should have verified or be in possession of that documentation before signing;

4) have no conflict of interest in the commercial aspects of the animals or animal products being certified and be independent from the commercial parties.

Article 5.2.3.

Preparation of international veterinary certificates

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

1) Certificates should be designed so as to minimize the potential for fraud including use of a unique identification number, or other appropriate means to ensure security. Paper certificates should bear the signature of the certifying veterinarian and the official identifier (stamp) of the issuing Veterinary Authority. Each page of a multiple page certificate should bear the unique certificate number and a number indicating the number of the page out of the total number of pages. Electronic certification procedures should include equivalent safeguards.

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

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

4) Certificates should require appropriate identification of animals and animal products except where this is impractical (e.g. day-old birds).
5) Certificates should not require a veterinarian to certify matters that are outside his/her knowledge or which he/she cannot ascertain and verify.

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

7) The text of a certificate should not be amended except by deletions which should be signed and stamped by the certifying veterinarian.

8) The signature and stamp should be in a colour different from that of the printing of the certificate. The stamp may be embossed instead of being a different colour.

9) Replacement certificates may be issued by a Veterinary Authority to replace certificates that have been, for example, lost, damaged, contain errors, or where the original information is no longer correct. These replacements should be provided by the issuing authority and be clearly marked to indicate that they are replacing the original certificate. A replacement certificate should reference the number and the issue date of the certificate that it supersedes. The superseded certificate should be cancelled and, where possible, returned to the issuing authority.

10) Only original certificates are acceptable.

Article 5.2.4.

Electronic certification

1) Certification may be provided by electronic documentation sent directly from the Veterinary Authority of the exporting country to the Veterinary Authority of the importing country. Such systems also normally provide an interface with the commercial organisation marketing the commodity for provision of information to the certifying authority. The certifying veterinarian should have access to all information such as laboratory results and animal identification data.

2) Electronic certificates may be in a different format but should carry the same information as conventional paper certificates.

3) The Veterinary Authority should have in place systems for the security of electronic certificates against access by unauthorised persons or organisations.

4) The certifying veterinarian should be officially responsible for the secure use of his/her electronic signature.
CHAPTER 5.3.

OIE PROCEDURES RELEVANT TO THE AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES OF THE WORLD TRADE ORGANIZATION

Article 5.3.1.

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

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

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

The SPS Agreement, in Article 7, obliges WTO Members to notify changes in, and provide relevant information on, sanitary measures which may, directly or indirectly, affect international trade.

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

Article 5.3.2.

Introduction on the judgement of the equivalence of sanitary measures

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

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

Article 5.3.3.

General considerations on the judgement of the equivalence of sanitary measures

Before trade in animals or their products may occur, an importing country must be satisfied that its animal health status will be appropriately protected. In most cases, the risk management measures drawn up will rely in part on judgements made about the animal health and production system(s) in the exporting country and the effectiveness of sanitary procedures undertaken there. Systems operating in the exporting country may differ from those in the importing country and from those in other countries with which the importing country has traded. Differences may be with respect to infrastructure, policies and/or operating procedures, laboratory systems, approaches to the pests and diseases present, border security and internal movement controls.
International recognition of the legitimacy of different approaches to achieving the importing country's appropriate level of protection (ALOP) has led to the principle of equivalence being included in trade agreements, including the SPS Agreement of the WTO.

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

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

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

Article 5.3.4.

Prerequisite considerations in a judgement of equivalence

1) Application of risk assessment

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

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

2) Categorisation of sanitary measures

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

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

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

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

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

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

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

In some cases, a comparison of specific technical requirements may suffice. In many instances, however, a judgement as to whether the same level of protection is likely to be achieved may only be able to be determined through an evaluation of all relevant components of an exporting country's animal health and production system. For example, a judgement of equivalence for a specific sanitary measure at the programme design/implementation level may require a prior examination of infrastructure while a judgement of equivalence for a specific measure at the specific technical requirement level may require that the specific measure be judged in its context through examination of infrastructure and programmes.
Chapter 5.3.- OIE procedures relevant to the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization

Article 5.3.5.

Principles for judgement of equivalence

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

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

2) the **importing country** should be able to describe the reason for each sanitary measure i.e. the level of protection intended to be achieved by application of the identified measure against a hazard;

3) **an importing country** should recognise that sanitary measures different from the ones it has proposed may be capable of providing the same level of protection;

4) the **importing country** should, upon request, enter into consultations with the **exporting country** with the aim of facilitating a judgement of equivalence;

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

6) an interactive process should be followed that applies a defined sequence of steps, and utilises an agreed process for exchange of information, so as to limit data collection to that which is necessary, minimise administrative burden, and facilitate resolution of claims;

7) the **exporting country** should be able to demonstrate objectively how the alternative sanitary measure(s) proposed as equivalent will provide the same level of protection;

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

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

10) the **importing country** should take into account any knowledge of and prior experience with the Veterinary Authority or other Competent Authority of the **exporting country**;

11) the **exporting country** should provide access to enable the procedures or systems which are the subject of the equivalence judgement to be examined and evaluated upon request of the **importing country**;

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

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

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

15) **an importing country** should give positive consideration to a request by an exporting developing country for appropriate technical assistance that would facilitate the successful completion of a judgement of equivalence.

Article 5.3.6.

Sequence of steps to be taken in judgement of equivalence

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

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

Recommended steps are:

1) the **exporting country** identifies the measure(s) for which it wishes to propose an alternative measure(s), and requests from the **importing country** a reason for its sanitary measure in terms of the level of protection intended to be achieved against a hazard(s);

2) the **importing country** explains the reason for the measure(s), in terms which would facilitate comparison with an alternative sanitary measure(s) and consistent with the principles set out in these provisions;
3) the **exporting country** demonstrates the case for equivalence of an alternative **sanitary measure(s)** in a form which facilitates analysis by an **importing country**;

4) the **exporting country** responds to any technical concerns raised by the **importing country** by providing relevant further information;

5) **judgement of equivalence by the importing country** takes into account as appropriate:
   a) the impact of biological variability and uncertainty;
   b) the expected effect of the alternative **sanitary measure(s)** on all relevant **hazards**;
   c) OIE standards;
   d) application of solely qualitative frameworks where it is not possible or reasonable to conduct **quantitative risk assessment**;

6) the **importing country** notifies the **exporting country** of its judgement and the underlying reasons within a reasonable period of time:
   a) recognition of the equivalence of the **exporting country**'s alternative **sanitary measure(s)**;
   b) request for further information; or
   c) rejection of the case for equivalence of the alternative **sanitary measure(s)**;

7) an attempt should be made to resolve any differences of opinion over judgement of a case, either interim or final, by using an agreed mechanism to reach consensus (e.g. the OIE informal procedure for dispute mediation), or by referral to an agreed expert;

8) depending on the category of measures involved, the **importing country** and the **exporting country** may enter into a formal **equivalence agreement** giving effect to the judgement or a less formal acknowledgement of the equivalence of a specific measure(s) may suffice.

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

**Article 5.3.7.**

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

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

1. **For zoning**
   a) The **exporting country** identifies a geographical area within its territory, which it considers to contain an animal **subpopulation** with a distinct health status with respect to a specific **disease**/specific **diseases**, based on **surveillance**.
   b) The **exporting country** describes in the **biosecurity plan** for the zone the measures which are being, or will be, applied to distinguish such an area epidemiologically from other parts of its territory, in accordance with the recommendations in the **Terrestrial Code**.
   c) The **exporting country** provides:
      i) the above information to the **importing country**, with an explanation of why the area can be treated as an epidemiologically separate zone for **international trade** purposes;
      ii) access to enable the procedures or systems that establish the zone to be examined and evaluated upon request by the **importing country**.
   d) The **importing country** determines whether it accepts such an area as a zone for the importation of **animals** and animal products, taking into account:
      i) an evaluation of the **exporting country**'s **Veterinary Services**;
      ii) the result of a **risk assessment** based on the information provided by the **exporting country** and its own research;
      iii) its own animal health situation with respect to the **disease(s)** concerned; and
iv) other relevant OIE standards.

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

i) recognition of the zone; or

ii) request for further information; or

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

f) An attempt should be made to resolve any differences over recognition of the zone, either in the interim or finally, by using an agreed mechanism to reach consensus such as the OIE informal procedure for dispute mediation (Article 5.3.8.).

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

2. **For compartmentalisation**

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

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

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

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

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

d) The **exporting country** provides:

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

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

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

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

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

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

iv) other relevant OIE standards.

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

i) recognition of the *compartment*; or

ii) request for further information; or

iii) rejection of such a *subpopulation* as a *compartment for international trade* purposes.

g) An attempt should be made to resolve any differences over recognition of the *compartment*, either in the interim or finally, by using an agreed mechanism to reach consensus such as the OIE informal procedure for dispute mediation (Article 5.3.8.).

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

i) The **Veterinary Authority** of the **exporting country** should promptly inform **importing countries** of any occurrence of a *disease* in respect of which the *compartment* was defined.
Article 5.3.8.

The OIE informal procedure for dispute mediation

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

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

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

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

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

5) The expert or experts shall submit a confidential report to the Director General of the OIE, who will transmit it to both parties.
CHAPTER 5.4.

ANIMAL HEALTH MEASURES APPLICABLE BEFORE AND AT DEPARTURE

Article 5.4.1.

Animals for breeding, rearing or slaughter

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

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

3) Observation of the animals before leaving the country may be carried out either in the establishment where they were reared, or in a quarantine station. The animals should be transported to the place of shipment in specially constructed vehicles, previously cleansed and, if required, disinfected. This must be done without delay and without the animals coming into contact with other susceptible animals, unless these animals have animal health guarantees similar to those of the transported animals. An international veterinary certificate should attest that the animals have been found to be clinically healthy and of the health status agreed by the importing country and exporting country.

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

Article 5.4.2.

Semen, embryo/ova and hatching eggs

Countries should only undertake the export from its territory of:

1) semen,
2) embryos/ova,
3) hatching eggs,

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

Article 5.4.3.

Notification

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

Article 5.4.4.

Certificate

Before the departure of animals, semen, embryos/ova, hatching eggs and brood-combs of bees, an Official Veterinarian should, within the 24 hours prior to shipment, provide an international veterinary certificate conforming with the models approved by the OIE (as shown in Chapters 5.10. to 5.12.) and worded in the languages agreed upon between the exporting country and the importing country, and, where necessary, with the transit countries.
Chapter 5.4.- Animal health measures applicable before and at departure

Article 5.4.5.

Live animals

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

2) The Veterinary Authority referred to in point 1 above should take necessary measures to:
   a) prevent the shipment of animals affected or suspected of being affected with any listed disease or with any other infectious disease as agreed by the importing country and the exporting country;
   b) avoid entry into the vehicle of possible vectors or causal agents of infection.

Article 5.4.6.

Products of animal origin

1) Countries should only authorise the export from their territory of meat and products of animal origin intended for human consumption, which are fit for human consumption. They must be accompanied by an international veterinary certificate conforming with the models approved by the OIE (as shown in Chapters 5.10. to 5.12.). These must be worded in the languages agreed upon between the exporting country and the importing country, and, where necessary, with the transit countries.

2) Products of animal origin intended for use in animal feeding, or for pharmaceutical or surgical or agricultural or industrial use, should be accompanied by an international veterinary certificate conforming with the models approved by the OIE (as shown in Chapters 5.10. to 5.12.).
CHAPTER 5.5.

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

Article 5.5.1.

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

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

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

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

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

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

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

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

Article 5.5.2.

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

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

Article 5.5.3.

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

1) semen,
2) embryos/ova,
3) hatching eggs,
4) brood-combs of bees,
5) animal products,
and which allows the importation of those products, should not refuse their transit, subject to the following conditions:

1) Advance notice shall be given of the proposed transit to the Veterinary Authority in charge of the control of the border posts.
   This advance notice shall contain information on the identification of the species and the quantity of the products, the method of transport, and the border posts of entry into and exit from the country, in accordance with a previously arranged and authorised itinerary in the transit country.

2) If inspection indicates that the above-mentioned products are capable of being dangerous to the health of persons or animals, the Veterinary Authority of the transit country may order their return to the exporting country. If they cannot be returned, the Veterinary Authority of the exporting country shall be informed immediately, thereby providing an opportunity for confirming the findings before destruction of the products.

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

Article 5.5.4.

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

Article 5.5.5.

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

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

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

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

5) In an emergency, the captain of the ship or aircraft shall take all necessary measures to maintain the health and safety of the passengers, crew, attendants and animals on board.
CHAPTER 5.6.

BORDER POSTS AND QUARANTINE STATIONS IN THE IMPORTING COUNTRY

Article 5.6.1.

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

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

Article 5.6.2.

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

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

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

3) carrying out disinfection and possibly disinestation of vehicles used to transport animals and animal products.

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

The presence of disease or infection in imported animals in a quarantine station does not affect the animal health status of the country or zone.

Article 5.6.3.

When required for the transit of commodities in international trade, airports should provide areas of direct transit. These should, however, comply with the conditions required by Veterinary Authorities, especially to prevent the contact between animals of different health status and the risk of introducing diseases transmitted by insects.

Article 5.6.4.

Each Veterinary Authority, when requested, should make available for the Headquarters and any interested country on request:

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

2) the period of time required for notice to be given for the application of the arrangements contained in point 2 of Articles 5.7.1. to 5.7.4.;

3) a list of airports in its territory which are provided with an area of direct transit, approved by the relevant Veterinary Authority and placed under its immediate control, where animals stay for a short time pending further transport to their final destination.
CHAPTER 5.7.

ANIMAL HEALTH MEASURES APPLICABLE ON ARRIVAL

Article 5.7.1.

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

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

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

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

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

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

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

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

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

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

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

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

Article 5.7.2.

1) Any importing country should only accept into its territory:

a) semen,

b) embryos/ova,

c) hatching eggs,

d) brood-combs of bees,

which are accompanied by an international veterinary certificate.

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

3) A country may prohibit the importation of the above-mentioned products into its territory if it considers that certain diseases exist in the exporting country, or in the transit countries which precede it in the itinerary, which are capable of being introduced by these products into its territory.
Article 5.7.3.

1) An importing country should only accept into its territory meat and products of animal origin intended for human consumption which comply with point 1 of Article 5.4.6.

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

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

Article 5.7.4.

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

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

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

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

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

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

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

Article 5.7.5.

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

1) unloading of the vehicle and immediate transportation of the animal or animals, in a leak-proof vehicle direct to:
   a) an establishment approved by the Veterinary Authority for the slaughter of the animal or animals and the destruction or possibly sterilisation of their carcasses; or
   b) a quarantine station or, in the absence of a quarantine station, to a place assigned in advance which is well isolated and near the border post;
2) unloading of the vehicle and immediate transportation of the litter, forage and any other potentially contaminated material to an establishment assigned in advance for their destruction, and strict application of the animal health measures required by the importing country;

3) disinfection of:
   a) all baggage of the attendants;
   b) all parts of the vehicle which were used in the transport, feeding, watering, moving and unloading of the animal or animals;

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

Article 5.7.6.

On the arrival at a border post of a vehicle transporting an animal or animals suspected of being affected with any listed disease, the vehicle shall be considered as being contaminated, and the Veterinary Authority may apply the measures provided in Article 5.7.5.

Article 5.7.7.

The vehicle shall no longer be considered as contaminated when the measures prescribed by the Veterinary Authority in accordance with Article 5.7.5. have been carried out.

The vehicle may then be allowed to enter.

Article 5.7.8.

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

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

Article 5.7.9.

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

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

2) Any aircraft coming from a foreign country where animal diseases transmitted by insect vectors are present shall be subjected to disinfestation immediately after landing, except when such a disinfestation was carried out immediately before departure or during the flight.
CHAPTER 5.8.

INTERNATIONAL TRANSFER AND LABORATORY CONTAINMENT OF ANIMAL PATHOGENS

Article 5.8.1.

Object

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

Article 5.8.2.

Introduction

1) The consequences of the introduction into a country of an infectious disease or an animal pathogen or new strain of animal pathogen from which it is currently free, are potentially very serious. This is because animal health, human health, the agricultural economy and trade may all be adversely affected to a greater or a lesser degree. Countries will already have in place a range of measures, such as requirements for pre-import testing and quarantine, to prevent such introductions through the importation of live animals or their products.

2) However, there is also the risk that disease may occur as a result of the accidental release of animal pathogens from laboratories that are using them for various purposes such as research, diagnosis or the manufacture of vaccines. Such pathogens may already occur in the country or they may have been imported deliberately or inadvertently. It is therefore necessary to have in place measures to prevent their accidental release. These measures may be applied either at national borders by prohibiting or controlling the importation of specified pathogens or their carriers (see Article 5.8.4.) or within national boundaries by specifying the conditions under which laboratories must handle them. In practice, a combination of external and internal controls is likely to be applied depending on the risk to animal health posed by the pathogen in question.

Article 5.8.3.

Classification of pathogens

Pathogens should be categorised according to the risk they pose to both human and animal health. They are grouped into four risk categories. Detailed information is provided in the Terrestrial Manual.

Article 5.8.4.

Importation of animal pathogens

1) The importation of any animal pathogen, pathological material or organisms carrying the pathogen should be permitted only under an import licence issued by the relevant authority. The import licence should contain conditions appropriate to the risk posed by the pathogen and, in relation to air transport, the appropriate standards of the International Air Transport Association concerning the packaging and transport of hazardous substances. The import licence for risk groups 2, 3 or 4 should only be granted to a laboratory that is licensed to handle the particular pathogen as in Article 5.8.5.

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

1) Guidance on the laboratory containment of animal pathogens and on the import conditions applicable to animal pathogens is found in Chapter 1.1.2. of the Terrestrial Manual. Additional guidance on human safety is also found in this chapter.

2) A laboratory should be allowed to possess and handle animal pathogens in group 3 or 4 only if it can satisfy the relevant authority that it can provide containment facilities appropriate to the group. However, depending on the particular circumstances of an individual country, the authority might decide that the possession and handling of certain pathogens in group 2 should also be controlled. The authority should first inspect the facilities to ensure they are adequate and then issue a licence specifying all relevant conditions. There should also be a requirement for appropriate records to be kept and for the authority to be notified if it is suspected that a material being handled contains a pathogen not covered by the licence. The authority should visit the laboratory periodically to ensure compliance with the licence conditions. It is important that authority staff carrying out the visit should not have any contact with species susceptible to the pathogens being handled at the laboratory for a specified period after visiting the laboratory. The length of this period will depend on the pathogen.

3) Licences should specify:
   a) how the pathogen is to be transported and the disposal of the packaging;
   b) the name of the person responsible for the work;
   c) whether the pathogen may be used in vivo (and if so whether in laboratory animals or other animals) and/or only in vitro;
   d) how the pathogen and any experimental animals should be disposed of when the work is completed;
   e) limitations on contact by laboratory staff with species susceptible to the pathogens being used;
   f) conditions for the transfer of pathogens to other laboratories;
   g) specific conditions relating to the appropriate containment level and biosecurity procedures and practices.
CHAPTER 5.9.

QUARANTINE MEASURES APPLICABLE TO NON-HUMAN PRIMATES

Article 5.9.1.

General principles

The present chapter defines the standards to be followed in the case of a non-human primate being imported directly from a country within the natural range of the animal’s species concerned, and where only limited health guarantees can be given, or in cases where Article 6.11.2., last paragraph, applies.

Quarantine programmes are designed to both facilitate the detection of communicable diseases and to make accurate assessments of the overall health status of individuals and/or groups entering a new population. Prudence dictates that for public health and safety the infectious disease status of all incoming animals is considered at best uncertain. Non-human primates can harbour infectious organisms that cause only mild disease for their species but can be severely pathogenic to other species of non-human primate, either in captive collections or in wild populations, or to humans.

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

The minimal duration of the quarantine period, as defined by Articles 6.11.4., 6.11.5. and 6.11.6., may be extended until any adverse events during the quarantine period are fully investigated and resolved, and no evidence of transmission of infectious agents within the quarantined group exists.

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

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

Article 5.9.2.

Management policies

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

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

Management may prohibit persons who may be at increased risk of acquiring infections or for whom an infection might be unusually hazardous from the quarantine facility. Management may require other personnel health promotion activities, such as those mentioned in point 5 of Article 6.11.7.

Article 5.9.3.

Quarantine facility infrastructure design and equipment

1) The construction or location, and the operation of the quarantine facility should provide for strict segregation and isolation of quarantined animals from other animals and from personnel not essential to the operation of the quarantine.
Chapter 5.9.- Quarantine measures applicable to non-human primates

2) Methods to attain this isolation include:
   a) The use of security measures such as physical barriers and procedural access control systems.
   b) As part of the security system, a hazard warning sign should be posted at the entrance to the quarantine stating that exposure to infectious diseases may occur in the quarantine. The names and telephone numbers of contact persons responsible for the quarantine area should be provided, and all special requirements for entering the quarantine area should be listed.
   c) The implementation of an effective rodent, feral animal, and insect control programme, which does not pose a health risk to the quarantined animals.
   d) The complete physical separation of groups of quarantined animals from other groups of quarantined animals to prevent exposure to and the introduction of infectious agents from one group to another during the quarantine period. As a rule, only animals arriving in one shipment from the same exporter should be grouped together. Animals may not be exchanged between groups or groups mixed during the quarantine period, unless the newly formed group restarts the entire quarantine process.

3) The quarantine facility should be designed to allow for the secure holding of quarantined animals and to allow for the safe, easy and efficient cleaning and decontamination of the animal holding area and the access area during and after use.
   a) A quarantine facility should consist of a minimum of two discrete areas physically separated from the outside and from each other, including an access area where clothes, footwear and protective articles are changed, and where locker, hand-washing and, if possible, showering facilities are provided. Procedures should be in place to prevent the cross-contamination of clothes and footwear worn outside the quarantine facility from potentially contaminated protective clothing worn inside the animal holding area.
   b) Animal holding room wall, floor, and ceiling surfaces should be water resistant to facilitate cleaning and disinfecting. Any holes or penetrations in these surfaces should be sealed or be capable of being sealed to facilitate fumigation or space decontamination. Doors to animal rooms should open inward, and should always be kept closed when animals are present. Any windows should be closed and sealed, unless the facility is sufficiently separated (distance, fences, other means of separation) from non-quarantined area.
   c) In facilities that are operated with the windows closed and sealed, a ventilation system should be operated and monitored in such a manner to assure the provision of an optimal isolation of these animals, while also providing for their health and comfort. The direction of the airflow in the quarantine facility should be inward from the outside of the quarantine facility, to quarantine access areas, to animal holding rooms. Air exhausted or re-circulated within the facility must be filtered. In addition, exhaust air should be dispersed away from the building and other occupied areas. Heating, ventilating, and air-conditioning systems should be designed so that their operation can be continued, even at reduced capacity in the event of electrical or other support system failure.
   d) If floor drains are present, their drain traps should always be filled with water or a suitable disinfectant.
   e) A hand washing sink should be available in the animal holding room for personnel usage.
   f) Adequate equipment and space should be available both in the animal holding area and in the quarantine facility in general for the adequate decontamination and the proper disposal or processing and storing of all supplies and equipment used in the quarantine.

Article 5.9.4.

Personnel protection practices

1) Eating, drinking, smoking and storing of food for human use should not be permitted in the quarantine facility.
2) All staff entering the quarantine should wear (preferably disposable) protective clothing and devices.
3) Protective clothing, gloves, and mucus membrane protection should not be used in more than one quarantine animal holding room. This may require the changing of protective clothing by staff as they go between rooms in the performance of their duties.
4) Foot or shoe baths should be provided and used at the exits of the animal holding area and of each animal holding room. They should be changed often enough to remain fresh and free of organic matter.
5) Showering after contact with non-human primates, their body waste or secretions or at a minimum before leaving the quarantine facility is highly recommended.
6) Intermittent and frequent hand washing while working in the quarantine facility is highly recommended. This is especially important as protective gloves may become inadvertently torn or ruptured.
7) Baseline serum samples from quarantine personnel should be collected and stored. Additional serum samples may be collected periodically, as an aid to epidemiological investigations.
Chapter 5.9.- Quarantine measures applicable to non-human primates

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

Article 5.9.5.

Husbandry and animal care practices

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

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

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

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

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

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

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

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

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

9) After animals are removed from quarantine, a thorough decontamination of the animal holding room is necessary whether there is a history of communicable disease presence in the room or not.
CHAPTER 5.10.

MODEL VETERINARY CERTIFICATES
FOR INTERNATIONAL TRADE IN
LIVE ANIMALS, HATCHING EGGS AND
PRODUCTS OF ANIMAL ORIGIN

Article 5.10.1.

Notes for guidance on the veterinary certificates for international trade in live animals, hatching eggs and products of animal origin

1. General

Please complete the certificate on paper in capitals. To confirm an option, mark the box with a cross (X). Ensure that no portion of certificate is left blank in a manner that would allow it to be amended. Non-applicable fields may be crossed out.

2. Part I. Details of dispatched consignment

| Box I.1. | Name and full address of the natural or legal person dispatching the consignment. Information on telephone and fax numbers or e-mail address is recommended. |
| Box I.2. | The certificate reference number is the number used by the Veterinary Authority of the country to identify the certificate. |
| Box I.3. | Name of the Veterinary Authority. |
| Box I.4. | Name and full address of the natural or legal person to whom the consignment is destined at the time the certificate is issued. |
| Box I.5. | Name of the country from which the animals, hatching eggs, embryos, semen, ova or brood combs are being exported. For products, name the country(ies) where the finished products were produced, manufactured or packed. |
| "ISO code" refers to the international standard two-letter code (ISO 3166-1 Alpha-2 Code) for a country produced by the International Organization for Standardization. |
| Box I.6. | Name of the zone or compartment of origin, if relevant, in part II of the certificate. |
| Box I.7. | Name of the country of destination. "ISO code" refers to the international standard two-letter code (ISO 3166-1 Alpha-2 Code) for a country produced by the International Organization for Standardization. |
| Box I.8. | Name of the zone or compartment of destination, if relevant, in part II of the certificate. |
| Box I.9. | Name and full address of the place(s) from which the animals or products are being exported; and official approval or registration number when required. |
| For animals and hatching eggs: the establishment(s), wildlife or hunting reserves. |
| For semen: the artificial insemination centre. |
| For embryos and ova: the name, address and official approval number of the collection team (not the premises of storage). |
**Chapter 5.10.- Model veterinary certificates for international trade in live animals, hatching eggs and products of animal origin**

<table>
<thead>
<tr>
<th>Box I.9. (contd)</th>
<th>For products of animal origin: the premises from which the products are to be dispatched.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Box I.10.</td>
<td>Name of the place from which the animals or products are being shipped (this will be a land, sea or airport).</td>
</tr>
<tr>
<td>Box I.11.</td>
<td>Date of departure. For animals include the expected time of departure.</td>
</tr>
<tr>
<td>Box I.12.</td>
<td>Details of the means of transport. Identification of the means of transport at the time the certificate is issued: for air transport, the flight number; for maritime transport, the name of the vessel; for rail transport, the number of the train and the wagon and for road transport, the registration number of the road vehicle and the number of the trailer where used.</td>
</tr>
<tr>
<td>Box I.14.</td>
<td>CITES permit number(s) if the commodity concerns species listed in the Convention on International Trade in Endangered Species of Wild Fauna and Flora.</td>
</tr>
<tr>
<td>Box I.15.</td>
<td>Describe the commodity or use the titles as they appear in the Harmonised System of the World Customs Organization.</td>
</tr>
<tr>
<td>Box I.16.</td>
<td>Heading or HS Code of the Harmonized System set up by the World Customs Organization.</td>
</tr>
<tr>
<td>Box I.17.</td>
<td>Total quantity of the commodity. For animals, hatching eggs and animal products (semen, ova, embryos) give the total count of animals, eggs or straws. For products give the gross weight and the net weight in kg of the whole consignment.</td>
</tr>
<tr>
<td>Box I.18.</td>
<td>Temperature of products for transport and storage.</td>
</tr>
<tr>
<td>Box I.19.</td>
<td>Total number of boxes, cages or stalls in which the animals or hatching eggs are being transported. Total number of cryogenic containers for semen, ova, embryos. Total number of packages for products.</td>
</tr>
<tr>
<td>Box I.20.</td>
<td>Identify the containers/seal numbers where required.</td>
</tr>
<tr>
<td>Box I.21.</td>
<td>Identify the type of packaging of products as defined in Recommendation No. 21 – Code of Passengers, Type of Cargo, Package and Packaging Materials of UN/CEFACT (United Nation Centre for Trade Facilitation and Electronic Business).</td>
</tr>
<tr>
<td>Box I.22.</td>
<td>Intended use of the imported animals or products. Breeding/rearing: applies to animal for breeding or rearing and hatching eggs. Slaughter: applies to animal for slaughter. Wildlife management: applies to wildlife for the purpose of managing populations. Pet: applies to animals kept for companionship or enjoyment. This excludes livestock species. Exhibition/education: applies to animals exhibited in zoos, circuses or sporting activities or for educational purposes. Human consumption: applies to products intended for human consumption. Animal feed: means any product of animal origin (single or multiple), whether processed, semi-processed or raw, which is intended to be fed to animals. Further processing: applies to products of animal origin which have to be further processed before being suitable for end use. Technical use: applies to products not intended for human or animal consumption. These include animal products that are intended for use in the pharmaceutical, medical, cosmetic and other industries. Such products may be subjected to extensive further processing. Other: intended for purposes not listed elsewhere in this classification.</td>
</tr>
</tbody>
</table>
### Chapter 5.10. - Model veterinary certificates for international trade in live animals, hatching eggs and products of animal origin

#### Box I.23.
Mark, if appropriate.

#### Box I.24.
Details on the nature of the commodity sufficient to identify it.

For animals and hatching eggs: Species (scientific name); Identification system; Identification number or other identification details; Quantity and if required, Breed / Category (e.g. heifer, steer, layer, broiler); Age; Sex. For animals holding an official passport, the international animal passport number should be provided, and a copy of the details on the passport attached to the certificate.

For embryos, ova and semen: Species (Scientific name); Identification mark according to the International Embryo Transfer Society (IETS) or the International Committee for Animal Recording (ICAR); Collection date; Approval number of the centre/team; Identification of the donor animal; Quantity; If required, Breed.

For bees and brood combs: Category means hive with bees, swarm, consignment of bees (worker bees, drones), queen bees, brood-combs, royal cells, etc. Identification details include peculiarities (e.g. Marks or age or weight or surface). Breed / Variety if required.

For products of animal origin: Species (Scientific name); Nature of commodity; Treatment type; approval number of establishment(s) (e.g. abattoir; cutting plant; processing plant; cold store); Lot identification/date code; Quantity; Number of packages; Net weight.

#### 3. Part II. Zoosanitary information

| Box II. | Complete this part in accordance with the requirements agreed between the Veterinary Authorities of the importing and exporting countries in accordance with the recommendations in the Terrestrial Code. |
| Box II.a. | Reference number: see box I.2. |
| Official veterinarian | Name, address, official position, date of signature and official stamp of the Veterinary Services. |
**Article 5.10.2.**

**Model veterinary certificate for international trade in live animals and hatching eggs**

**COUNTRIES:**

| Part I: Details of dispatched consignment                                                                 |
|--------------------------------------------------|--------------------------------------------------|
| Name:                                            |                                                 |
| Address:                                         | I.3. Veterinary Authority:                      |
|                                                 |                                                 |
| I.4. Consignee:                                  |                                                 |
| Name:                                            |                                                 |
| Address:                                         |                                                 |
|                                                 |                                                 |
| I.5. Country of origin:                          | I.6. Zone or compartment of origin**:            |
| ISO Code*:                                      |                                                 |
| I.7. Country of destination:                     | I.8. Zone or compartment of destination**:       |
| ISO Code*:                                      |                                                 |
| I.9. Place of origin:                            |                                                 |
| Name:                                            |                                                 |
| Address:                                         |                                                 |
| I.10. Place of shipment:                         | I.11. Date of departure:                        |
| I.12. Means of transport:                        |                                                 |
| Aeroplane ☐                                      | I.13. Expected border post:                     |
| Ship ☐                                           |                                                 |
| Railway wagon ☐                                  | I.14. CITES permit No(s)**:                     |
| Road vehicle ☐                                   |                                                 |
| Other ☐                                          |                                                 |
| Identification:                                  |                                                 |

**Part II: Description of commodity:**

|                                                 | I.17. Total quantity:                          |

**I.18.**

| I.19. Total number of packages:                   | I.20. Identification of container/seal number: |
|                                                 |                                                |

**I.21.**

| I.22. Commodities intended for use as:            |
| Breeding/rearing ☐                                |
| Competition ☐                                    |
| Slaughter ☐                                      |
| Wildlife management ☐                            |
| Pets ☐                                           |
| Exhibition/education ☐                           |
| Other ☐                                          |

**I.23. For import or admission:**

| Definitive import ☐                              |
| Re-entry ☐                                      |
| Temporary admission ☐                           |

**I.24. Identification of commodities:**

| Species (Scientific name): Breed*/Category*:      |
| Identification system:                           |
| Identification number/details:                   |
| Age*:                                            |
| Sex*:                                            |
| Quantity:                                        |

* Optional.

**If referenced in Part II.**
Chapter 5.10.- Model veterinary certificates for international trade in live animals, hatching eggs and products of animal origin

COUNTRIES:

<table>
<thead>
<tr>
<th>Part II. Zoosanitary information</th>
<th>II.a. Certificate reference number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>The undersigned Official Veterinarian certifies that the animal(s)/hatching egg(s) described above satisfy(ies) the following requirements:</td>
<td></td>
</tr>
</tbody>
</table>

Official Veterinarian:  
Name and address (in capital letters):  
Official position:  
Date:  
Signature:  
Stamp:  

### Article 5.10.3.

**Model veterinary certificate for international trade in embryos, ova and semen**

### COUNTRIES:

| Part I: Details of dispatched consignment |  |
|-----------------------------------------|  |
| Name:                                   | I.3. Veterinary Authority: |
| Address:                                |  |
| I.4. Consignee:                         |  |
| Name:                                   |  |
| Address:                                |  |
| I.9. Place of origin: Name:             |  |
| Address:                                |  |
| I.10. Place of shipment:                | I.11. Date of departure: |
| Aeroplane □ Ship □ Railway wagon □      | I.14. CITES permit No(s)**: |
| Road vehicle □ Other □ Identification: |  |
| I.18. Temperature of the product:       | I.17. Total quantity: |
| Ambient □ Chilled □ Frozen □           | I.19. Total number of packages: |
| I.20. Identification of container/seal number: | I.21. Type of packaging: |
| I.22. Commodities intended for use as:  |  |
| Human consumption □ Animal feed □ Other □ |  |
| Further processing □ Technical use □   |  |
| I.23.                                  |  |
| I.24. Identification of commodities:   |  |
| Species (Scientific name): Nature of commodity*: Treatment type: |
| Approval of number of establishments:  |  |
| Number of packages: Net weight: Lot ID/date code: |  |

* Optional.

** If referenced in Part II.
**COUNTRIES:**

<table>
<thead>
<tr>
<th>Part II: Zoosanitary information</th>
<th>II.a. Certificate reference number:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The undersigned Official Veterinarian certifies that the embryos, ova and semen described above satisfy(ies) the following requirements:</td>
</tr>
</tbody>
</table>
Chapter 5.10.- Model veterinary certificates for international trade in live animals, hatching eggs and products of animal origin

Article 5.10.4.

Model veterinary certificate for international trade in products of animal origin

COUNTRIES:

<table>
<thead>
<tr>
<th>Part I: Details of dispatched consignment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Consignor:</td>
</tr>
<tr>
<td>Name:</td>
</tr>
<tr>
<td>Address:</td>
</tr>
<tr>
<td>2. Certificate reference number:</td>
</tr>
<tr>
<td>3. Veterinary Authority:</td>
</tr>
<tr>
<td>4. Consignee:</td>
</tr>
<tr>
<td>Name:</td>
</tr>
<tr>
<td>Address:</td>
</tr>
<tr>
<td>5. Country of origin:</td>
</tr>
<tr>
<td>ISO Code*:</td>
</tr>
<tr>
<td>6. Zone or compartment of origin**:</td>
</tr>
<tr>
<td>7. Country of destination:</td>
</tr>
<tr>
<td>ISO Code*:</td>
</tr>
<tr>
<td>8. Zone or compartment of destination**:</td>
</tr>
<tr>
<td>9. Place of origin:</td>
</tr>
<tr>
<td>Name:</td>
</tr>
<tr>
<td>Address:</td>
</tr>
<tr>
<td>10. Place of shipment:</td>
</tr>
<tr>
<td>11. Date of departure:</td>
</tr>
<tr>
<td>12. Means of transport:</td>
</tr>
<tr>
<td>Aeroplane □ Ship □ Railway wagon □</td>
</tr>
<tr>
<td>Road vehicle □ Other □</td>
</tr>
<tr>
<td>Identification:</td>
</tr>
<tr>
<td>13. Expected border post:</td>
</tr>
<tr>
<td>14. CITES permit No(s)**:</td>
</tr>
<tr>
<td>15. Description of commodity:</td>
</tr>
<tr>
<td>16. Commodity code (HS code):</td>
</tr>
<tr>
<td>17. Total quantity:</td>
</tr>
<tr>
<td>18. Temperature of the product:</td>
</tr>
<tr>
<td>Ambient □ Chilled □ Frozen □</td>
</tr>
<tr>
<td>19. Total number of packages:</td>
</tr>
<tr>
<td>20. Identification of container/seal number:</td>
</tr>
<tr>
<td>21. Type of packaging:</td>
</tr>
<tr>
<td>22. Commodities intended for use as:</td>
</tr>
<tr>
<td>Human consumption □ Animal feed □</td>
</tr>
<tr>
<td>Technical use □ Other □</td>
</tr>
<tr>
<td>Further processing □</td>
</tr>
<tr>
<td>23.</td>
</tr>
<tr>
<td>24. Identification of commodities:</td>
</tr>
<tr>
<td>Species (Scientific name):</td>
</tr>
<tr>
<td>Nature of the commodity:</td>
</tr>
<tr>
<td>Treatment type:</td>
</tr>
<tr>
<td>Approval number of establishments:</td>
</tr>
<tr>
<td>Number of packages:</td>
</tr>
<tr>
<td>Net weight:</td>
</tr>
<tr>
<td>Lot ID/date code:</td>
</tr>
</tbody>
</table>

* Optional.

** If referenced in Part II.
COUNTRIES:

<table>
<thead>
<tr>
<th>Part II. Zoosanitary information</th>
<th>II.a. Certificate reference number:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The undersigned Official Veterinarian certifies that the product(s) of animal origin described above satisfy(ies) the following requirements:</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Official Veterinarian:</td>
<td>Official position:</td>
</tr>
<tr>
<td>Name and address (in capital letters):</td>
<td>Official position:</td>
</tr>
<tr>
<td>Date:</td>
<td>Signature:</td>
</tr>
<tr>
<td>Stamp:</td>
<td></td>
</tr>
</tbody>
</table>
### Article 5.10.5.

**Model veterinary certificate for international trade in bees and brood combs**

**COUNTRIES:**

<table>
<thead>
<tr>
<th>Part I: Details of dispatched consignment</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>I.1. Consignor:</strong></td>
<td><strong>I.2. Certificate reference number:</strong></td>
</tr>
<tr>
<td>Name:</td>
<td><strong>I.3. Veterinary Authority:</strong></td>
</tr>
<tr>
<td>Address:</td>
<td></td>
</tr>
<tr>
<td><strong>I.4. Consignee:</strong></td>
<td></td>
</tr>
<tr>
<td>Name:</td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td></td>
</tr>
<tr>
<td><strong>I.5. Country of origin:</strong></td>
<td><strong>I.6. Zone or compartment of origin</strong>:</td>
</tr>
<tr>
<td>ISO Code*:</td>
<td></td>
</tr>
<tr>
<td><strong>I.7. Country of destination:</strong></td>
<td><strong>I.8. Zone or compartment of destination</strong>:</td>
</tr>
<tr>
<td>ISO Code*:</td>
<td></td>
</tr>
<tr>
<td><strong>I.9. Place of origin:</strong></td>
<td><strong>I.10. Place of shipment:</strong></td>
</tr>
<tr>
<td>Name:</td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td></td>
</tr>
<tr>
<td><strong>I.11. Date of departure:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>I.12. Means of transport:</strong></td>
<td><strong>I.13. Expected border post:</strong></td>
</tr>
<tr>
<td>Aeroplane □ Ship □ Railway wagon □</td>
<td><strong>I.14. CITES permit No(s)</strong>:</td>
</tr>
<tr>
<td>Road vehicle □ Other □ Identification:</td>
<td></td>
</tr>
<tr>
<td><strong>I.15. Description of commodity:</strong></td>
<td><strong>I.16. Commodity code (HS code):</strong></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>I.17. Total quantity:</strong></td>
<td><strong>I.18.</strong></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>I.19. Total number of packages:</strong></td>
<td><strong>I.20. Identification of container/seal number:</strong></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>I.21.</strong></td>
<td></td>
</tr>
<tr>
<td><strong>I.22. Commodities intended for use as:</strong></td>
<td>Other □</td>
</tr>
<tr>
<td>Breeding/rearing □ Other □ Identification:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>I.23.</strong></td>
<td></td>
</tr>
<tr>
<td><strong>I.24. Identification of commodities:</strong></td>
<td></td>
</tr>
<tr>
<td>Category: Breed<em>Variety</em>: Identification details:</td>
<td></td>
</tr>
<tr>
<td>Quantity:</td>
<td></td>
</tr>
</tbody>
</table>

* Optional.

**If referenced in Part II.**
### Part II. Zoosanitary information

<table>
<thead>
<tr>
<th>II.a. Certificate reference number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>The undersigned Official Veterinarian certifies that the bee(s)/brood comb(s) described above satisfy(ies) the following requirements:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Official Veterinarian:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name and address (in capital letters):</td>
</tr>
<tr>
<td>Date:</td>
</tr>
<tr>
<td>Stamp:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Official position:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signature:</td>
</tr>
</tbody>
</table>
CHAPTER 5.11.

MODEL

VETERINARY CERTIFICATE FOR
INTERNATIONAL MOVEMENT OF
DOGS, CATS AND FERRETS
ORIGINATING FROM COUNTRIES
CONSIDERED INFECTED WITH RABIES

I. OWNER
Name and address: ...................................................................................................................................................
..................................................................................................................................................................................
..................................................................................................................................................................................
..................................................................................................................................................................................

II. DESCRIPTION
Species of animal: ..................................................................................................................................................
Age or date of birth: ..................................................................................................................................................
Sex: ...........................................................................................................................................................................
Breed: .......................................................................................................................................................................
Colour: ......................................................................................................................................................................
Coat type and marking/Distinguishing marks: ...........................................................................................................
..................................................................................................................................................................................
..................................................................................................................................................................................
..................................................................................................................................................................................
Identification number, location on the animal and date of marking (see note 1)

III. ADDITIONAL INFORMATION
Country of origin: ..................................................................................................................................................
..................................................................................................................................................................................
Countries visited over the past six months as declared by the owner (give dates) ..................................................
..................................................................................................................................................................................
..................................................................................................................................................................................
IV. VACCINATION (Rabies)

I the undersigned declare herewith that I have vaccinated the animal described in Part II, or I have seen evidence that the animal has been vaccinated against rabies as shown below.

<table>
<thead>
<tr>
<th>Date of vaccination (dd/mm/yy)</th>
<th>Name of vaccine (see note 2)</th>
<th>1. Manufacturing laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1. ...........................</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. ...........................</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. ...........................</td>
</tr>
</tbody>
</table>

**PERIOD OF VALIDITY OF VACCINATION FOR INTERNATIONAL MOVEMENT**

(see note 3)

<table>
<thead>
<tr>
<th>Name (in capital letters) and signature of the Certifying Veterinarian (see note 6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>from (dd/mm/yy) to (dd/mm/yy)</td>
</tr>
</tbody>
</table>

V. SEROLOGICAL TESTING (Rabies)

I the undersigned declare herewith that a blood sample has been taken from the animal described in Part II with the following result from the official diagnostic laboratory which carried out the antibody titration test (see note 4).

<table>
<thead>
<tr>
<th>Date of sampling (dd/mm/yy)</th>
<th>Name and address of the official diagnostic laboratory</th>
<th>Result of the antibody titration test (in International Units [IU/ml])</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**PERIOD OF VALIDITY OF SEROLOGICAL TESTING FOR INTERNATIONAL MOVEMENT**

(see note 4)

<table>
<thead>
<tr>
<th>Name (in capital letters) and signature of the Certifying Veterinarian (see note 6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>from (dd/mm/yy) to (dd/mm/yy)</td>
</tr>
</tbody>
</table>
VI. CLINICAL EXAMINATION (Rabies)

I, the undersigned, declare herewith that I have examined the animal described in Part II on the date indicated below, or that I have seen evidence that the animal was examined on that date, and that the animal was found to be free from clinical signs of rabies (see note 5).

### NOTE

1) The identification should be by a permanent marking. The identification number stated in the certificate should be identical to that on the animal. When electronic identification is used, the type of microchip and the name of the manufacturer should be specified.

2) Only vaccines produced in compliance with the recommendations of the Terrestrial Manual should be used.

3) Vaccination or re-vaccination should be carried out in accordance with the recommendations of the manufacturer.

4) When serological testing is required, the animal should have been subjected not less than 3 months and not more than 12 months prior to its introduction into the importing country, to an antibody titration test carried out by an official diagnostic laboratory approved by the Competent Authority of the exporting country, as prescribed in the Terrestrial Manual with a positive result of at least 0.5 IU.

5) The clinical examination referred to in Part VI of the certificate must be carried out as per the requirements in Chapter 8.11.

The Competent Authority of the importing country may require the placing of the animals which do not comply with any of the above-mentioned conditions in a quarantine station located on its territory; the conditions of stay in quarantine are laid down by the legislation of the importing country.

6) The certification should be undertaken in accordance with Chapters 5.1. and 5.2.

7) If so required, the certificate should be written in the language of the importing country. In such circumstances, it should also be written in a language understood by the certifying veterinarian.
CHAPTER 5.12.

MODEL PASSPORT FOR INTERNATIONAL MOVEMENT OF COMPETITION HORSES

INTRODUCTION

The object is to establish criteria which will assist in the unrestricted movement of competition horses between countries or zones of countries, while still protecting the health status of the respective countries or zones. To achieve this aim, it is intended that the passport of any competition horse shall serve as a unique identification document including harmonised information in the form of records of vaccinations and results of laboratory tests.

In addition to the passport, a separate veterinary certificate may be required by the importing country.

CONTENTS OF THE PASSPORT

The passport should contain:

1. **Details of ownership**
   Information regarding the name and address of the owner of the horse should be indicated according to Appendix A, and be authenticated by the National Federation issuing the passport.

2. **Identification of the horse**
   The horse should be identified by the competent authority according to Appendices B and C.

3. **Movement records**
   The identification of the horse should be checked at each time it is required by rules and regulations and recorded in accordance with Appendix D.

4. **Vaccination record**
   All vaccinations should be recorded according to Appendix E (equine influenza only) and Appendix F (all other vaccinations).

5. **Laboratory health tests**
   The result of every test undertaken for a transmissible disease will be recorded according to Appendix G.

BASIC HEALTH REQUIREMENTS

Appendix H is a document which outlines the basic health requirements which apply to the international movement of competition horses.

For the movement of competition horses between countries or zones of countries with a different health status, Veterinary Services may require additional veterinary certification.

The reverse side of Appendix H lists diseases which may be considered for inclusion in the veterinary certificate.
## Appendix A

<table>
<thead>
<tr>
<th>Propriétaires successifs</th>
<th>Details of ownership</th>
<th>Detalles del propietario</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. La nationalité du cheval est celle de son propriétaire.</td>
<td>1. The nationality of the horse is that of its owner.</td>
<td>1. La nacionalidad del caballo es la nacionalidad de su propietario.</td>
</tr>
<tr>
<td>2. Lors de tout changement de propriétaire, le passeport doit être immédiatement retourné, en mentionnant le nom et l'adresse du nouveau propriétaire, à la Fédération équestre nationale, qui le remettra au nouveau propriétaire après enregistrement.</td>
<td>2. On change of ownership the passport must immediately be lodged with the National Equestrian Federation, giving the name and address of the new owner, for re-registration and forwarding to the new owner.</td>
<td>2. En caso de cambio de propietario, el pasaporte debe ser entregado inmediatamente, indicando el nombre y la dirección del nuevo propietario, a la Federación Ecuestre Nacional, que lo remitirá al nuevo propietario después de haberlo registrado.</td>
</tr>
<tr>
<td>3. S'il y a plus d'un seul propriétaire, ou si le cheval appartient à une société, on indiquera dans le passeport le nom de la personne responsable du cheval et sa nationalité. Si les propriétaires sont de nationalités différentes, ils doivent préciser la nationalité du cheval.</td>
<td>3. If there is more than one owner or the horse is owned by a company, then the name of the individual responsible for the horse shall be entered in the passport together with his nationality. If the owners are of different nationalities, they have to determine the nationality of the horse.</td>
<td>3. Si el caballo tiene más de un propietario, o si pertenece a una sociedad, el nombre y la nacionalidad de la persona responsable del caballo deben inscribirse en el pasaporte. Si los propietarios son de diferente nacionalidad, deben precisar la nacionalidad del caballo.</td>
</tr>
<tr>
<td>4. Lorsqu'il y a location du cheval, dûment enregistrée par une Fédération équestre internationale avec accord de la Fédération équestre internationale, celle-ci doit être mentionnée sur cette page par cette Fédération nationale.</td>
<td>4. When the Federation Equestre Internationale approves the leasing of a horse by a National Equestrian Federation, the details of these transactions must be recorded on this page by the National Equestrian Federation concerned.</td>
<td>4. Cuando la Federación Ecuestre Internacional aprueba el alquiler de un caballo por una Federación Ecuestre Nacional, la Federación Ecuestre Nacional debe registrar los detalles de la transacción en esta página.</td>
</tr>
<tr>
<td>Date d'enregistrement par la Fédération équestre nationale</td>
<td>Nom du propriétaire</td>
<td>Adresse du propriétaire</td>
</tr>
<tr>
<td>-------------------------------------------------------------</td>
<td>---------------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>Date of registration by the National Equestrian Federation</td>
<td>Name of owner</td>
<td>Address of owner</td>
</tr>
<tr>
<td>Fecha de registro por la Federación Ecuestre Nacional</td>
<td>Nombre del propietario</td>
<td>Dirección del propietario</td>
</tr>
</tbody>
</table>
# Appendix B

(1) N° d'identification :
Identification No.:
N° de identificación:

(2) Nom : (3) Sexe : (4) Robe :
Name: Sex: Colour:
Nombre: Sexo: Color:

(5) Race : (6) par : (7) et : (8) par :
Breed: by: out of: by:
Raza: por: y: por:

(9) Date de naissance :
Date of foaling:
N° de identificación:

(10) Lieu d'élevage :
Place where bred:
Lugar de cria

(11) Naisseur(s) :
Breeder(s):
Criador(es):
| (12) Certificat d'origine validé le : | Origin certificate validated on: |
| par : | by: |
| -Nom de l'autorité compétente : | Name of the competent authority: |
| Nombre de la autoridad competente: | |
| Adresse : | Address: |
| Dirección: | |
| -N° de téléphone : - N° de télécopie : | Telephone No.: - Telecopy No.: |
| N° de teléfono: - N° de fax: | |
| -Signature : | (Name in capital letters and capacity of signatory) |
| -Signature: | |
| -Cachet | Stamp |
| Sello | |
Appendix C

(12) Côté droit
Right side
Lado derecho

(13) Côté gauche
Left side
Lado izquierdo

(14) Ligne superieur
dos yeux
Upper eye level
Linea superior
de los ojos

(15) Antérior
Vue antérieure
Post - rear view
Membres antérieurs
Vista anterior

(16) Vue inférieure
Nick
Lower view
Cuello
Vista inferior

(17) Nuee
Muscle
Muscle

(18) Vue postérieure
Post - rear view
Membres postérieurs
Vista posterior
<table>
<thead>
<tr>
<th>(2) Nom:</th>
<th>(5) Race:</th>
<th>(3) Sexe:</th>
<th>(4) Robe:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
<td>Breed:</td>
<td>Sex:</td>
<td>Colour:</td>
</tr>
<tr>
<td>Nombre:</td>
<td>Raza:</td>
<td>Sexo:</td>
<td>Color:</td>
</tr>
</tbody>
</table>

(19) Signalement relevé sous la mère par:
Description taken with dam by:
Descripción registrada con la madre por:

Tête:
Head:
Cabeza:


Corps:  
Body:  
Cuerpo:  

(21) Signature et cachet du vétérinaire agréé  
(or de l'autorité compétente)  
Signature and stamp of qualified veterinary surgeon  
(or competent authority)  

Marques:
Markings:  
Marcas:  

Fait le (date):  
Made on (date):  
A (fecha):  

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### Appendix D

<table>
<thead>
<tr>
<th>Date</th>
<th>Ville et pays</th>
<th>Motif du contrôle (concours, certificat sanitaire, etc.)</th>
<th>Signature, nom en lettres capitales et position de la personne ayant vérifié l'identité</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>Town and country</td>
<td>Purpose of control (event, veterinary certificate, etc.)</td>
<td>Signature, name (in capital letters) and status of official verifying the identification</td>
</tr>
<tr>
<td>Fecha</td>
<td>Ciudad y país</td>
<td>Motivo del control (concurso, certificado sanitario, etc)</td>
<td>Firma, nombre (en letras mayúsculas) y calidad de la persona que controla la identidad</td>
</tr>
</tbody>
</table>

The identity of the horse must be checked each time it is required by the rules and regulations and certified that it conforms with the description given on the diagram page of this passport.

Se controlará la identidad del caballo cada vez que lo exijan las leyes y reglamentos, y se certificará, firmando esta página, que el caballo presentado corresponde al caballo descrito en este pasaporte.
### Appendix E

<table>
<thead>
<tr>
<th>Date</th>
<th>Lieu</th>
<th>Pays</th>
<th>Vaccin/Vaccine/Vacuna</th>
<th>Nom en lettres capitales et signature du vétérinaire</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>Place</td>
<td>Country</td>
<td>Name</td>
<td>Numéro de lot</td>
</tr>
<tr>
<td>Fecha</td>
<td>Lugar</td>
<td>País</td>
<td>Nombre</td>
<td>Batch number</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Número de lote</td>
</tr>
</tbody>
</table>

Toute vaccination subie par le cheval doit être portée dans le cadre ci-dessous de façon lisible et précise avec le nom et la signature du vétérinaire.

Details of every vaccination which the horse undergoes must be entered clearly and in detail, and certified with the name and signature of the veterinarian.

Todas las vacunas administradas al caballo, así como el nombre y la firma del veterinario, deben figurar de manera clara y detallada en el cuadro siguiente.
### Appendix F

**MALADIES AUTRES QUE LA GRIPPE ÉQUINE**  
Enregistrement des vaccinations

**DISEASES OTHER THAN EQUINE INFLUENZA**  
Vaccination record

**ENFERMEDADES DISTINTAS DE LA GRIPE EQUINA**  
Registro de vacunas

Toute vaccination subie par le cheval doit être portée dans le cadre ci-dessous de façon lisible et précise avec le nom et la signature du vétérinaire.

Details of every vaccination which the horse undergoes must be entered clearly and in detail, and certified with the name and signature of the veterinarian.

Todas las vacunas administradas al caballo, así como el nombre y la firma del veterinario, deben figurar de manera clara y detallada en el cuadro siguiente.

<table>
<thead>
<tr>
<th>Date</th>
<th>Lieu</th>
<th>Pays</th>
<th>Vaccin/Vaccine/Vacuna</th>
<th>Nom en lettres capitales et signature du vétérinaire</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Place</td>
<td>Country</td>
<td>Name (in capital letters) and signature of the veterinarian</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lugar</td>
<td>País</td>
<td>Numéro de lot</td>
<td>Nombre</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Batch number</td>
<td>Número de lote</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Maladie(s)</td>
<td>Enfermedad(es)</td>
</tr>
</tbody>
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</table>
Appendix G

<table>
<thead>
<tr>
<th>Date</th>
<th>Maladies transmissibles concernées</th>
<th>Nature de l'examen</th>
<th>Résultat de l'examen</th>
<th>Laboratoire officiel ayant analysé le prélèvement</th>
<th>Nom en lettres capitales et signature du vétérinaire</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>Transmissible diseases tested for</td>
<td>Type of test</td>
<td>Result of test</td>
<td>Official laboratory to which sample transmitted</td>
<td>Name (in capital letters) and signature of Veterinarian</td>
</tr>
<tr>
<td>Fecha</td>
<td>Enfermedades transmisibles examinadas</td>
<td>Tipo de examen</td>
<td>Resultado del examen</td>
<td>Laboratorio oficial que ha analizado la muestra</td>
<td>Nombre (en letras mayúsculas) y firma del veterinario</td>
</tr>
</tbody>
</table>

The result of every test undertaken for a transmissible disease by a veterinarian or a laboratory authorised by the Government Veterinary Service of the country must be entered clearly and in detail by the veterinarian acting on behalf of the authority requesting the test.

Le résultat de tout contrôle effectué par un vétérinaire pour une maladie transmissible ou par un laboratoire agréé par le Service vétérinaire gouvernemental du pays doit être noté clairement et en détail par le vétérinaire qui représente l'autorité demandant le contrôle.

El veterinario que representa a la autoridad que solicita el control sanitario debe inscribir en el cuadro siguiente, de manera clara y detallada, el resultado de cada control relativo a una enfermedad transmisible efectuado por un veterinario o por un Servicio Veterinario gubernamental.
Appendix H

EXIGENCES SANITAIRES DE BASE - BASIC HEALTH REQUIREMENTS - REQUISITOS SANITARIOS BÁSICOS

Je soussigné certifie(1) que le cheval décrit dans le passeport n° .......... délivré par .......... satisfait aux conditions suivantes :

I, the undersigned, certify(1) that the horse described in the Passport No. .......... issued by .......... meets the following requirements:

El que suscribe certifica(1) que el caballo descrito en el pasaporte n° .......... extendido por .......... cumple con los siguientes requisitos:

(a) il a été examiné ce jour, ne présente aucun signe clinique de maladie et est apte au transport ;

(a) it has been examined today, shows no clinical sign of disease and is fit for transport;

(a) ha sido examinado hoy, no presenta ningún signo clínico de enfermedad y se encuentra en condiciones de ser transportado;

(b) il n’est pas destiné à l’abattage dans le cadre d’un programme national d’éradication d’une maladie transmissible ;

(b) it is not intended for slaughter under a national programme of transmissible disease eradication;

(b) no ha sido destinado al sacrificio sanitario en el marco de un programa nacional de erradicación de una enfermedad transmisible;

(c) il ne provient pas d’une écurie mise en interdit pour des raisons zoosanitaires et n’a pas été en contact avec des équidés d’une écurie de ce type ;

(c) it does not come from a holding which was subject to prohibition for animal health reasons nor had contact with equidae from a holding which was subject to such prohibition;

(c) no procede de una cuadra sujeta a interdicción por razones zoosanitarias ni ha estado en contacto con équidos procedentes de una cuadra sujeta a interdicción;

(d) à ma connaissance, après avoir dûment enquêté, il n’a pas été en contact avec des équidés atteints d’une maladie transmissible au cours des 15 jours précédant l’embarquement.

(d) to the best of my knowledge and after due inquiry, it has not been in contact with equidae suffering from transmissible disease during 15 days prior to embarkation.

(d) según me consta, tras haber efectuado las indagaciones pertinentes, no ha estado en contacto con équidos afectados de enfermedades transmisibles durante los 15 días anteriores a su embarque.
LE PRÉSENT CERTIFICAT EST VALABLE 10 JOURS À COMPTER DE LA DATE DE SA SIGNATURE.
THIS CERTIFICATE IS VALID FOR 10 DAYS FROM THE DATE OF SIGNATURE.
EL PRESENTE CERTIFICADO ES VÁLIDO 10 DÍAS A PARTIR DE LA FECHA DE SU FIRMA.

<table>
<thead>
<tr>
<th>Date</th>
<th>Lieu</th>
<th>Pour des raisons épidémiologiques particulières, un certificat sanitaire séparé accompagne le présent passeport.</th>
<th>Nom en lettres capitales et signature du vétérinaire officiel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>Place</td>
<td>For special epizootic reasons a separate veterinary certificate accompanies this passport.</td>
<td>Name (in capital letters) and signature of official veterinarian</td>
</tr>
<tr>
<td>Fecha</td>
<td>Lugar</td>
<td>Por razones epidemiológicas particulares se adjunta al presente pasaporte un certificado sanitario.</td>
<td>Nombre en letras mayúsculas y firma del veterinario oficial</td>
</tr>
</tbody>
</table>

(1) Ce document doit être signé dans les 48 heures précédant le déplacement international du cheval.
(1) The document should be signed within the 48 hours prior to international movement of the horse.
(1) Este documento debe ser firmado 48 horas antes del desplazamiento internacional del caballo.
LIST OF DISEASES WHICH SHOULD BE CONSIDERED FOR INCLUSION IN THE VETERINARY CERTIFICATE WHICH ACCOMPANIES THE PASSPORT

1) African horse sickness
2) Vesicular stomatitis
3) Dourine
4) Glanders
5) Equine encephalomyelitis (all types)
6) Equine infectious anaemia
7) Rabies
8) Anthrax

For the movement of competition horses between countries or zones of countries with a different health status, Veterinary Services may require additional veterinary certification.
CHAPTER 5.13.
MODEL VETERINARY CERTIFICATES
FOR INTERNATIONAL TRADE IN
LABORATORY ANIMALS

Article 5.13.1.

Introduction and scope
Transportation of laboratory animals between institutes is a specialised and important activity supporting scientific research. The use, and transportation, of laboratory animals is essential to some types of medical and veterinary research.

The majority of laboratory animals used and transported are rats, mice, and fish. Other species, including guinea pigs, ferrets, gerbils, hamsters, rabbits, cats, dogs, pigs, amphibians, and a few species of non-human primates are used in relatively small numbers.

This chapter applies to all animals except bees.

Article 5.13.2.

Notes for guidance on the use of the veterinary certificate

1. General
Please complete the certificate on paper in capitals. To confirm an option, mark the box with a cross (X). Ensure that no portion of certificate is left blank in a manner that would allow it to be amended. Non-applicable fields may be crossed out.

2. Part I. Details of consignment for export

| Box I.1. | Name and full address of the natural or legal person dispatching the consignment. It is recommended to provide contact information, such as telephone and fax numbers or e-mail address. |
| Box I.2. | The certificate reference number used by the Veterinary Authority of the country issuing the certificate. |
| Box I.3. | Name of the Veterinary Authority. |
| Box I.4. | Name and full address of the natural or legal person to whom the consignment is destined. |
| Box I.5. | Name of the country from which the consignment is being exported. "ISO code" refers to the international standard two-letter code (ISO 3166-1 Alpha-2 Code) for a country produced by the International Organization for Standardization. |
| Box I.6. | Name of the zone or compartment of origin, if given in part III of the certificate (in accordance with Chapter 4.3. of the Terrestrial Code). |
| Box I.7. | Name of the country of destination. "ISO code" refers to the international standard two-letter code (ISO 3166-1 Alpha-2 Code) for a country produced by the International Organization for Standardization. |
| Box I.8. | Name of the zone or compartment of destination, if given in part III of the certificate (in accordance with Chapter 4.3 of the Terrestrial Code). |
Box I.9. Name and full address of the place(s) from which the animals are being exported; and official approval or registration number when required.

Box I.10. Name of the air, land or sea facility from which the consignment is being shipped.

Box I.11. Date of departure and, if known, expected time of departure.

Box I.12. Identify the means of transport if known at the time of issuance of the certificate. The flight number, airline and airport designation (for air transport). The name and address of the carrier (for road transport). The name and contact details of the emergency contact person.

Box I.13. Name of border post to which the consignment is directed. It is also recommended to provide the border post's United Nations Code for Trade and Transport Locations - see http://live.unece.org/cefact/locale/service/location.html.

Box I.14. If the species is listed in the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), provide permit number(s).

Box I.15. Description of animals. World Customs Organization HS Code, if known, see: www.wcoomd.org.

Box I.16. Total number of animals.

Box I.17. Temperature around the shipping container should generally be maintained in the range 10-28°C during shipment. For animals with different requirements, the specific temperature range should be listed here.

Box I.18. The total number of units (e.g. boxes, cages or stalls) in which the animals in the consignment are being transported.

Box I.19. Identification of the containers and seal numbers, if provided.

Box I.20. Details of the nature of the animals. Provide: species (scientific name); identification system; identification number or other relevant details; quantity and, if required, strain or stock designation, sex, and age or weight. When available, international designation conventions should be used, for example: http://www.informatics.jax.org/mghome/nomen/strains.shtml http://www.informatics.jax.org/mghome/nomen/gene.shtml. For animals with an official international animal passport, the passport number should also be provided.

3. Part II. Classification of pathogen free status

Box II. Conventional animals are those for which the presence or absence of specific microorganisms and parasites is unknown due to the absence of testing, treatment or vaccination. This category includes wild-caught animals and domestic animals maintained under uncontrolled microbiological conditions.

Specific Pathogen Free (SPF) animals are free of one or more parasites or infectious microorganisms. SPF animals can be further subdivided into two categories: Conditioned SPF animals have undergone testing, treatment and/or vaccination to ensure the absence of one or more parasites or microbial agents. The agents are most commonly of human or agricultural significance or are species-specific infectious agents that are capable of producing significant clinical disease or research effects.

Conditioned SPF animals are often not maintained in specialised housing to prevent introduction of other infectious agents and are usually shipped in unfiltered containers. Larger species such as nonhuman primates, dogs, and cats are often maintained as conditioned SPF animals. Barrier raised SPF animals have been raised in the absence of one or more parasites or microbial agents in specialised facilities to exclude these agents as well as agents of agricultural and human significance. Their pathogen free status has been established either by testing each individual animal or by sampling representative animals from the colony. Filtered SPF shipping containers are required for transport of these animals as are special procedures and equipment for packing, unpacking, and handling them. This subcategory also includes animals that are either axenic (microbe free) or possess only a few well defined species of microorganisms. They must be produced and maintained in a sterile environment (usually isolators) without contact with human, animal, or environmental commensal infectious microorganisms.
4. Part III. Zoosanitary information

<table>
<thead>
<tr>
<th>Box III.</th>
<th>Complete this part in accordance with the requirements agreed between the Veterinary Authorities of the importing and exporting countries in accordance with the recommendations in the Terrestrial Code. Attestation of fitness for transportation subject to any conditions or special requirements stated in the certificate.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Official veterinarian</td>
<td>Name, address, official position, date of signature and official stamp of the Veterinary Services for the country of export.</td>
</tr>
</tbody>
</table>
Article 5.13.3.

**Model veterinary certificate for international trade in laboratory animals**

**COUNTRIES:**

<table>
<thead>
<tr>
<th>Part I: Details of dispatched consignment</th>
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<tbody>
<tr>
<td>I.1. Consignor:</td>
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<tr>
<td>Name:</td>
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<tr>
<td>Address:</td>
<td></td>
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<tr>
<td>I.2. Certificate reference number:</td>
<td></td>
</tr>
<tr>
<td>I.3. Veterinary Authority:</td>
<td></td>
</tr>
<tr>
<td>I.4. Consignee:</td>
<td></td>
</tr>
<tr>
<td>Name:</td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td></td>
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<td>I.5. Country of origin:</td>
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<td>I.6. Zone or compartment of origin**:</td>
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<td>I.7. Country of destination:</td>
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<td>ISO Code*:</td>
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<td>I.8. Zone or compartment of destination**:</td>
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<td>I.9. Place of origin:</td>
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<td>Name:</td>
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<td>Address:</td>
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<tr>
<td>I.10. Place of shipment:</td>
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<td>I.11. Date of departure:</td>
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<td>I.12. Primary means of transport:</td>
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<td>Road vehicle □ Vessel □</td>
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<tr>
<td>I.13. Expected border post:</td>
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<td>I.14. CITES permit No(s)**:</td>
<td></td>
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<tr>
<td>I.15. Description of animals:</td>
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<tr>
<td>*HS Code if known:</td>
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<tr>
<td>I.16. Total number of animals:</td>
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<td>I.17. Temperature:</td>
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<tr>
<td>I.18. Total number of units:</td>
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</tr>
<tr>
<td>I.19. Identification of container/seal number:</td>
<td></td>
</tr>
<tr>
<td>I.20. Details of the nature of the animals and quantity of each:</td>
<td></td>
</tr>
<tr>
<td>Species (Scientific name):</td>
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<tr>
<td>Identification number/details:</td>
<td></td>
</tr>
<tr>
<td>Strain/Stock (use international designation if known)*:</td>
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<tr>
<td>Passport number(s) if issued*:</td>
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<tr>
<td>Age or weight:</td>
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<tr>
<td>Sex:</td>
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* Optional.

** If referenced in Part III.
### Part II. Zoosanitary Information

<table>
<thead>
<tr>
<th>II.a. Certificate reference number:</th>
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</table>

#### II. Pathogen Free Status

- Conventional:
- Conditioned SPF:
- Barrier raised SPF:
- Other - specify:

#### III. Fitness for transportation

The undersigned Official Veterinarian certifies that the consignment described above is fit for transport, subject to any conditions specified below, and that the animals satisfy the following zoosanitary requirements:

- Special conditions for transport: Yes ☐ No ☐

If there are special conditions for transport, provide complete information of these conditions.

Official Veterinarian:

- Name and address (in capital letters):
- Official position:
- Date:
- Signature:
- Stamp:
SECTION 6.

VETERINARY PUBLIC HEALTH

CHAPTER 6.1.

THE ROLE OF THE VETERINARY SERVICES IN FOOD SAFETY

Article 6.1.1.

Purpose

The purpose of this chapter is to provide guidance to Member Countries in regard to the role and responsibilities of the Veterinary Services in food safety, to assist them in meeting the food safety objectives laid down in national legislations and the requirements of importing countries.

Article 6.1.2.

Background

Historically, the Veterinary Services were set up to control livestock diseases at the farm level. There was an emphasis on prevention and control of the major epizootic diseases of livestock and of diseases that could affect man (zoonotic diseases). As countries begin to bring the serious diseases under control, the scope of official animal health services normally increases to address production diseases of livestock, where control leads to more efficient production and/or better quality animal products.

The role of the Veterinary Services has traditionally extended from the farm to the slaughterhouse, where veterinarians have a dual responsibility – epidemiological surveillance of animal diseases and ensuring the safety and suitability of meat. The education and training of veterinarians, which includes both animal health (including zoonoses) and food hygiene components, makes them uniquely equipped to play a central role in ensuring food safety, especially the safety of foods of animal origin. As described below, in addition to veterinarians, several other professional groups are involved in supporting integrated food safety approaches throughout the food chain. In many countries the role of the Veterinary Services has been extended to include subsequent stages of the food chain in the “farm to fork” continuum.

Article 6.1.3.

Approaches to food safety

1. The concept of the food production continuum

Food safety and quality are best assured by an integrated, multidisciplinary approach, considering the whole of the food chain. Eliminating or controlling food hazards at source, i.e. a preventive approach, is more effective in reducing or eliminating the risk of unwanted health effects than relying on control of the final product, traditionally applied via a final ‘quality check’ approach. Approaches to food safety have evolved in recent decades, from traditional controls based on good practices (Good Agricultural Practice, Good Hygienic Practice, etc.), via more targeted food safety systems based on hazard analysis and critical control points (HACCP) to risk-based approaches using food safety risk analysis.
2. Risk-based management systems

The development of risk-based systems has been heavily influenced by the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement"). This Agreement stipulates that signatories shall ensure that their sanitary and phytosanitary measures are based on an assessment of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by relevant international organizations. Risk assessment, the scientific component of risk analysis, should be functionally separated from risk management to avoid interference from economic, political or other interests. The SPS Agreement specifically recognises as the international benchmarks the standards developed by the OIE for animal health and zoonoses and by the Codex Alimentarius Commission for food safety. In recent decades there has also been a trend towards a redefinition of responsibilities. The traditional approach, whereby food operators were primarily held responsible for food quality while regulatory agencies were charged with assuring food safety, has been replaced by more sophisticated systems that give food operators primary responsibility for both the quality and the safety of the foods they place on the market. The role of the supervisory authorities is to analyse scientific information as a basis to develop appropriate food safety standards (both processing and end product standards) and verification inspections to ensure that the control systems used by food operators are appropriate, validated, effective and operated in such a way that the standards are met. In the event of non-compliance, regulatory agencies are responsible to ensure that appropriate corrective actions are taken and sanctions are applied.

The Veterinary Services play an essential role in the application of the risk analysis process and the implementation of risk-based recommendations for regulatory systems, including the extent and nature of veterinary involvement in food safety activities throughout the food chain, as outlined above. Each country should establish its health protection objectives, for animal health and public health, through consultation with stakeholders (especially livestock producers, processors and consumers) in accordance with the social, economic, cultural, religious and political contexts of the country. These objectives should be put into effect through national legislation and policies and steps taken to raise awareness of them both within the country and to trading partners.

3. Functions of Veterinary Services

The Veterinary Services contribute to the achievement of these objectives through the direct performance of some veterinary tasks and through the auditing of animal and public health activities conducted by other government agencies, private sector veterinarians and other stakeholders. In addition to veterinarians, several other professional groups are involved in ensuring food safety throughout the food chain, including analysts, epidemiologists, food technologists, human and environmental health professionals, microbiologists and toxicologists. Irrespective of the roles assigned to the different professional groups and stakeholders by the administrative system in the country, close cooperation and effective communication between all involved is imperative to achieve the best results from the combined resources. Where veterinary or other professional tasks are delegated to individuals or enterprises outside the Veterinary Authority, clear information on regulatory requirements and a system of checks should be established to monitor and verify performance of the delegated activities. The Veterinary Authority retains the final responsibility for satisfactory performance of delegated activities.

4. At the farm level

Through their presence on farms and appropriate collaboration with farmers, the Veterinary Services play a key role in ensuring that animals are kept under hygienic conditions and in the early detection, surveillance and treatment of animal diseases, including conditions of public health significance. The Veterinary Services may also provide livestock producers with information, advice and training on how to avoid, eliminate or control food safety hazards (e.g. drug and pesticide residues, mycotoxins and environmental contaminants) in primary production, including through animal feed. Producers' organisations, particularly those with veterinary advisors, are in a good position to provide awareness and training as they are regularly in contact with farmers and are well placed to understand their priorities. Technical support from the Veterinary Services is important and both private veterinarians and employees of the Veterinary Authority can assist. The Veterinary Services play a central role in ensuring the responsible and prudent use of biological products and veterinary drugs, including antimicrobials, in animal husbandry. This helps to minimise the risk of developing antimicrobial resistance and unsafe levels of veterinary drug residues in foods of animal origin. Chapters 6.7. to 6.10. contain recommendations on the use of antimicrobials.

5. Meat inspection

Slaughterhouse inspection of live animals (ante-mortem) and their carcasses (post-mortem) plays a key role in both the surveillance network for animal diseases and zoonoses and ensuring the safety and suitability of meat and by-products for their intended uses. Control and/or reduction of biological hazards of animal and public health
importance by ante- and post-mortem meat inspection is a core responsibility of the Veterinary Services and they should have primary responsibility for the development of relevant inspection programmes.

Wherever practicable, inspection procedures should be risk-based. Management systems should reflect international standards and address the significant hazards to both human and animal health in the livestock being slaughtered. The Codex Alimentarius Code of Hygienic Practice for Meat (CHPM) constitutes the primary international standard for meat hygiene and incorporates a risk-based approach to application of sanitary measures throughout the meat production chain. Chapter 6.2. contains recommendations for the control of biological hazards of animal health and public health importance through ante- and post-mortem meat inspection, which complement the CHPM.

Traditionally, the primary focus of the Terrestrial Code was on global animal health protection and transparency. Under its current mandate, the OIE also addresses animal production food safety risks. The Terrestrial Code includes several standards and recommendations aimed at protecting public health (such as Chapter 6.2. on the control of biological hazards of animal health and public health importance through ante- and post-mortem meat inspection) and work is underway developing new standards to prevent the contamination of animal products by Salmonella spp. and Campylobacter spp. The OIE and Codex collaborate closely in the development of standards to ensure seamless coverage of the entire food production continuum. The recommendations of the OIE and the Codex Alimentarius Commission on the production and safety of animal commodities should be read in conjunction.

The Veterinary Authority should provide for flexibility in the delivery of the meat inspection service. Countries may adopt different administrative models, involving degrees of delegation to officially recognised competent bodies operating under the supervision and control of the Veterinary Authority. If personnel from the private sector are used to carry out ante- and post-mortem inspection activities under the overall supervision and responsibility of the Veterinary Authority, the Veterinary Authority should specify the competency requirements for all such persons and verify their performance. To ensure the effective implementation of ante- and post-mortem inspection procedures, the Veterinary Authority should have in place systems for the monitoring of these procedures and the exchange of information gained. Animal identification and animal traceability systems should be integrated in order to be able to trace slaughtered animals back to their place of origin, and products derived from them forward in the meat production chain.

6. Certification of animal products for international trade

Another important role of the Veterinary Services is to ensure that health certification for international trade complies with animal health and food safety standards. Certification in relation to animal diseases, including zoonoses, and meat hygiene should be the responsibility of the Veterinary Authority. Certification may be provided by other professions (a sanitary certificate) in connection with food processing and hygiene (e.g. pasteurisation of dairy products) and conformance with product quality standards.

7. The roles of the Veterinary Services

Most reported outbreaks of foodborne disease are due to contamination of foods with zoonotic agents, often during primary production. The Veterinary Services play a key role in the investigation of such outbreaks all the way back to the farm and in formulating and implementing remedial measures once the source of the outbreak has been identified. This work should be carried out in close collaboration with human and environmental health professionals, analysts, epidemiologists, food producers, processors and traders and others involved.

In addition to the roles mentioned above, veterinarians are well equipped to assume important roles in ensuring food safety in other parts of the food chain, for example through the application of HACCP-based controls and other quality assurance systems during food processing and distribution. The Veterinary Services also play an important role in raising the awareness of food producers, processors and other stakeholders of the measures required to assure food safety.

8. Optimising the contribution of the Veterinary Services to food safety

In order for Veterinary Services to make the best possible contribution to food safety, it is important that the education and training of veterinarians in the roles outlined in this chapter meets high standards and that there are national programmes for ongoing and comprehensive professional development. The Veterinary Services should comply with the OIE fundamental principles of quality given in Chapter 3.1. Recommendations for the evaluation of Veterinary Services are provided in Chapter 3.2. and in the OIE Tool for the Evaluation of Performance of Veterinary Services.

There should be a clear and well documented assignment of responsibilities and chain of command within the Veterinary Services. The national Competent Authority should provide an appropriate institutional environment to allow the Veterinary Services to develop and implement the necessary policies and standards and adequate resources for them to carry out their tasks in a sustainable manner. In developing and implementing policies and
programmes for food safety, the Veterinary Authority should collaborate with other responsible agencies to ensure that food safety risks are addressed in a coordinated manner.
CHAPTER 6.2.

CONTROL OF BIOLOGICAL HAZARDS OF ANIMAL HEALTH AND PUBLIC HEALTH IMPORTANCE THROUGH ANTE- AND POST-MORTEM MEAT INSPECTION

Article 6.2.1.

Introduction

Foodborne disease and zoonoses are important public health problems and causes of decreased economic productivity in developed and developing countries. Similarly, transmission of hazards of animal health importance via the meat production chain and associated by-products can result in significant economic loss in livestock. Inspection of animals at slaughter can provide a valuable contribution to surveillance for certain diseases of animal and public health importance. Control and/or reduction of biological hazards of animal and public health importance by ante- and post-mortem meat inspection are a core responsibility of Veterinary Services.

Article 6.2.2.

Purpose

These recommendations provide a basis for future development of OIE standards for animal production food safety.

Article 6.2.3.

Hygienic practice throughout the meat production chain

The Codex Alimentarius Code of Hygienic Practice for Meat (CHPM) constitutes the primary international standard for meat hygiene and incorporates a risk-based approach to application of sanitary measures throughout the meat production chain. Ante-mortem inspection is described as a primary component of meat hygiene before slaughter, and post-mortem inspection is described as a primary component of process control in post-slaughter meat hygiene. The CHPM specifically recognises the dual objectives that slaughterhouse inspection activities deliver in terms of animal and public health.

The CHPM does not provide inspection measures for specific hazards, which remain the responsibility of national competent authorities. The animal and public health risks associated with livestock populations vary across regions and animal husbandry systems, and ante- and post-mortem inspection needs to be tailored to the individual country situation and its animal and public health objectives.

The CHPM provides a platform for development of meat hygiene systems that are based on risk assessment. There are few risk assessment models and little relevant scientific information available on public health hazards derived specifically from animals and their products, making difficult the development of risk-based standards for foodborne diseases and zoonoses. While this scientific information is being accumulated, ante- and post-mortem inspection systems will remain dependent on traditional approaches.

Article 6.2.4.

Veterinary Services and meat inspection programmes

Veterinary Services are primarily responsible for the development of ante- and post-mortem meat inspection programmes. Wherever practicable, inspection procedures should be risk-based and management systems should reflect international norms and cover the significant hazards to both human and animal health in the livestock being
slaughtered, as determined by the Veterinary Services. In respect of ante- and post-mortem inspection as a component of meat hygiene, responsibilities of Veterinary Services include:

1) risk assessment and risk management;
2) establishment of policies and standards;
3) design and management of inspection programmes;
4) assurance and certification of appropriate delivery of inspection and compliance activities;
5) dissemination of information throughout the meat production chain.

Article 6.2.5.

Risk assessment and risk management

Veterinary Services should utilise risk assessment to the greatest extent practicable in the development of sanitary measures. Veterinary Services should give priority to addressing microbiological contamination, while not neglecting gross abnormalities detected at ante- and post-mortem inspection, as this has been found to be the most important source of hazards.

Microbiological, serological or other testing at single-animal and herd level as part of ante- and post-mortem inspection should be used to support surveillance, as well as risk assessment of prioritised foodborne hazards. The information gathered should be linked to human disease data to allow an assessment of the effectiveness of various management options, as well as a general evaluation of food sources of foodborne disease.

Application of a generic framework should provide a systematic and consistent process for managing all biosecurity risks, while accommodating the different risk assessment methodologies used in animal and public health.

Article 6.2.6.

Establishment of policies and standards

The national competent authority(ies) should provide an appropriate institutional environment to allow Veterinary Services to develop the necessary policies and standards.

As well as meeting public health objectives, policies and standards relating to ante- and post-mortem inspection should aim to detect and remove hazards of animal health significance from the meat production chain. This may be achieved by the removal of live animals at ante-mortem inspection or by the removal of specific tissues at post-mortem inspection.

Veterinary Services should integrate their activities to the maximum extent practicable so as to prevent duplication of effort and unnecessary costs e.g. within the process of international certification.

Article 6.2.7.

Design and management of inspection programmes

In meeting animal and public health objectives prescribed in national legislations or required by importing countries, Veterinary Services contribute through the direct performance of some veterinary tasks or through the auditing of animal and public health activities conducted by other agencies or the private sector. To this end, Veterinary Services provide assurances domestically and to trading partners that safety and suitability standards have been met.

Veterinary Services should allow flexibility in meat inspection service delivery through an officially recognised competent body operating under its supervision and control. In recognition of the contribution of industry to food safety, quality assurance systems may be extended in the case of ante- and post-mortem inspection to systems that integrate industry and Veterinary Services activities. Nevertheless, Veterinary Services should take into account the factors identified in Chapter 3.1. on the fundamental principles of quality of Veterinary Services. For example, if personnel from the private sector are used to carry out ante- and post-mortem inspection activities under the overall supervision and responsibility of the Veterinary Services, the Veterinary Services should specify the competency requirements for all such persons and verify their performance.
Article 6.2.8.

Assurance and certification

Assurance and certification of appropriate delivery of inspection and compliance activities is a vital function of Veterinary Services. International health certificates providing official assurances for trading of meat must engender full confidence to the country of importation.

Article 6.2.9.

Dissemination of information

Organisation and dissemination of information throughout the meat production chain involves multidisciplinary inputs. To ensure the effective implementation of ante- and post-mortem inspection procedures, Veterinary Services should have in place systems for the monitoring of these procedures and the exchange of information gained. Further, there should be an ongoing programme for monitoring of hazards at appropriate points throughout the meat production chain so as to help evaluate the efficacy of controls. Animal identification and animal traceability systems should be integrated in order to be able to trace slaughtered animals back to their place of origin, and products derived from them forward through the meat production chain.
CHAPTER 6.3.

THE CONTROL OF HAZARDS OF ANIMAL HEALTH AND PUBLIC HEALTH IMPORTANCE IN ANIMAL FEED

Article 6.3.1.

Introduction

Animal feed is a critical component of the food chain that has a direct impact on animal health and welfare and also on food safety and public health.

Historically, the OIE primarily addressed animal feed as an important pathway for the entry and spread of contagious epidemic diseases, such as foot and mouth disease, swine vesicular disease and avian influenza. In recent years, the role of feed as a vector for disease agents, including zoonotic organisms, was a focus of standards development in regards to bovine spongiform encephalopathy. Animal feed and feed ingredients are widely traded internationally and trade disruptions have the potential to impact economies in both developed and developing countries. Since 2002 the OIE has expanded its zoonotic disease mandate to encompass animal production food safety, working in collaboration with the Codex Alimentarius Commission (CAC) and other international organisations. In 2006 the International Committee resolved that the OIE should develop guidance on foodborne zoonoses and animal feeding, complementing relevant CAC texts.

Article 6.3.2.

Objective and scope

The objective of this chapter is to provide guidance on animal feeding in relation to animal health and to complement the guidance provided by the Codex Code of Practice on Good Animal Feeding (CAC/RCP 54-2004) which deals primarily with food safety, and related other Codex texts covering animal feeding, e.g. Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals (CAC/RCP 49-2001).

This chapter aims at ensuring the control of animal and public health hazards through adherence to recommended practices during the production (growing, procurement, handling, storage, processing and distribution) and use of both commercial and on-farm produced animal feed and feed ingredients for terrestrial animals.

This chapter applies to the production and use of all products destined for animal feed and feed ingredients at all levels whether produced commercially or on farm. It also includes grazing or free-range feeding, forage crop production and water for drinking. Swill feeding is a particular aspect of on-farm practice that is specifically addressed because of its recognised role in disease transmission.

This chapter deals with feed for terrestrial animals (except bees).

Article 6.3.3.

Definitions

Contamination: means the unwanted presence of a material, infectious agent or product in a feed or feed ingredient that is potentially harmful to animal or public health or restricted under current regulations.

Feed: means any material (single or multiple), whether processed, semi-processed or raw, which is intended to be fed directly to terrestrial animals (except bees).

Feed additive: means any intentionally added ingredient not normally consumed as feed by itself, whether or not it has nutritional value or other effect on the animal, which affects the characteristics of feed or of the animal products.
Microorganisms, enzymes, pH regulators, trace elements, vitamins and other products fall within the scope of this definition depending on the purpose of use and method of administration. This excludes veterinary drugs.

**Feed ingredient:** means a component part or constituent of any combination or mixture making up a feed, whether or not it has a nutritional value in the animal's diet, including feed additives. Ingredients are of plant (including aquatic plants) or terrestrial or aquatic animal origin, or other organic or inorganic substances.

**Article 6.3.4.**

**General principles**

1. **Roles and responsibilities**
   
   The **Competent Authority** has the legal power to set and enforce regulatory animal feeding requirements, and has final responsibility for verifying that these requirements are met. The **Competent Authority** may establish regulatory requirements for relevant parties to provide it with information and assistance. Refer to Chapters 3.1. and 3.2.
   
   Those involved in the production and use of animal feed and feed ingredients have the primary responsibility to ensure that these products meet regulatory requirements. Records and, as appropriate, contingency plans should be in place to enable tracing and recall of non-compliant products. All personnel involved in the manufacture, storage and handling of feed and feed ingredients should be adequately trained and aware of their role and responsibility in preventing the introduction or spread of hazards. Manufacturing equipment, storage and transport facilities should be adequate and maintained in good working order and in a sanitary condition.
   
   Those providing specialist services to producers and to the feed industry (e.g. private veterinarians, nutritionists and laboratories) may be required to meet specific regulatory requirements pertaining to the services they provide (e.g. disease reporting, quality standards, transparency).

2. **Regulatory safety standards**
   
   All feed and feed ingredients should meet regulatory safety standards. Scientific evidence, including the sensitivity of analytical methods and on the characterisation of risks, should be taken into account in defining limits and tolerances for hazards.

3. **Risk analysis (risk assessment, risk management and risk communication)**
   
   Internationally accepted principles and practices on risk analysis (Section 2 of the Terrestrial Code and relevant Codex texts) should be used in developing and applying the regulatory framework.
   
   Application of a generic framework should provide a systematic and consistent process for managing all biosecurity risks, while recognising the different risk assessment methodologies used in animal and public health.

4. **Good practices**
   
   Where national guidelines exist, good agricultural practices and good manufacturing practices (including good hygienic practices) should be followed. Countries without such guidelines are encouraged to develop them or adopt suitable international standards or recommendations.
   
   Where appropriate, Hazard Analysis and Critical Control Point (HACCP) principles should be followed to control hazards that may occur in the manufacture, distribution and feeding of feed and feed additives and feed ingredients.

5. **Geographic and environmental considerations**
   
   Epidemiological links between potential sources of hazards for animal health or food safety should be considered when assessing water sources, land or facilities for suitability for the production of animal feed and feed ingredients. Animal health considerations include factors such as disease status, location of quarantined premises and existence of zones/compartments of specified health status. Food safety considerations include factors such as industrial operations that generate pollutants and waste treatment plants.

6. **Zoning and compartmentalisation**
   
   Feed is an important component of biosecurity and needs to be considered when defining a compartment or zone in accordance with Chapter 4.3.

7. **Sampling and analysis**
   
   Sampling and analysis should be based on scientifically recognised principles and procedures.
8. Labelling

Labelling should be informative, unambiguous, legible and conspicuously placed on the package if sold in package form and on the waybill and other sales documents if sold in bulk, un-packaged form, and should comply with regulatory requirements and Section 4.2.10 Labelling of Codex Code of Practice on Good Animal Feeding (CAC/RCP 54-2004), including listing of ingredients and instructions on the handling, storing and use. All claims made on a label should be able to be substantiated.

9. Design and management of inspection programmes

In meeting animal and public health objectives prescribed in national legislation or required by importing countries, Competent Authorities contribute through the inspection or through the auditing of animal and public health activities conducted by other agencies or the private sector.

Feed and feed ingredients business operators and other relevant parts of industry should practice self-regulation to secure compliance with required standards for procurement, handling, storage, processing, distribution and use. Operators have full responsibility for implementing systems for quality control. The Competent Authority should verify that process control systems and safety standards achieve all regulatory requirements.

10. Assurance and certification

Feed business operators are responsible for demonstrating the safety of the establishments under their control. Competent Authorities are responsible for providing assurances domestically and to trading partners that regulatory safety standards have been met. For international trade in animal product based feeds, Veterinary Services are required to provide international veterinary certificates.

11. Hazards associated with animal feed

a) Biological hazards

Biological hazards that may occur in feed and feed ingredients include agents such as bacteria, viruses, prions, fungi, parasites and poisonous plants.

b) Chemical hazards

Chemical hazards that may occur in feed and feed ingredients include naturally occurring chemicals (such as mycotoxins and gossypol), industrial and environmental contaminants (such as dioxins and PCBs), residues of veterinary drugs and pesticides and also radionuclides.

c) Physical hazards

Physical hazards that may occur in feed and feed ingredients include foreign objects (such as pieces of glass, metal, plastic or wood).

12. Contamination

Procedures to minimise the risk of contamination during the production, processing, storage, distribution (including transport) and use of feed and feed ingredients should be included in current regulations and standards. Scientific evidence, including the sensitivity of analytical methods and on the characterisation of risks, should be drawn upon in developing this framework.

Procedures, such as flushing, sequencing and physical clean-out, should be used to reduce the likelihood of contamination between batches of feed or feed ingredients.

13. Antimicrobial resistance

Concerning the use of antimicrobials in animal feed refer to Chapters 6.7. to 6.10.

14. Management of information

The Competent Authority should establish clear requirements for the provision of information by the private sector as this relates to regulatory requirements.

Records should be maintained in a readily accessible form regarding the production, distribution and use of feed and feed ingredients. These records are required to facilitate the prompt trace-back of feed and feed ingredients to...
the immediate previous source, and trace-forward to the next subsequent recipients, to address identified animal health or public health concerns (see Section 4.3. of CAC/RCP 54-2004).

*Animal identification and animal traceability* are tools for addressing animal health (including zoonoses), and food safety risks arising from animal feed (see Chapters 4.1. and 4.2.).

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CHAPTER 6.4.

BIOSECURITY PROCEDURES IN POULTRY PRODUCTION

Article 6.4.1.

Introduction

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

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

Article 6.4.2.

Purpose and scope

This chapter deals with biosecurity procedures in intensive poultry production. It should be read in conjunction with the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005), Code of Hygienic Practice for Eggs and Egg Products (CAC/RCP 15-1976) and Guidelines for the control of Campylobacter and Salmonella in chicken meat (CAC/GL 78-2011).

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

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

Article 6.4.3.

Definitions

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

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

Article 6.4.4.

Recommendations on the location and construction of poultry establishments

1. **All establishments (poultry farms and hatcheries)**
   a) A suitably isolated geographical location is recommended. Factors to consider include the location of other poultry and livestock establishments, wild bird concentrations and the distance from roads used to transport poultry.
   b) **Poultry establishments** should be located and constructed to provide adequate drainage for the site. Run-off or untreated site waste water should not discharge into waterfowl habitats.
   c) **Poultry** houses and hatcheries should be designed and constructed (preferably of smooth impervious materials) so that cleaning and disinfection can be carried out effectively. Ideally, the area immediately
surrounding the poultry houses and hatcheries should be paved with concrete or other impervious material to facilitate cleaning and disinfection.

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

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

2. Additional measures for poultry farms

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

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

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

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

3. Additional measures for hatcheries

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

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

      i) personnel changing, showering and sanitary facilities;

      ii) receipt, storage and transfer of eggs;

      iii) incubation;

      iv) hatching;

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

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

      vii) equipment washing;

      viii) waste disposal;

      ix) dining facilities for personnel;

      x) office space.

Article 6.4.5.

Recommendations applicable to the operation of poultry establishments

1. All establishments (poultry farms and hatcheries)

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

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

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

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

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

   f) To avoid the development of antimicrobial resistance, antimicrobial agents should be used according to relevant directions of the Veterinary Services and manufacturer’s instructions and in accordance with Chapters 6.8., 6.9., 6.10. and 6.11.

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

   h) Procedures for the prevention of entry of wild birds into poultry houses and buildings, and the control of vermin such as rodents and arthropods should be implemented.
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2. Additional measures for all poultry farms

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

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

c) Any equipment should be cleaned and sanitized before being taken into a poultry house.

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

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

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

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

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

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

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

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

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

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

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

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

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

n) For poultry flocks that are allowed to range outdoors, feeders, feed and other items which may attract wild birds should be kept indoors. Poultry should not be allowed access to sources of contamination, such as household waste, litter storage areas, other animals, stagnant water and water of unknown quality. The nesting area should be inside the poultry house.
3. Additional measures for layers
   Refer to Section 3 of the Codex Alimentarius Code of Hygienic Practice for Eggs and Egg Products (CAC/RCP 15-1976).

4. Additional measures for breeders
   a) Nest box litter and liners should be kept clean.
   b) Hatching eggs should be collected at frequent intervals, at least daily, and placed in new or clean and disinfected packaging materials.
   c) Grossly dirty, cracked, broken, or leaking eggs should be collected separately and should not be used as hatching eggs.
   d) Hatching eggs should be cleaned and sanitized as soon as possible after collection using an approved sanitising agent, in accordance with the manufacturer’s instructions.
   e) Hatching eggs or their packaging materials should be marked to assist traceability and veterinary investigations.
   f) The hatching eggs should be stored in a dedicated room as soon as possible after cleaning and sanitisation. Storage conditions should minimise the potential for microbial contamination and growth and ensure maximum hatchability. The room should be well ventilated, kept clean, and regularly disinfected using disinfectants approved for this purpose.

5. Additional measures for hatcheries
   a) Dead in shell embryos should be removed from hatcheries as soon as they are found and disposed of in a safe and effective manner.
   b) All hatchery waste, garbage and discarded equipment should be contained or at least covered while on site and removed from the hatchery and its environs as soon as possible.
   c) After use, hatchery equipment, tables and surfaces should be promptly and thoroughly cleaned and disinfected with an approved disinfectant.
   d) Egg handlers and sexers and handlers of day-old birds should wash their hands with soap and water before commencing work and between working with batches of hatching eggs or day-old birds from different breeder flocks.
   e) Hatching eggs and day-old birds from different breeder flocks should be identifiable during incubation, hatching, sorting and transportation.
   f) Day-old birds should be delivered to the farm in new containers or in clean, disinfected containers.

Article 6.4.6.

Prevention of further dissemination of infectious agents of poultry

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

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

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

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

4) Depending on the epidemiology of the disease, the results of a risk assessment, and public and animal health policies, destruction or slaughter of a flock before the end of the normal production period may be used. When infected flocks are destroyed or slaughtered, they should be processed in a manner to minimise exposure of humans and other flocks to the infectious agent, and in accordance with recommendations of the Veterinary
Chapter 6.4.- Biosecurity procedures in poultry production

Service and relevant chapters in the Terrestrial Code. Based on risk assessment, non-infected, high risk flocks may be destroyed or slaughtered before the end of their normal production period. Before restocking, the poultry house including equipment should be cleaned, disinfected and tested to verify that the cleaning has been effective. Special attention should be paid to feed equipment and water systems. Microbiological monitoring of the efficacy of disinfection procedures is recommended when pathogenic agents have been detected in the previous flock.

5) Depending on the epidemiology of the disease, risk assessment, vaccine availability and public and animal health policies, vaccination is an option to minimise the dissemination of the infectious agent. When used, vaccines should be administered in accordance with the directions of the Veterinary Services and the manufacturer’s instructions. Recommendations in the Terrestrial Manual should be followed as appropriate.

Article 6.4.7.

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

1) Personnel should be educated on the significance of infectious agents and the need to apply biosecurity practices to prevent dissemination of these agents. Education should be targeted to personnel at all levels of operations in these markets, such as drivers, owners, handlers and processors. Programmes should be implemented to raise consumer awareness about the risks associated with activities of live bird markets.

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

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

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

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

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

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

8) Efforts should be made to ensure the possibility of tracing all birds entering and leaving the markets.
CHAPTER 6.5.

PREVENTION, DETECTION AND CONTROL OF SALMONELLA IN POULTRY

Article 6.5.1.

Introduction

This chapter provides recommendations on the prevention, detection and control of *Salmonella* in poultry.

Salmonellosis is one of the most common foodborne bacterial diseases in the world. The great majority of *Salmonella infections* in humans are foodborne with *Salmonella Enteritidis* and *Salmonella Typhimurium* accounting for a major part of the problem. *Salmonella* serotypes and prevalence may vary considerably between localities, districts, regions and countries and therefore, surveillance and identification of the prevalent *Salmonella* serotypes in humans and poultry should be carried out in order to develop a control programme for the area.

In most food animal species, *Salmonella* can establish a clinically inapparent infection of variable duration, which is significant as a potential zoonosis. Such animals may be important in relation to the spread of infection between flocks and as causes of human foodborne infection. In the latter case, this can occur when meat and eggs, or their products, enter the food chain thus producing contaminated food.

Article 6.5.2.

Purpose and scope

This chapter deals with methods for on farm prevention, detection and control of *Salmonella* in poultry, and complements the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005) and Code of Hygienic Practice for Eggs and Egg Products (CAC/RCP 15-1976). A pathogen reduction strategy at the farm level is seen as the first step in a continuum that will assist in reducing the presence of foodborne pathogens in eggs and meat.

Hygiene and biosecurity procedures to be implemented in poultry farms and hatcheries are described in Chapter 6.4. on Biosecurity Procedures in Poultry Production.

The recommendations presented in this chapter are relevant to the control of all *Salmonella* with special attention to *S. Enteritidis* and *S. Typhimurium*, as these are common *Salmonella* serotypes in many countries. It should be noted that the epidemiology of animal and human salmonellosis in a particular locality, district, region or country is important for effective control of *Salmonella*.

Article 6.5.3.

Definitions

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

**Competitive exclusion**: means the administration of defined or undefined bacterial flora to poultry to prevent gut colonisation by enteropathogens, including *Salmonella*.

**Culling**: means the destruction or slaughter of a flock before the end of its normal period.

**Layers**: means poultry during the period of laying eggs for human consumption.
Article 6.5.4.

Surveillance of poultry flocks for *Salmonella*

Where justified by *risk assessment*, surveillance should be carried out to identify infected flocks in order to take measures that will reduce the prevalence in *poultry* and the risk of transmission of *Salmonella* to humans. Sampling methods, frequency and type of samples required should be determined by the *Veterinary Services* based on a *risk assessment*. Microbiological testing is preferred to serological testing because of its higher sensitivity in broiler flocks and higher specificity in breeder and layer flocks. In the framework of regulatory programmes for the control of *Salmonella in poultry* and salmonellosis in humans, confirmatory testing may be required to exclude false positive or negative results.

1. **Available methods for sampling**
   - Drag swabs: sampling is done by dragging swabs throughout the *poultry* house.
   - Boot swabs: sampling is done by walking throughout the *poultry* house with absorbent material placed over the footwear of the sampler.
   - Dust samples: sampling is done by collecting dust from exhaust fans, screens and other equipment in the *poultry* house.
   - Faecal samples: multiple fresh faecal/caecal samples collected from different areas in the *poultry* house.
   - Meconium, chick box liners, dead in shell and culled *day-old birds* at the hatchery.
   - Hatchery samples: throughout the hatchery, including inside the incubators.

2. **Sample size**
   - Refer to the *Terrestrial Manual* (under development).

3. **Laboratory methods**
   - Refer to the *Terrestrial Manual* (under development).

4. **Time and frequency of testing**
   - Time and frequency of sampling for each *poultry* type are listed below:
     a) **Breeders and hatcheries**
        i) Breeder flocks before lay
           - Before the end of the first week of life when the status of the breeder *flock* or the hatchery is not known or does not comply with this chapter.
           - Within the four weeks before being moved to another house, or before going into production if the birds will remain in the same house for the production period.
           - One or more times during the growing period if there is a culling policy in place. The frequency would be determined on commercial considerations.
        ii) Breeder flocks in lay
            - At least at monthly intervals during the laying period.
            - Additional testing should be determined by the *Veterinary Services*.
        iii) Hatcheries
            - Testing at hatcheries should complement on farm testing.
            - The minimal frequency should be determined by the *Veterinary Services*.
     b) **Poultry for the production of eggs for human consumption**
        i) Flocks grown to be layers
           - Before the end of the first week of life when the status of the breeder *flock* or the hatchery is not known or does not comply with this chapter.
           - Within the four weeks before being moved to another house, or before going into production if the birds will remain in the same house for the production period.
           - One or more times during the growing period if there is a culling policy in place. The frequency would be determined by commercial considerations.
        ii) Layer flocks
           - At expected peak of lay for each production cycle (the period of time in the laying cycle when the production of the *flock* is highest).
Chapter 6.5.- Prevention, detection and control of Salmonella in poultry

– One or more times if there is a culling policy in place or if eggs are diverted to processing for the inactivation of the pathogen. The minimal frequency should be determined by the Veterinary Services.

c) Poultry for the production of meat
  i) Flocks should be sampled at least once.
  ii) When sampling occurs on farms and when there is a long period (two weeks or more) between thinning and final depopulation, further testing should be considered.
  iii) When sampling occurs on farms, flocks should be sampled as late as possible before the first birds are transported to the slaughterhouse. In order to allow for the implementation of control measures during processing, this should be done at a time that ensures the results are available before slaughter.

Whether sampling occurs on the farm which is more appropriate for consequent control measures or at the processing plant, there should be an integrated system in place which allows for investigation of the source of positive flocks.

d) Testing of empty poultry houses

Bacteriological monitoring of the efficacy of disinfection procedures is recommended when Salmonella have been detected in the previous flock. As appropriate, sampling of equipment and surfaces as well as boot swabs or drag swabs of the empty poultry house after depopulation, cleaning and disinfection.

Results from surveillance may lead to the implementation of additional prevention and control measures to reduce the risk of transmission of Salmonella to humans:

1) In breeders, control measures may be implemented to reduce the transmission of Salmonella to the next generation, especially for trans-ovarian transmitted serotypes such as S. Enteritidis.

2) In layer flocks, control measures will reduce and may eliminate contamination of eggs with Salmonella.

3) In poultry for meat production, control measures may be implemented at slaughter or further down the food chain.

Article 6.5.5.

Prevention and control measures

Salmonella prevention and control may be achieved by adopting Good Agricultural Practices and Hazard Analysis Critical Control Point (HACCP), and general measures detailed in Chapter 6.4. on Biosecurity Procedures in Poultry Production, in combination with the following additional measures, where appropriate. No single measure used alone will achieve effective Salmonella control.

Additional prevention and control measures include vaccination, competitive exclusion, use of organic acids, culling and product diversion to processing.

Antimicrobial agents should not be used to control infection with Salmonella in poultry because the effectiveness of the treatment is limited, may mask the infection at sampling, has the potential to produce residues in meat and eggs and can contribute to the development of antimicrobial resistance. Antimicrobial agents may also reduce normal flora in the gut and increase the likelihood of colonisation with Salmonella. In special circumstances antimicrobial agents may be used to salvage birds with high genetic value.

1) Day-old birds used to stock a poultry house should be obtained from breeder flocks and hatcheries that have been monitored according to this chapter and in which no evidence of S. Enteritidis and S. Typhimurium has been detected.

2) Layer and breeder flocks should be stocked from flocks that have been monitored according to this chapter and in which no evidence of S. Enteritidis and S. Typhimurium has been detected.

3) Feed contamination with Salmonella is known to be a source of infection for poultry. Therefore, it is recommended to monitor the Salmonella status of poultry feed, and if found positive to take corrective measures. Heat treated feeds with or without the addition of other bactericidal or bacteriostatic treatments, e.g. organic acids, are recommended. Where heat treatment is not possible, the use of bacteriostatic or bacteridical treatments is recommended. Feed should be stored in clean closed containers to prevent access by wild birds and rodents. Spilled feed should be cleaned up immediately to remove attractants for wild birds and rodents.

4) Competitive exclusion may be used in day-old birds to reduce colonisation by Salmonella.

When used, competitive exclusion should be administered according to the instructions provided by the manufacturer and in accordance with the standards and recommendations of the Veterinary Services.
5) Vaccines are used against *Salmonella infections* caused by different serotypes in various poultry species, including single or combined vaccines. Vaccines produced according to the *Terrestrial Manual* should be used.

If live vaccines are used, it is important that field and vaccine strains be easily differentiated in the laboratory. If serology is used as the surveillance method, it may not be possible to distinguish between vaccination and infection with a field strain.

*Vaccination* can be used as part of an overall *Salmonella* control programme. It is recommended that *vaccination* not be used as the sole control measure.

When the status of the breeder flock or the hatchery from which the flock originates is not known or does not comply with this chapter, *vaccination of flocks*, starting with *day-old birds*, against the *Salmonella* serotypes known to be significant should be considered.

*Vaccination* against the *Salmonella* serotypes known to be significant should be considered when moving *day-old birds* to a previously contaminated shed so as to minimise the risk of the birds contracting *Salmonella infection*.

When used, vaccines should be administered according to the instructions provided by the manufacturer and in accordance with the standards and recommendations of the Veterinary Services.

*Vaccination* against *S. Enteritidis* can cause cross-reactions in *Salmonella* Pullorum/*S. Gallinarum* serological tests and needs to be considered when implementing measures for these pathogens.

6) Depending on animal health, *risk assessment*, and public health policies, culling is an option to manage infected breeder and layer flocks. Infected flocks should be destroyed or slaughtered and processed to minimise human exposure to *Salmonella*.

If culling is not applied, eggs for human consumption should be diverted for processing for inactivation of *Salmonella*.

7) *S. Enteritidis* is characterised by its ovarian transmission pattern. Countries should set targets for eradicating (or significantly reducing) *S. Enteritidis* from egg-producing flocks through a guided policy for eradication from the top of the production pyramid, i.e. from grandparent flocks through breeder flocks to layer flocks.

8) The responsible *veterinarian* should evaluate the results of *surveillance* testing for *Salmonella* and supervise the implementation of appropriate control measures. These results should be available to the *veterinarian* before marketing if a veterinary certificate for *flock* *Salmonella* status is required. When required by the *Competent Authority*, the *veterinarian* or other person responsible for notification should notify the *Competent Authority* if the presence of *Salmonella* of the relevant serotype is confirmed.

Article 6.5.6.

**Prevention of *Salmonella* spread from infected flocks**

If a *flock* is found infected with specific *Salmonella* serotypes of concern, the following actions should be taken in addition to general measures detailed in Chapter 6.4. on Biosecurity Procedures in Poultry Production:

1) According to the epidemiological situation, investigations should be carried out to determine the origin of the infection.

2) Movement of *poultry flocks* at the end of the production cycle should only be allowed for *slaughter* or destruction. Special precautions should be taken in the transport, *slaughter* and processing of the birds, e.g. they could be sent to a separate slaughterhouse or processed at the end of a shift before cleaning and disinfection of the equipment.

3) Litter should not be reused as such. Used *poultry* litter, carcasses and other potentially contaminated farm waste should be disposed of in a safe manner to prevent the direct or indirect exposure of humans, livestock and wildlife to *Salmonella*. Particular care needs to be taken when utilising used *poultry* litter to fertilise plants intended for human consumption. If litter is not removed, it should be treated in a manner to inactivate infectious agents, to prevent the spread from one *flock* to the next.

4) Particular care should be taken in cleaning and disinfection of the *poultry* house and equipment.

5) Before restocking the facility, a bacteriological examination should be carried out as detailed in this chapter and the *Terrestrial Manual*. 
Article 6.5.7.

Recommendations for importation of live poultry (other than day-old birds)

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

1) the poultry originated from a flock that participates in a Salmonella surveillance programme in accordance with the recommendations in Article 6.5.4.;

2) the poultry originated from a flock in which no evidence of S. Enteritidis and S. Typhimurium has been detected prior to shipment and have had no contact with birds or other material from flocks that do not comply with this chapter;

3) the poultry originated from a flock that complies with the recommendations of Chapter 6.4.

Article 6.5.8.

Recommendations for importation of day-old birds

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

1) the day-old birds showed no clinical signs of salmonellosis on the day of shipment;

2) the day-old birds originated from a breeder flock and a hatchery that participate in a Salmonella surveillance programme in accordance with the recommendations in Article 6.5.4.;

3) the day-old birds originated from a breeder flock and a hatchery in which no evidence of S. Enteritidis and S. Typhimurium has been detected and have had no contact during setting, incubation or hatching with hatchling eggs or other material from establishments that do not comply with this chapter;

4) the day-old birds originated from a breeder flock and a hatchery that comply with the recommendations of Chapter 6.4.;

5) the day-old birds were shipped in new and clean containers.

Article 6.5.9.

Recommendations for importation of hatching eggs

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

1) the hatching eggs originated from a breeder flock that participates in a Salmonella surveillance programme in accordance with the recommendations in Article 6.5.4.;

2) the hatching eggs originated from a breeder flock in which no evidence of S. Enteritidis and S. Typhimurium has been detected and have had no contact with poultry or other material from establishments that do not comply with this chapter;

3) the hatching eggs originated from a breeder flock that complies with the recommendations of Chapter 6.4.;

4) the hatching eggs were shipped in new and clean packaging materials.
CHAPTER 6.6.

INTRODUCTION TO THE RECOMMENDATIONS FOR CONTROLLING ANTIMICROBIAL RESISTANCE

Article 6.6.1.

Objective

The purpose of Chapters 6.7., 6.8., 6.9. and 6.10. is to provide methodologies for Member Countries to appropriately address the emergence or spread of resistant bacteria from the use of antimicrobial agents in animal husbandry and to contain antimicrobial resistance through controlling the use of antimicrobial agents.

Antimicrobial agents are essential drugs for human and animal health and welfare. The OIE recognises the need for access to antimicrobial agents in veterinary medicine: antimicrobial agents are essential for treating and controlling infectious diseases in animals. The OIE therefore considers that ensuring continued access to effective antimicrobial agents is important.

The OIE recognises that antimicrobial resistance is a global public and animal health concern that is influenced by the usage of antimicrobial agents in humans, animals and elsewhere. Those working in the human, animal and plant sectors have a shared responsibility to prevent or minimise pressures for the selection of antimicrobial resistance factors in humans and animals. Arising from its mandate for the protection of animal health and food safety, the OIE developed these chapters to provide guidance to Member Countries in regard to risks in the animal sector.

The application of risk assessment measures should be based on relevant international standards on risk analysis and supported by sound data and information when available. The methodologies provided in these chapters should be consulted as part of the standard approach to prevent and reduce antimicrobial resistance.
CHAPTER 6.7.

HARMONISATION OF NATIONAL ANTIMICROBIAL RESISTANCE SURVEILLANCE AND MONITORING PROGRAMMES

Article 6.7.1.

Objective

This chapter provides criteria for the:

1) development of national antimicrobial resistance surveillance and monitoring programmes,
2) harmonisation of existing national antimicrobial resistance surveillance and monitoring programmes,
in food-producing animals and in products of animal origin intended for human consumption.

Article 6.7.2.

Purpose of surveillance and monitoring

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

Surveillance and monitoring of antimicrobial resistance is necessary to:

1) assess and determine the trends and sources of antimicrobial resistance in bacteria;
2) detect the emergence of new antimicrobial resistance mechanisms;
3) provide the data necessary for conducting risk analyses as relevant to animal and human health;
4) provide a basis for policy recommendations for animal and human health;
5) provide information for evaluating antimicrobial prescribing practices and for prudent use recommendations.

Article 6.7.3.

The development of antimicrobial resistance surveillance and monitoring programmes

1. General aspects

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

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

National antimicrobial resistance monitoring and surveillance programmes should be scientifically based and may include the following components:
Chapter 6.7.- Harmonisation of national antimicrobial resistance surveillance and monitoring programmes

1. Sample collection methods

a) statistically based surveys;

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

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

d) analysis of veterinary practice and diagnostic laboratory records.

2. Sampling strategies

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

   – the sample is representative of the population of interest;

   – the robustness of the sampling method.

b) The following criteria are to be considered:

   – sample source such as food-producing animal, food, animal feed;

   – animal species;

   – category of animal within species such as age group, production type;

   – health status of the animals such as healthy, diseased;

   – sample selection such as targeted, systematic random;

   – type of sample (e.g. faecal, carcass, food product);

   – sample size.

3. Sample size

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

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

4. Sample sources

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

   a) Animal feed

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

   b) Food-producing animals

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

   c) Food

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

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

<table>
<thead>
<tr>
<th>Desired precision</th>
<th>90% Level of confidence</th>
<th>95% Level of confidence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1%</td>
<td>10%</td>
</tr>
<tr>
<td>10%</td>
<td>24</td>
<td>97</td>
</tr>
<tr>
<td>20%</td>
<td>43</td>
<td>173</td>
</tr>
<tr>
<td>30%</td>
<td>57</td>
<td>227</td>
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<td>40%</td>
<td>65</td>
<td>260</td>
</tr>
<tr>
<td>50%</td>
<td>68</td>
<td>270</td>
</tr>
<tr>
<td>60%</td>
<td>65</td>
<td>260</td>
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<tr>
<td>70%</td>
<td>57</td>
<td>227</td>
</tr>
<tr>
<td>80%</td>
<td>43</td>
<td>173</td>
</tr>
<tr>
<td>90%</td>
<td>24</td>
<td>97</td>
</tr>
</tbody>
</table>

5. **Type of sample to be collected**

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

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

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

Existing food processing microbiological monitoring, risk-based management and other food safety programmes may provide useful samples for surveillance and monitoring of resistance in the food chain after slaughter. Table 2 provides examples of sampling sources, sample types and monitoring outcomes.

6. **Bacterial isolates**

The following categories of bacteria could be monitored:

a) Animal bacterial pathogens relevant to the countries’ priorities

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

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

ii) guide veterinarians in their prescribing decisions.

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

i) *Salmonella*

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

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

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

Serovars of public health importance such as *S.* Typhimurium and *S.* Enteritidis should be included. The inclusion of other relevant serovars will depend on the epidemiological situation in each country. All *Salmonella* isolates should be serotyped and, where appropriate, phage-typed according to standard methods used at the nationally designated laboratories. For those countries that have the capabilities, *Salmonella* could be genotyped using genetic finger-printing methods.

ii) *Campylobacter*

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

iii) Other emerging bacterial pathogens

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

<p>| Table 2: Examples of sampling sources, sample types and monitoring outcomes. |</p>
<table>
<thead>
<tr>
<th>Source</th>
<th>Sample type</th>
<th>Outcome</th>
<th>Additional information required or additional stratification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Herd or flock of origin</td>
<td>Faecal or bulk milk</td>
<td>Prevalence of resistant bacteria originating from animal populations (of different production types). Relationship resistance - antimicrobial use.</td>
<td>Age categories, production types, etc. Antimicrobial use over time.</td>
</tr>
<tr>
<td>Abattoir</td>
<td>Faecal</td>
<td>Prevalence of resistant bacteria originating from animals at slaughter.</td>
<td>As above.</td>
</tr>
<tr>
<td>Caeca or intestine</td>
<td>Hygiene, contamination during slaughter.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carcass</td>
<td>Hygiene, contamination during processing and handling.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Processing, packing</td>
<td>Food products</td>
<td>Prevalence of resistant bacteria originating from food, exposure data for consumers.</td>
<td></td>
</tr>
<tr>
<td>Point of sales (Retail)</td>
<td>Food products</td>
<td>Hygiene, contamination during processing and handling.</td>
<td></td>
</tr>
<tr>
<td>Various origin</td>
<td>Animal feed</td>
<td>Prevalence of resistance in bacteria originating from animal feed, exposure data for animals.</td>
<td></td>
</tr>
</tbody>
</table>

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

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

7. Storage of bacterial strains

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

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

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

9. Recording, storage and interpretation of data

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

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

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

i) as distributions of MICs in milligrams per litre;

ii) or inhibition zone diameters in millimetres.

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

i) sampling programme;

ii) sampling date;

iii) animal species or type;

iv) type of sample;

v) purpose of sampling;

vi) type of antimicrobial susceptibility testing method used;

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

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

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

i) identity of laboratory,

ii) isolation date,

iii) reporting date,

iv) bacterial species,

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

v) serotype or serovar,

vi) phage type,

vii) antimicrobial susceptibility result or resistance phenotype,

viii) genotype.

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

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

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

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

j) Ideally, data should be collected at the individual isolate level, allowing antimicrobial resistance patterns to be recorded.
10. Reference laboratory and annual reports

a) Member Countries should designate a national reference centre that assumes the responsibility to:
   i) coordinate the activities related to the antimicrobial resistance surveillance and monitoring programmes;
   ii) coordinate and collect information from participating surveillance laboratories within the country;
   iii) produce an annual report on the antimicrobial resistance situation in the country.

b) The national reference centre should have access to the:
   i) raw data;
   ii) complete results of quality assurance and inter-laboratory calibration activities;
   iii) inter-laboratory proficiency testing results;
   iv) information on the structure of the monitoring system;
   v) information on the chosen laboratory methods.
CHAPTER 6.8.

MONITORING OF THE QUANTITIES AND USAGE PATTERNS OF ANTIMICROBIAL AGENTS USED IN FOOD-PRODUCING ANIMALS

Article 6.8.1.

Purpose

The purpose of these recommendations is to describe an approach to the monitoring of the quantities of antimicrobial agents used in food-producing animals. In order to evaluate antimicrobial exposure in food-producing animals, quantitative information should be collected to monitor usage patterns by animal species, antimicrobial agents or class, type of use (therapeutic or non-therapeutic) and route of administration.

Article 6.8.2.

Objectives

The information provided in these recommendations is essential for antimicrobial resistance risk analyses and planning purposes and should be read in conjunction with Chapters 6.7. and 6.10. This information is necessary for interpreting antimicrobial resistance surveillance data and can assist in responding to problems of antimicrobial resistance in a precise and targeted way. The continued collection of this basic information will also help to give an indication of trends in the use of antimicrobial agents in animals over time and potential associations with antimicrobial resistance in animals. This information may also assist in risk management to evaluate the effectiveness of efforts to ensure responsible and prudent use and mitigation strategies (for example, by identifying changes in veterinary prescribing practices) and to indicate where change of antimicrobial usage practices might be appropriate. The publication of these data is important to ensure transparency and to allow all interested parties to assess trends, to perform risk assessments and for risk communication purposes.

Article 6.8.3.

Development and standardisation of antimicrobial monitoring systems

Systems to monitor antimicrobial usage consist of the following elements:

1. Sources of antimicrobial data
   a) Basic sources
      Sources of data will vary from country to country. Such sources may include customs, import and export data, manufacturing and sales data.
   b) Direct sources
      Data from veterinary medicinal product registration authorities, wholesalers, retailers, pharmacists, veterinarians, feed stores, feed mills and pharmaceutical industry associations can be efficient and practical sources. A possible mechanism for the collection of this information is to make the provision of appropriate information by pharmaceutical manufacturers to the regulatory authority one of the requirements of antimicrobial registration.
c) End-use sources (veterinarians and food animal producers)

This may be appropriate when basic or direct sources cannot be used for the routine collection of the information or when more accurate and locally specific information is required (such as off label use).

Periodic collection of this type of information may be sufficient.

Collection, storage and processing of data from end-use sources should be carefully designed, well managed and have the capability to produce accurate and targeted information.

d) Other sources

Non-conventional sources including Internet sales data related to antimicrobial agents could be collected where available.

Member Countries may wish to consider, for reasons of cost and administrative efficiency, collecting medical, food-producing animal, agricultural and other antimicrobial use data in a single programme. A consolidated programme would also facilitate comparisons of animal use with human use data for risk analysis purposes and help to promote optimal usage of antimicrobial agents.

2. Types and reporting formats of antimicrobial usage data

a) Type of antimicrobial use data

The data collected at minimum should be the weight in kilograms of the active ingredient of the antimicrobial(s) used in food-producing animals per year. It is possible to estimate total usage by collecting sales data, prescribing data, manufacturing data, import and export data or any combination of these.

The total number of food-producing animals by species, type of production and their weight in kilograms for food production per year (as relevant to the country of production) is essential basic information.

Information on dosage regimens (dose, dosing interval and duration of the treatment) and route of administration are elements to include when estimating antimicrobial usage in food-producing animal.

b) Reporting formats of antimicrobial use data

The antimicrobial agents, classes or sub-classes to be included in data reporting should be based on current known mechanisms of antimicrobial activity and antimicrobial resistance data.

Nomenclature of antimicrobial agents should comply with international standards where available.

For active ingredients present in the form of compounds or derivatives, the mass of active entity of the molecule should be recorded. For antimicrobial agents expressed in International Units, the factor used to convert these units to mass of active entity should be stated.

The reporting of antimicrobial use data may be further organised by species, by route of administration (specifically in-feed, in-water, injectable, oral, intramammary, intra-uterine and topical) and by type of use (therapeutic or non-therapeutic).

Regarding data coming from end-use sources, further breakdown of data for analysis of antimicrobial use at the regional, local, herd and individual veterinarian or veterinary practice levels may be possible.

Interpretation

According to the OIE risk assessment guidelines (refer to Chapter 6.10.), factors such as the number or percentage of animals treated, treatment regimes, type of use and route of administration are key elements to consider.

When comparing antimicrobial use data over time, changes in the size and composition of animal populations should also be taken into account.

The interpretation and communication of results should take into account factors such as seasonality and disease conditions, animal species and age affected, agricultural systems (e.g. extensive range conditions and feedlots), animal movements, and dosage regimens with antimicrobial agents.
CHAPTER 6.9.

RESPONSIBLE AND PRUDENT USE OF ANTIMICROBIAL AGENTS IN VETERINARY MEDICINE

Article 6.9.1.

Purpose

This document provides guidance for the responsible and prudent use of antimicrobial agents in veterinary medicine, with the aim of protecting both animal and human health as well as the environment. It defines the respective responsibilities of the Competent Authority and stakeholders such as the veterinary pharmaceutical industry, veterinarians, animal feed manufacturers, distributors and food-animal producers who are involved in the authorisation, production, control, importation, exportation, distribution and use of veterinary medicinal products (VMP) containing antimicrobial agent(s).

Responsible and prudent use is determined taking into account the specifications detailed in the marketing authorisation and their implementation when antimicrobial agents are administered to animals and is part of good veterinary and good agricultural practice.

Activities associated with the responsible and prudent use of antimicrobial agents should involve all relevant stakeholders.

Coordination of these activities at the national or regional level is recommended and may support the implementation of targeted actions by the stakeholders involved and enable clear and transparent communications.

Article 6.9.2.

Objectives of responsible and prudent use

Responsible and prudent use includes implementing practical measures and recommendations intended to improve animal health and animal welfare while preventing or reducing the selection, emergence and spread of -resistant bacteria in animals and humans. Such measures include:

1) ensuring the rational use of antimicrobial agents in animals with the purpose of optimising both their efficacy and safety;

2) complying with the ethical obligation and economic need to keep animals in good health;

3) preventing or reducing, as far as possible, the transfer of resistant micro-organisms or resistance determinants within animal populations, the environment and between animals and humans;

4) contributing to the maintenance of the efficacy and usefulness of antimicrobial agents used in animal and human medicine;

5) protecting consumer health by ensuring the safety of food of animal origin with respect to residues of antimicrobial agents.
Responsibilities of the Competent Authority

1. Marketing authorisation

All Member Countries should combat the unauthorised manufacture, compounding, importation, advertisement, trade, distribution, storage and use of unlicensed, adulterated and counterfeit products, including bulk active ingredients, through appropriate regulatory controls and other measures.

The Competent Authority is responsible for granting marketing authorisation which should be done in accordance with the provisions of the Terrestrial Code. It has a significant role in specifying the terms of this authorisation and in providing the appropriate information to veterinarians and all other relevant stakeholders.

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

Member Countries lacking the necessary resources to implement an efficient registration procedure for VMP containing antimicrobial agent(s), and which are importing them, should undertake the following measures:

a) evaluate the efficacy of administrative controls on the import of these VMP;

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

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

The Competent Authorities of importing countries should request the pharmaceutical industry to provide quality certificates prepared by the Competent Authority of the exporting and manufacturing country as appropriate.

Marketing authorisation is granted on the basis of the data submitted by the pharmaceutical industry or applicant and only if the criteria of safety, quality and efficacy are met.

Member Countries are encouraged to apply the existing guidelines established by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).

An evaluation of the potential risks and benefits to both animals and humans resulting from the use of antimicrobial agents, with particular focus on use in food-producing animals, should be carried out. The evaluation should focus on each individual antimicrobial agent and the findings should not be generalised to the antimicrobial class to which the particular active ingredient belongs. Guidance on usage should be provided for all target, route of administration, dosage regimens, withdrawal period and different durations of treatment that are proposed.

The Competent Authority should expedite the process for new antimicrobial agent(s) in order to address a specific need for the treatment of animal disease.

2. Quality control of antimicrobial agent(s) and VMP containing antimicrobial agent(s)

Quality controls should be performed:

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

b) to ensure that analysis specifications of antimicrobial agent(s) used as active ingredients comply with the provisions of registration documentations (such as monographs) approved by the relevant Competent Authority;

c) to ensure that the quality of antimicrobial agent(s) in the marketed dosage form(s) are maintained until the expiry date, established under the recommended storage conditions;

d) to ensure the stability of antimicrobial agent(s) when mixed with feed or drinking water;

e) to ensure that all antimicrobial agents and the VMP containing them are manufactured to the appropriate quality and purity in order to guarantee their safety and efficacy.

3. Assessment of therapeutic efficacy

a) Preclinical trials

i) Preclinical trials should:

− establish the spectrum of activity of antimicrobial agent(s) against relevant pathogens and non-pathogens (commensals);

− assess the capacity of the antimicrobial agent(s) to select for resistance in vitro and in vivo, taking into consideration intrinsically resistant and pre-existing resistant strains;

− establish an appropriate dosage regimen (dose, dosing interval and duration of the treatment) and route of administration necessary to ensure the therapeutic efficacy of the antimicrobial agent(s)
and limit the selection of antimicrobial resistance. Pharmacokinetic and pharmacodynamic data and models can assist in this appraisal.

ii) The activity of antimicrobial agent(s) towards the targeted microorganism should be established by pharmacodynamics. The following criteria should be taken into account:

- spectrum of activity and mode of action;
- minimum inhibitory and bactericidal concentrations against recent isolates;
- time- or concentration-dependent activity or co-dependency;
- activity at the site of infection.

iii) The dosage regimens allowing maintenance of effective antimicrobial levels should be established by pharmacokinetics. The following criteria should be taken into account:

- bio-availability according to the route of administration;
- distribution of the antimicrobial agent(s) in the treated animal and concentration at the site of infection;
- metabolism
- excretion routes.

Use of combinations of antimicrobial agents should be scientifically supported.

b) Clinical trials

Clinical trials in the target animal species should be performed to confirm the validity of the claimed therapeutic indications and dosage regimens established during the preclinical phase. The following criteria should be taken into account:

i) diversity of the clinical cases encountered when performing multi-centre trials;
ii) compliance of protocols with good clinical practice;
iii) eligibility of studied clinical cases, based on appropriate criteria of clinical and bacteriological diagnoses;
iv) parameters for qualitatively and quantitatively assessing the efficacy of the treatment.

4. Assessment of the potential of antimicrobial agent(s) to select for resistance

Other studies may be requested in support of the assessment of the potential of antimicrobial agents to select for resistance. The party applying for market authorisation should, where possible, supply data derived in target animal species under the intended conditions of use.

For this the following may be considered:

a) the concentration of either active antimicrobial agent(s) or metabolite(s) in the gut of the animal (where the majority of potential foodborne pathogens reside) at the defined dosage level;

b) pathway for the human exposure to antimicrobial resistant microorganisms;

c) the degree of cross-resistance;

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

5. Establishment of acceptable daily intake (ADI), maximum residue limit (MRL) and withdrawal periods in food-producing animals

a) When setting the ADI and MRL for an antimicrobial agent, the safety evaluation should also include the potential biological effects on the intestinal flora of humans.

b) The establishment of an ADI for each antimicrobial agent, and an MRL for each animal-derived food, should be undertaken before a VMP containing it is granted marketing authorisation.

c) For all VMP containing antimicrobial agents, withdrawal periods should be established for each animal species in order to ensure compliance with the MRLs, taking into account:

i) the MRLs established for the antimicrobial agent in the target animal edible tissues;
ii) the composition of the product and the pharmaceutical form;
iii) the dosage regimen;
iv) the route of administration.

d) The applicant should describe methods for regulatory testing of residues in food based on the established marker residues.

6. Protection of the environment

An assessment of the impact of the proposed antimicrobial use on the environment should be conducted.
7. Establishment of a summary of product characteristics for each VMP containing antimicrobial agent(s)

The summary of product characteristics contains the information necessary for the appropriate use of VMP containing antimicrobial agent(s) and constitutes the official reference for their labelling and package insert. This summary should contain the following items:

a) active ingredient and class;

b) pharmacological properties;

c) any potential adverse effects;

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

e) therapeutic indications;

f) target micro-organisms;

g) dosage regimen and route of administration;

h) withdrawal periods;

i) incompatibilities and interactions;

j) storage conditions and shelf-life;

k) operator safety;

l) particular precautions before use;

m) particular precautions for the proper disposal of un-used or expired products;

n) information on conditions of use relevant to the potential for selection of resistance;

o) contraindication.

8. Post-marketing antimicrobial surveillance

The information collected through existing pharmacovigilance programmes, including lack of efficacy, and any other relevant scientific data, should form part of the comprehensive strategy to minimise antimicrobial resistance. In addition to this, the following should be considered:

a) General epidemiological surveillance

The surveillance of animal microorganisms resistant to antimicrobial agent(s) is essential. The relevant authorities should implement a programme according to Chapter 1.4.

b) Specific surveillance

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

9. Supply and administration of the VMP containing antimicrobial agent(s)

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

a) prescribed by a veterinarian or other suitably trained person authorised to prescribe VMP containing antimicrobial agent(s) in accordance with the national legislation and under the supervision of a veterinarian;

b) supplied only through licensed or authorised distribution systems;

c) administered to animals by a veterinarian or under the supervision of a veterinarian or by other authorised persons.

The relevant authorities should develop effective procedures for the safe collection and disposal or destruction of unused or expired VMPs containing antimicrobial agent(s). Their labels should have appropriate instructions for disposal and destruction.

10. Control of advertising

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

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

b) is restricted to a veterinarian or other suitably trained person authorised to prescribe VMP containing antimicrobial agent(s) in accordance with the national legislation and under the supervision of a veterinarian.
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11. Training on the usage of antimicrobial agents

The training on the usage of antimicrobial agents should include all the relevant organisations, such as the Competent Authority, pharmaceutical industry, veterinary schools, research institutes, veterinary professional organisations and other approved users such as food-animal owners and manufacturers of medicated animal feed.

This training should focus on preserving the effectiveness of antimicrobial agents and include:

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

b) the ability of antimicrobial agent(s) to select for resistant microorganisms in animals and the relative importance of that resistance to public and animal health;

c) the need to observe responsible use recommendations for the use of antimicrobial agent(s) in animal husbandry in agreement with the provisions of the marketing authorisations;

d) appropriate storage conditions, proper disposal of unused or expired VMP;

e) record keeping.

12. Research

The relevant authorities should encourage public- and industry-funded research, for example on methods to identify and mitigate the public health risks associated with specific antimicrobial agent uses, or on the ecology of antimicrobial resistance.

Article 6.9.4.

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

1. Marketing authorisation

The veterinary pharmaceutical industry has responsibilities to:

a) supply all the information requested by the national Competent Authority;

b) guarantee the quality of this information in compliance with the provisions of good manufacturing, laboratory and clinical practices;

c) implement a pharmacovigilance programme and on request, specific surveillance for bacterial susceptibility and resistance data.

2. Marketing and export

For the marketing and export of VMP containing antimicrobial agent(s):

a) only licensed and officially approved VMP containing antimicrobial agent(s) should be sold and supplied, and then only through licensed/authorised distribution systems;

b) the pharmaceutical industry should provide quality certificates prepared by the Competent Authority of the exporting and manufacturing countries to the importing country;

c) the national regulatory authority should be provided with the information necessary to evaluate the amount of antimicrobial agents marketed.

3. Advertising

The veterinary pharmaceutical industry should respect principles of responsible and prudent use and should comply with established codes of advertising standards, including to:

a) distribute information in compliance with the provisions of the granted authorisation;

b) discourage the advertising of VMP containing antimicrobial agent(s) directly to the food-animal producer.

4. Training

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

5. Research

The veterinary pharmaceutical industry should contribute to research as defined in point 15 of Article 6.9.3.
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Article 6.9.5.

Responsibilities of wholesale and retail distributors

1) Distributors of VMP containing antimicrobial agent(s) should only do so on the prescription of a veterinarian or other suitably trained person authorised to prescribe VMP containing antimicrobial agent(s) in accordance with the national legislation and under the supervision of a veterinarian. All products should be appropriately labelled.

2) The recommendations on the responsible and prudent use of VMP containing antimicrobial agent(s) should be reinforced by retail distributors who should keep detailed records of:
   a) date of supply;
   b) name of prescriber;
   c) name of user;
   d) name of product;
   e) batch number;
   f) expiration date;
   g) quantity supplied;
   h) copy of prescription.

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

Article 6.9.6.

Responsibilities of veterinarians

The veterinarian's responsibility is to promote public health, animal health and welfare, including identification, prevention and treatment of animal diseases. The promotion of sound animal husbandry methods, hygiene procedures, biosecurity and vaccination strategies can help to minimise the need for antimicrobial use in food-producing animals.

Veterinarians should only prescribe antimicrobial agent(s) for animals under their care.

1. Use of antimicrobial agent(s)

   The responsibilities of veterinarians are to carry out a proper clinical examination of the animal(s) and then:
   a) administer or prescribe antimicrobial agent(s) only when necessary and taking into consideration the OIE list of antimicrobial agents of veterinary importance;
   b) make an appropriate choice of antimicrobial agent(s) based on clinical experience and diagnostic laboratory information (pathogen isolation, identification and antibiogram) where possible;
   c) provide a detailed treatment protocol, including precautions and withdrawal times, especially when prescribing extra-label or off-label use.

2. Choosing antimicrobial agent(s)

   a) The expected efficacy of the treatment is based on:
      i) the clinical experience of the veterinarians, their diagnostic insight and therapeutic judgement;
      ii) diagnostic laboratory information (pathogen isolation, identification and antibiogram);
      iii) pharmacodynamics including the activity towards the pathogens involved;
      iv) the appropriate dosage regimen and route of administration;
      v) pharmacokinetics and tissue distribution to ensure that the selected therapeutic agent is effective at the site of infection;
      vi) the epidemiological history of the rearing unit, particularly in relation to the antimicrobial resistance profiles of the pathogens involved.

   Should a first-line antimicrobial treatment fail or should the disease recur, a second line treatment should ideally be based on the results of diagnostic tests. In the absence of such results, an appropriate antimicrobial agent belonging to a different class or sub-class should be used.

   In emergencies, a veterinarian may treat animals without recourse to an accurate diagnosis and antimicrobial susceptibility testing, to prevent the development of clinical disease and for reasons of animal welfare.
b) Use of combinations of antimicrobial agents should be scientifically supported. Combinations of antimicrobial agents may be used for their synergistic effect to increase therapeutic efficacy or to broaden the spectrum of activity.

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

A prescription for VMP containing antimicrobial agent(s) should indicate precisely the dosage regimen, the withdrawal period where applicable and the amount of VMP containing antimicrobial agent(s) to be provided, depending on the dosage and the number of animals to be treated.

The extra-label or off-label use of VMP containing antimicrobial agent(s) may be permitted in appropriate circumstances and should be in agreement with the national legislation in force including the withdrawal periods to be used, as applicable. It is the veterinarian's responsibility to define the conditions of responsible use in such a case including the dosage regimen, the route of administration and the withdrawal period.

The use of compounded VMP containing antimicrobial agent(s) and extra-label or off-label use of registered VMP containing antimicrobial agent(s) should be limited to circumstances where an appropriate registered product is not available.

4. Recording of data

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

a) quantities of VMP used per animal species;

b) a list of all VMP supplied to each food-producing animal holding;

c) treatment schedules including animal identification and withdrawal period;

d) antimicrobial susceptibility data;

e) comments concerning the response of animals to treatment;

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

Veterinarians should also periodically review farm records on the use of VMP containing antimicrobial agent(s) to ensure compliance with their directions or prescriptions and use these records to evaluate the efficacy of treatments.

5. Labelling

All VMP supplied by a veterinarian should be labelled according to the national legislation.

6. Training and continued professional development

Veterinary professional organisations should participate in the training programmes as defined in point 14 of Article 6.9.3. It is recommended that veterinary professional organisations develop for their members species-specific clinical practice recommendations on the responsible and prudent use of VMP containing antimicrobial agent(s).

Responsibilities of food-animal producers

1) Food-animal producers, with the assistance and guidance of a veterinarian, are responsible for implementing animal health and welfare programmes on their farms in order to promote animal health and food safety.

2) Food-animal producers should:

a) draw up a health plan with the attending veterinarian that outlines preventive measures (e.g. feedlot health plans, mastitis control plans, endo- and ectoparasite control, vaccination programmes and biosecurity measures);

b) use VMP containing antimicrobial agent(s) only on the prescription of a veterinarian or other suitably trained person authorised to prescribe VMP containing antimicrobial agent(s) in accordance with the national legislation and under the supervision of a veterinarian;

c) use VMP containing antimicrobial agent(s) in accordance with product label instructions, including storage conditions, or the instructions of the attending veterinarian;

d) isolate sick animals, when appropriate, to avoid the transfer of pathogens; dispose of dead or dying animals promptly under conditions approved by the relevant authorities;
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- e) address on-farm biosecurity measures and take basic hygiene precautions as appropriate;
- f) comply with and record the recommended withdrawal periods to ensure that residue levels in animal-derived food do not present a risk for the consumer;
- g) use VMP containing antimicrobial agent(s) within the expiry date and dispose of unused and expired surplus VMP containing antimicrobial agent(s) under conditions safe for the environment;
- h) maintain all the laboratory records of bacteriological and susceptibility tests; these data should be made available to the veterinarian responsible for treating the animals;
- i) keep adequate records of all VMP containing antimicrobial agent(s) used, including the following:
  - name of the product and active substance, batch number and expiry date;
  - name of prescriber and the supplier;
  - date of administration;
  - identification of the animal or group of animals to which the antimicrobial agent was administered;
  - clinical conditions treated;
  - dosage;
  - withdrawal periods including the end-date of the withdrawal periods;
  - result of laboratory tests;
  - effectiveness of therapy;
- j) inform the responsible veterinarian of recurrent disease problems.

3) Training

Food-animal producers should participate in the training programmes as defined in point 14 of Article 6.9.3. It is recommended that food-animal producer organisations work in cooperation with the veterinary professional organisations to implement existing guidelines for the responsible and prudent use of VMP containing antimicrobial agent(s).

Article 6.9.8.

Responsibilities of animal feed manufacturers

1) The supply of medicated feed containing antimicrobial agents to farmers keeping food-producing animals by animal feed manufacturers should be allowed only on the prescription of a veterinarian. Alternatively, such medicated feed may be prescribed by other suitably trained persons authorised to prescribe VMP containing antimicrobial agent(s) in accordance with the national legislation and under the supervision of a veterinarian. Animal feed manufacturers preparing medicated feed should do so following rules put in place by the Competent Authority in accordance with the national legislation. All medicated feed and medicated premixes should be appropriately labelled.

2) The regulations and recommendations on the responsible and prudent use of VMP containing antimicrobial agent(s) should be reinforced by animal feed manufacturers who should keep detailed records.

3) Use only approved sources of medications: Animal feed manufacturers preparing medicated feed should ensure that only approved sources of medications are added to feed at a level, purpose and species as permitted by the drug premix label or a veterinary prescription.

4) Ensure appropriate labelling with product identification, direction for use and withdrawal time: Animal feed manufacturers preparing medicated feed should ensure that medicated animal feed are labelled with the appropriate information (e.g. level of medication, approved claim, intended species, directions for use, warning, cautions) so as to ensure effective and safe use by the producer.

5) Implement appropriate production practices to prevent contamination of other feed: Animal feed manufacturers preparing medicated feed should implement appropriate production practices to avoid unnecessary carry over and unsafe cross contamination of unmedicated feed.
CHAPTER 6.10.

RISK ASSESSMENT FOR
ANTIMICROBIAL RESISTANCE ARISING FROM THE
USE OF ANTIMICROBIALS IN ANIMALS

Article 6.10.1.

Recommendations for analysing the risks to animal and public health from antimicrobial resistant micro-organisms of animal origin

1. Introduction
   The use of antimicrobials for therapy, prophylaxis and growth promotion in animals can reduce their efficacy in animal and human medicine, through the development of antimicrobial resistant strains of pathogenic micro-organisms. This risk may be represented by the loss of therapeutic efficacy of one or several antimicrobial drugs and includes the emergence of multi-resistant micro-organisms.

2. Objective
   The principal aim of risk analysis for antimicrobial resistance in micro-organisms from animals is to provide Member Countries with a transparent, objective and scientifically defensible method of assessing and managing the human and animal health risks associated with the development of resistance arising from the use of antimicrobials in animals.

3. The risk analysis process
   The principles of risk analysis are described in Section 2 of this Terrestrial Code. A qualitative risk assessment should always be undertaken. Its outcome will determine whether progression to a quantitative risk assessment is feasible and/or necessary.

4. Hazard identification
   For the purposes of this chapter, the hazard is the resistance determinant that emerges as a result of the use of a specific antimicrobial in animals. This definition reflects the development of resistance in a species of pathogenic micro-organisms, as well as the development of a resistance determinant that may be passed from one species of micro-organisms to another. The conditions under which the hazard might produce adverse consequences include any scenarios through which humans or animals could become exposed to a pathogen which contains that resistance determinant, fall ill and then be treated with an antimicrobial that is no longer effective because of the resistance.

5. Risk assessment
   The assessment of the risk to human and animal health from antimicrobial-resistant micro-organisms resulting from the use of antimicrobials in animals should examine:
   a) the likelihood of emergence of resistant micro-organisms arising from the use of antimicrobial(s), or more particularly, production of the resistance determinants if transmission is possible between micro-organisms;
   b) consideration of all pathways and their importance, by which humans could be exposed to these resistant micro-organisms or resistance determinants, together with the possible degree of exposure;
   c) the consequences of exposure in terms of risks to human and/or animal health.

Article 6.10.2.

Analysis of risks to human health

1. Definition of the risk
   The infection of humans with micro-organisms that have acquired resistance to a specific antimicrobial used in animals, and resulting in the loss of benefit of antimicrobial therapy used to manage the human infection.
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2. Hazard identification

- Micro-organisms that have acquired resistance (including multiple resistance) arising from the use of an antimicrobial(s) in animals.
- Micro-organisms having obtained a resistance determinant(s) from other micro-organisms which have acquired resistance arising from the use of an antimicrobial(s) in animals.

The identification of the hazard must include consideration of the class or subclass of the antimicrobial(s). This definition should be read in conjunction with point 4 of Article 6.10.1.

3. Release assessment

A release assessment describes the biological pathways necessary for the use of a specific antimicrobial in animals to lead to the release of resistant micro-organisms or resistance determinants into a particular environment, and estimating either qualitatively or quantitatively the probability of that complete process occurring. The release assessment describes the probability of the release of each of the potential hazards under each specified set of conditions with respect to amounts and timing, and how these might change as a result of various actions, events or measures.

The following factors should be considered in the release assessment:
- species of animal treated with the antimicrobial(s) in question;
- number of animals treated, geographical distribution of those animals;
- variation in methods and routes of administration of the antimicrobial(s);
- the pharmacodynamics/pharmacokinetics of the antimicrobial(s);
- micro-organisms developing resistance as a result of the antimicrobial(s) use;
- mechanism of direct or indirect transfer of resistance;
- cross-resistance and/or co-resistance with other antimicrobials;
- surveillance of animals, products of animal origin and animal waste products for the existence of resistant micro-organisms.

4. Exposure assessment

An exposure assessment describes the biological pathways necessary for exposure of humans to the resistant micro-organisms or resistance determinants released from a given antimicrobial use in animals, and estimating the probability of the exposures occurring. The probability of exposure to the identified hazards is estimated for specified exposure conditions with respect to amounts, timing, frequency, duration of exposure, routes of exposure and the number, species and other characteristics of the human populations exposed.

The following factors should be considered in the exposure assessment:
- human demographics and food consumption patterns, including traditions and cultural practices;
- prevalence of resistant micro-organisms in food;
- environmental contamination with resistant micro-organisms;
- prevalence of animal feed contaminated with resistant micro-organisms;
- cycling of resistant micro-organisms between humans, animals and the environment;
- steps of microbial decontamination of food;
- microbial load in contaminated food at the point of consumption;
- survival capacity and redistribution of resistant micro-organisms during the food production process (including slaughtering, processing, storage, transportation and retailing);
- disposal practices for waste products and the opportunity for human exposure to resistant micro-organisms or resistance determinants in those waste products;
- point of consumption of food (professional catering, home cooking);
- variation in consumption and food-handling methods of exposed populations and subgroups of the population;
- capacity of resistant micro-organisms to become established in humans;
- human-to-human transmission of the micro-organisms under consideration;
- capacity of resistant micro-organisms to transfer resistance to human commensal micro-organisms and zoonotic agents;
- amount and type of antimicrobials used in response to human illness;
- pharmacokinetics (metabolism, bioavailability, access to intestinal flora).
5. Consequence assessment

A consequence assessment describes the relationship between specified exposures to resistant micro-organisms or resistance determinants and the consequences of those exposures. A causal process must exist by which exposures produce adverse health or environmental consequences, which may in turn lead to socio-economic consequences. The consequence assessment describes the potential consequences of a given exposure and estimates the probability of them occurring.

The following factors should be considered in the consequence assessment:
- dose-response relationships;
- variation in susceptibility of exposed populations or subgroups of the population;
- variation and frequency of human health effects resulting from loss of efficacy of antimicrobials;
- changes in human medicinal practices resulting from reduced confidence in antimicrobials;
- changes in food consumption patterns due to loss of confidence in the safety of food products and any associated secondary risks;
- associated costs;
- interference with first line/choice antimicrobial therapy in humans;
- perceived future usefulness of the antimicrobial (time reference);
- prevalence of resistance in human bacterial pathogens under consideration.

6. Risk estimation

A risk estimation integrates the results from the release assessment, exposure assessment and consequence assessment to produce overall estimates of risks associated with the hazards. Thus, risk estimation takes into account the whole of the risk pathway from hazard identification to the unwanted consequences.

The following factors should be considered in the risk estimation:
- number of people falling ill and the proportion of that number affected with resistant strains of micro-organisms;
- increased severity or duration of infectious disease;
- number of person/days of illness per year;
- deaths (total per year; probability per year or lifetime for a random member of the population or a member of a specific more exposed sub-population);
- importance of the pathology caused by the target micro-organisms;
- absence of alternate antimicrobial therapy;
- incidence of resistance observed in humans;
- consequences to allow weighted summation of different risk impacts (e.g. illness and hospitalisation).

7. Risk management options and risk communication

Risk management options and risk communication have to be continuously monitored and reviewed in order to ensure that the objectives are being achieved.

Article 6.10.3.

Analysis of risks to animal health

1. Definition of the risk

The infection of animals with micro-organisms that have acquired resistance from the use of a specific antimicrobial(s) in animals, and resulting in the loss of benefit of antimicrobial therapy used to manage the animal infection.

2. Hazard identification

- Micro-organisms that have acquired resistance (including multiple resistance) arising from the use of an antimicrobial(s) in animals.
- Micro-organisms having obtained a resistance determinant(s) from another micro-organisms which have acquired resistance arising from the use of an antimicrobial(s) in animals.

The identification of the hazard must include considerations of the class or subclass of the antimicrobial(s). This definition should be read in conjunction with point 4 of Article 6.10.1.
3. Release assessment
The following factors should be considered in the release assessment:
- animal species treated;
- number of animals treated, sex, age and their geographical distribution;
- amounts used and duration of treatment;
- variation in methods and routes of administration of the antimicrobial(s);
- the pharmacodynamics/ pharmacokinetics of the antimicrobial(s);
- site and type of infection;
- development of resistant micro-organisms;
- mechanisms and pathways of resistance transfer;
- cross-resistance and/or co-resistance;
- surveillance of animals, products of animal origin and animal waste products for the existence of resistant micro-organisms.

4. Exposure assessment
The following factors should be considered in the exposure assessment:
- prevalence and trends of resistant micro-organisms in clinically ill and clinically unaffected animals;
- prevalence of resistant micro-organisms in feed/the animal environment;
- animal-to-animal transmission of the resistant micro-organisms;
- number/percentage of animals treated;
- dissemination of resistant micro-organisms from animals (animal husbandry methods, movement of animals);
- quantity of antimicrobial(s) used in animals;
- treatment regimens (dose, route of administration, duration);
- survival capacity of resistant micro-organisms;
- exposure of wildlife to resistant micro-organisms;
- disposal practices for waste products and the opportunity for animal exposure to resistant micro-organisms or resistance determinants in those products;
- capacity of resistant micro-organisms to become established in animal intestinal flora;
- exposure to resistant micro-organisms from other sources;
- dose, route of administration and duration of treatment;
- pharmacokinetics (metabolism, bioavailability, access to intestinal flora);
- cycling of resistant micro-organisms between humans, animals and the environment.

5. Consequence assessment
The following factors should be considered in the consequence assessment:
- dose-response relationships;
- variation in disease susceptibility of exposed populations and subgroups of the populations;
- variation and frequency of animal health effects resulting from loss of efficacy of antimicrobials;
- changes in practices resulting from reduced confidence in antimicrobials;
- associated cost;
- perceived future usefulness of the drug (time reference).

6. Risk estimation
The following factors should be considered in the risk estimation:
- number of therapeutic failures due to resistant micro-organisms;
- animal welfare;
- economic cost;
- deaths (total per year; probability per year or lifetime for a random member of the population or a member of a specific more exposed sub-population);
- incidence of resistance observed in animals.
7. Risk management options and risk communication

Risk management options and risk communication have to be continuously monitored and reviewed in order to ensure that the objectives are being achieved.

The relevant recommendations (Articles 2.1.5., 2.1.6. and 2.1.7.) in the Terrestrial Code apply.

A range of risk management options is available to minimize the emergence and spread of antimicrobial resistance and these include both regulatory and non-regulatory risk management options, such as the development of codes of practice concerning the use of antimicrobials in animal husbandry. Risk management decisions need to consider fully the implications of these different options for human health and animal health and welfare and also take into account economic considerations and any associated environmental issues. Effective control of certain bacterial diseases of animals will have the dual benefit of reducing the risks linked to antimicrobial resistance, in cases where the bacterial disease under consideration has also developed antimicrobial resistance. Appropriate communication with all stakeholders is essential throughout the risk assessment process.
CHAPTER 6.11.
ZOO NOSES TRANSMISSIBLE FROM NON-HUMAN PRIMATES

Article 6.11.1.

Introduction

There are about 376 different species of non-human primates belonging to three suborders which are split into 15 families. The tree shrew family (previously considered as belonging to the primates) has not been included in these recommendations.

All non-human primate species are included in Appendix I or Appendix II of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) and may be transported internationally only if accompanied by the permits or certificates required under CITES.

Most imported non-human primates are destined for research, educational or breeding purposes and their sourcing should be in accordance with Article 7.8.7. Before non-human primates are used for any purpose, all alternatives to their use should be explored.

Public health and safety, animal welfare and pathogen introduction to wild populations are the primary issues of concern in the importation and keeping of non-human primates. This is especially true where close contact between humans and animals, their body fluids, faeces and tissues is likely to occur. Minimising the risk requires well-trained personnel and the following of stringent personal hygiene standards.

The likelihood of carrying zoonotic pathogens is related to the taxonomic position and the region of origin of the species concerned. It can be considered to increase from prosimians to marmosets and tamarins, then to other New World monkeys, to Old World monkeys and apes. The likelihood of carrying zoonotic agents is also greater in wild-caught non-human primates than in captive-bred animals which have been maintained in a well-defined environment under veterinary supervision. For non-human primates taken from the wild, usually only very limited health related information can be given by the supplier and by the Veterinary Authority of the exporting country.

Most pathogens referred to in this chapter are not included in the OIE List, and there is, consequently, no requirement to report them on a regular basis within the OIE animal disease reporting system. However, the requirement to report exceptional epidemiological events remains in effect.

Standards for diagnostic tests for some pathogens are described in the Terrestrial Manual.

Article 6.11.2.

General recommendations

Veterinary Authorities of exporting countries should issue international veterinary certificates only upon presentation of valid CITES documentation.

Veterinary Authorities should make sure that the animals are individually identified by approved methods that assure traceability and to avoid transmission of disease (see Chapter 4.15.).

For reasons of public health, animal welfare and pathogen introduction to wild populations, Veterinary Authorities of importing countries should not authorise the import of non-human primates for the purpose of being kept as pets.

In the case of a non-human primate being imported directly from a country within the natural range of the animal's species concerned, and where only limited diagnostic testing is available, Veterinary Authorities of importing countries should place more emphasis on quarantine procedures and less on veterinary certification. As a matter of principle, limited health guarantees given by the supplier or the Veterinary Authority of the country of origin should not constitute an obstacle to imports, but very strict post import quarantine requirements should be imposed. Particularly, the quarantine should meet the standards set in Chapter 5.9., and should be of sufficient length to minimise the risk of transmission of diseases where tests are not readily available or of limited value.
Veterinary Authorities of importing countries may reduce the quarantine requirements for non-human primates imported from premises with permanent veterinary supervision provided that the animals were born or have been kept for at least two years on these premises, are individually identified and accompanied by proper certification issued by qualified officials, and the official certification is supplemented by a complete documentation of the clinical history of each animal and its group of origin.

In cases where it is necessary to import non-human primates which are known or suspected to be carriers of a zoonotic disease, the import should not be restricted by any of these recommendations, provided that the Veterinary Authority of the importing country requires the placing of the animals in an establishment located on its territory which has been approved to receive them and which meets the standards set in Chapter 5.9.

Article 6.11.3.

General certification and transportation requirements

Veterinary Authorities of importing countries should require:

for all non-human primates

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

   a) have been individually identified (the means of identification should be stated in the certificate); and
   b) have been examined on the day of shipment and found to be healthy, free from clinical signs of contagious disease, and fit for transport;

2) the attachment to the international veterinary certificate of all relevant records, including all vaccinations, tests and treatments performed during the lifetime of each primate before shipment;

3) the necessary CITES permit from the relevant wildlife authority;

4) the transport of the animals by air in accordance with the Live Animals Regulations of the International Air Transport Association or by rail or road under equivalent standards for surface transport.

Article 6.11.4.

Quarantine requirements for non-human primates from an uncontrolled environment

Veterinary Authorities of importing countries should require for shipments which originate from the wild or other sources where they were not subjected to permanent veterinary supervision:

1) the presentation of the documentation referred to in Article 6.11.3.;

2) the immediate placement of the animals in a quarantine station meeting the standards set in Chapter 5.9. for at least 12 weeks; and during this quarantine:

   a) all animals to be monitored daily for signs of illness and, if necessary, be subjected to a clinical examination;
   b) all animals dying for any reason to be subjected to complete post-mortem examination at a laboratory approved for this purpose;
   c) any cause of illness or death to be determined before the group to which the animals belong is released from quarantine;
d) animals to be subjected to the following diagnostic tests and treatments in accordance with Chapter 4.15.:

<table>
<thead>
<tr>
<th>Disease/agent</th>
<th>Animal groups</th>
<th>Schedule</th>
<th>Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endo- and ectoparasites</td>
<td>All species</td>
<td>At least two tests, one of which should be at the start, the other towards the end of the quarantine.</td>
<td>Testing methods and antiparasitic treatment as appropriate to species of animal and parasitic agent.</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>Marmosets and tamarins</td>
<td>Two tests at an interval of 2 to 4 weeks.</td>
<td>Skin test or serology. In-vitro gamma interferon assay or polymerase chain reaction (PCR) assay. The skin test using mammalian tuberculin (old tuberculin) is the most reliable of all. Skin tests in marmosets, tamarins or small prosimians should be performed in the abdominal skin rather than in the eyelid. In some species (e.g. orang utan), skin tests for tuberculosis are notorious for false positive results. Comparative tests using both mammalian and avian PPD, together with cultures, radiography, ELISA, in-vitro gamma interferon assay and PCR of gastric or bronchial lavage, faeces or tissues may eliminate confusion.</td>
</tr>
<tr>
<td>(Mycobacterium tuberculosis complex)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>Prosimians, New World monkeys, Old World monkeys, gibbons and great apes</td>
<td>At least three tests at intervals of 2 to 4 weeks.</td>
<td></td>
</tr>
<tr>
<td>Other bacterial pathogens</td>
<td>All species</td>
<td>Daily test for 3 days after arrival, and at least one or two more tests at intervals of 2 to 4 weeks.</td>
<td>Faecal culture. The fresh faeces or rectal swabs should be cultured immediately or be placed immediately in the appropriate transportation medium.</td>
</tr>
<tr>
<td>(Salmonella, Shigella and Yersinia and others as appropriate)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>Gibbons and great apes</td>
<td>First test during first week; second test after 3 to 4 weeks.</td>
<td>Serological tests for anti-hepatitis B core antigen and for hepatitis B surface antigen, and additional parameters as appropriate.</td>
</tr>
</tbody>
</table>

Veterinary Authorities of importing countries should recognize the public health importance of zoonoses listed in the table below as well as measles (a human disease, sometimes affecting non-human primates), hepatitis A, monkey pox, Marburg disease or Ebola/Reston virus, retroviruses, etc., even though this article does not recommend specific testing or treatment protocols for these agents during the quarantine period. Veterinary Authorities should recognize that, if animals are infected, the importation and spread of many such agents will be best controlled by the detection of clinical signs of disease during a 12-week quarantine period.

Certain endemic viruses, such as herpesviruses or retroviruses, may be present in both wild and captive populations of primates. These viruses are often asymptomatic in primate species. If animals are being imported to be introduced to other populations of the same species, it may be advisable to determine if the animals selected for importation have similar viral profiles to the established population.

Article 6.11.5.

Certification and quarantine requirements for marmosets and tamarins from premises under veterinary supervision

Veterinary Authorities of importing countries should require:

for marmosets and tamarins from premises under veterinary supervision

1) the presentation of an international veterinary certificate attesting that the shipment meets the requirements specified in Article 6.11.3., and that the animals:
   a) are either born in the premises of origin or have been kept there for at least two years;
   b) come from premises which are under permanent veterinary supervision, and where a suitable health monitoring programme is followed, including microbiological and parasitological tests as well as necropsies;
   c) have been kept in buildings and enclosures in which no case of tuberculosis has occurred during the last two years prior to shipment;

2) a description of the health monitoring programme implemented by the establishment of origin;

3) the placement of the animals in a quarantine station meeting the standards set in Chapter 5.9. for at least 30 days; and during this period:
   a) all animals to be monitored daily for signs of illness and, if necessary, be subjected to a clinical examination;
Chapter 6.11.- Zoonoses transmissible from non-human primates

b) all animals dying for any reason to be subjected to complete post-mortem examination at a laboratory approved for this purpose;

c) animals to be subjected to the following diagnostic tests and treatments in accordance with Chapter 4.15.:

<table>
<thead>
<tr>
<th>Disease/agent</th>
<th>Animal groups</th>
<th>Schedule</th>
<th>Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial pathogens (Salmonella, Shigella and Yersinia and others as appropriate)</td>
<td>All species</td>
<td>Daily test for 3 days after arrival.</td>
<td>Faecal culture. (See further comments in the Table of Article 6.11.4.)</td>
</tr>
<tr>
<td>Endo- and ectoparasites</td>
<td>All species</td>
<td>At least two tests, one of which should be at the start, the other towards the end of the quarantine.</td>
<td>Testing methods and antiparasitic treatment as appropriate to species of animal and parasitic agent.</td>
</tr>
</tbody>
</table>

**Veterinary Authorities of importing countries** should not normally require any tests for viral infections or for tuberculosis. However, stringent precautions to ensure human health and safety should be followed as recommended in Article 6.11.7.

**Article 6.11.6.**

**Certification and quarantine requirements for other non-human primates from premises under veterinary supervision**

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

- **for prosimians, New World monkeys, Old World monkeys, gibbons and great apes from premises under veterinary supervision**
  1) the presentation of an *international veterinary certificate* attesting that the shipment meets the requirements specified in Article 6.11.3., and that the *animals*:
    - a) are either born in the premises of origin or have been kept there for at least two years;
    - b) come from premises which are under permanent veterinary supervision, and where a suitable health monitoring programme is followed, including microbiological and parasitological tests as well as necropsies;
    - c) have been kept in buildings and enclosures in which no case of tuberculosis has occurred during the last two years prior to shipment;
    - d) come from premises in which no case of tuberculosis or other major zoonoses including rabies has occurred during the last two years prior to shipment in the building where the *animals* were kept;
    - e) were subjected to a tuberculin test on two occasions with negative results, at an interval of at least two weeks between each test during the 30 days prior to shipment;
    - f) were subjected to a diagnostic test for pathogenic enteric bacteria including *Salmonella*, *Shigella* and *Yersinia*;
    - g) were subjected to diagnostic tests for, and appropriate treatment against, endo- and ectoparasites;
    - h) were subjected to a diagnostic test for hepatitis B virus and their current status documented (gibbons and great apes only);
  2) the placement of the *animals* in a *quarantine station* for at least 30 days, and during this period:
    - a) all *animals* to be monitored daily for signs of illness and, if necessary, subjected to a clinical examination;
    - b) all *animals* dying for any reason to be subjected to complete post-mortem examination at a laboratory approved for this purpose;
    - c) any cause of illness or death to be determined before the group to which the *animals* belong is released from quarantine;
Chapter 6.11.- Zoonoses transmissible from non-human primates

d) animals to be subjected to the following diagnostic tests and treatments in accordance with Chapter 4.15.: 

<table>
<thead>
<tr>
<th>Disease/agent</th>
<th>Animal groups</th>
<th>Schedule</th>
<th>Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tuberculosis (Mycobacterium tuberculosis complex)</td>
<td>All species</td>
<td>One test.</td>
<td>Skin test or serology. In-vitro gamma interferon assay or polymerase chain reaction (PCR) assay. (See further comments in the Table of Article 6.11.4.)</td>
</tr>
<tr>
<td>Other bacterial pathogens (Salmonella, Shigella and Yersinia and others as appropriate)</td>
<td>All species</td>
<td>Daily test for 3 days after arrival, and another test at least one week later.</td>
<td>Faecal culture. (See further comments in the Table of Article 6.11.4.)</td>
</tr>
<tr>
<td>Endo- and ectoparasites</td>
<td>All species</td>
<td>At least two tests, one of which should be at the start, the other towards the end of the quarantine.</td>
<td>Testing methods and antiparasitic treatment as appropriate to species of animal and parasitic agent.</td>
</tr>
</tbody>
</table>

Veterinary Authorities of importing countries may not normally require any tests for viral diseases. However, stringent precautions to ensure human health and safety should be followed as recommended in Article 6.11.7.

Article 6.11.7.

Precautionary measures to be followed by staff exposed to non-human primates or to their body fluids, faeces and tissues

The presence in most non-human primates of some zoonotic agents is almost unavoidable, even after release from quarantine. The relevant Authorities should, therefore, encourage the management of institutions whose staff are exposed to non-human primates or their body fluids, faeces or tissues (including when performing necropsies) to comply with the following recommendations:

1) to provide staff with training in the proper handling of primates, their body fluids, faeces and tissues, with respect to zoonoses containment and personal safety;
2) to inform their staff that certain species should be considered as having lifelong infections with some zoonotic agents, e.g. Asian macaques with Herpes B virus;
3) to ensure that the staff follows personal hygiene practices, including the use of protective clothing, and the prohibition of eating, drinking and smoking in potentially infective areas;
4) to implement a screening programme for personnel health, including monitoring for tuberculosis, pathogenic enteric bacteria and endoparasites and other agents that are deemed necessary;
5) to implement an immunisation programme as appropriate, including e.g. tetanus, measles, poliomyelitis, rabies, hepatitis A and B, and other diseases, such as yellow fever, endemic in the area of origin of the African and American non-human primates;
6) to develop guidelines for the prevention and treatment of zoonoses that may be transmitted by bites and scratches, e.g. rabies and herpes viruses;
7) to issue to their staff a card which states that they work with non-human primates or with their body fluids, faeces or tissues, and which may be presented to the medical profession in case of illness;
8) to dispose of carcasses, body fluids, faeces and tissues in a manner which is not detrimental to public health.
SECTION 7.

ANIMAL WELFARE

CHAPTER 7.1.

INTRODUCTION TO THE RECOMMENDATIONS FOR ANIMAL WELFARE

Article 7.1.1.

*Animal welfare* means how an *animal* is coping with the conditions in which it lives. An *animal* is in a good state of *welfare* if (as indicated by scientific evidence) it is healthy, comfortable, well nourished, safe, able to express innate behaviour, and if it is not suffering from unpleasant states such as pain, fear, and distress.

Good *animal welfare* requires *disease* prevention and appropriate *veterinary* treatment, shelter, management and *nutrition*, humane handling and humane *slaughter* or *killing*. *Animal welfare* refers to the state of the *animal*; the treatment that an *animal* receives is covered by other terms such as animal care, animal husbandry, and humane treatment.

Article 7.1.2.

**Guiding principles for animal welfare**

1) That there is a critical relationship between animal health and *animal welfare*.

2) That the internationally recognised ‘five freedoms’ (freedom from hunger, thirst and malnutrition; freedom from fear and distress; freedom from physical and thermal discomfort; freedom from pain, injury and disease; and freedom to express normal patterns of behaviour) provide valuable guidance in *animal welfare*.

3) That the internationally recognised ‘three Rs’ (reduction in numbers of *animals*, refinement of experimental methods and replacement of *animals* with non-animal techniques) provide valuable guidance for the use of *animals* in science.

4) That the scientific assessment of *animal welfare* involves diverse elements which need to be considered together, and that selecting and weighing these elements often involves value-based assumptions which should be made as explicit as possible.

5) That the use of *animals* in agriculture, education and research, and for companionship, recreation and entertainment, makes a major contribution to the wellbeing of people.

6) That the use of *animals* carries with it an ethical responsibility to ensure the *welfare* of such *animals* to the greatest extent practicable.

7) That improvements in farm *animal welfare* can often improve productivity and food safety, and hence lead to economic benefits.

8) That equivalent outcomes based on performance criteria, rather than identical systems based on design criteria, be the basis for comparison of *animal welfare* standards and recommendations.

Article 7.1.3.

**Scientific basis for recommendations**

1) *Welfare* is a broad term which includes the many elements that contribute to an *animal’s* quality of life, including those referred to in the ‘five freedoms’ listed above.
Chapter 7.1.- Introduction to the recommendations for animal welfare

2) The scientific assessment of animal welfare has progressed rapidly in recent years and forms the basis of these recommendations.

3) Some measures of animal welfare involve assessing the degree of impaired functioning associated with injury, disease, and malnutrition. Other measures provide information on animals' needs and affective states such as hunger, pain and fear, often by measuring the strength of animals' preferences, motivations and aversions. Others assess the physiological, behavioural and immunological changes or effects that animals show in response to various challenges.

4) Such measures can lead to criteria and indicators that help to evaluate how different methods of managing animals influence their welfare.

Article 7.1.4.

General principles for the welfare of animals in livestock production systems

1) Genetic selection should always take into account the health and welfare of animals.

2) Animals chosen for introduction into new environments should be suited to the local climate and able to adapt to local diseases, parasites and nutrition.

3) The physical environment, including the substrate (walking surface, resting surface, etc.), should be suited to the species so as to minimise risk of injury and transmission of diseases or parasites to animals.

4) The physical environment should allow comfortable resting, safe and comfortable movement including normal postural changes, and the opportunity to perform types of natural behaviour that animals are motivated to perform.

5) Social grouping of animals should be managed to allow positive social behaviour and minimise injury, distress and chronic fear.

6) For housed animals, air quality, temperature and humidity should support good animal health and not be aversive. Where extreme conditions occur, animals should not be prevented from using their natural methods of thermo-regulation.

7) Animals should have access to sufficient feed and water, suited to the animals' age and needs, to maintain normal health and productivity and to prevent prolonged hunger, thirst, malnutrition or dehydration.

8) Diseases and parasites should be prevented and controlled as much as possible through good management practices. Animals with serious health problems should be isolated and treated promptly or killed humanely if treatment is not feasible or recovery is unlikely.

9) Where painful procedures cannot be avoided, the resulting pain should be managed to the extent that available methods allow.

10) The handling of animals should foster a positive relationship between humans and animals and should not cause injury, panic, lasting fear or avoidable stress.

11) Owners and handlers should have sufficient skill and knowledge to ensure that animals are treated in accordance with these principles.
CHAPTER 7.2.
TRANSPORT OF ANIMALS BY SEA

Preamble: These recommendations apply to the following live domesticated animals: cattle, buffaloes, deer, camelids, sheep, goats, pigs and equines. They may also be applicable to other domesticated animals.

Article 7.2.1.

The amount of time animals spend on a journey should be kept to the minimum.

Article 7.2.2.

1. Animal behaviour

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

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

Most domestic livestock are kept in herds and follow a leader by instinct. Animals which are likely to be hostile to others in a group situation should not be mixed.

The desire of some animals to control their personal space should be taken into account in designing loading and unloading facilities, transport vessels and containers.

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

Animal handlers should use the point of balance at the animal’s shoulder to move animals, adopting a position behind the point of balance to move an animal forward and in front of the point of balance to move it backward. Domestic animals have a wide-angle vision but only have a limited forward binocular vision and poor perception of depth. This means that they can detect objects and movements beside and behind them, but can only judge distances directly ahead.

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

2. Distractions and their removal

Design of new loading and unloading facilities or modification of existing facilities should aim to minimise the potential for distractions that may cause approaching animals to stop, baulk or turn back. Below are examples of common distractions and methods for eliminating them:

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

b) dark entrances – illuminate with indirect lighting which does not shine directly into the eyes of approaching animals;

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

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

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

f) uneven floors or a sudden drop in floor levels – avoid uneven floor surfaces or install a solid false floor to provide an illusion of a solid and continuous walking surface;
g) sounds of air hissing from pneumatic equipment – install silencers or use hydraulic equipment or vent high pressure to the external environment using flexible hosing;

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

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

An example of a flight zone (cattle)

Handler movement pattern to move cattle forward

Article 7.2.3.

Responsibilities

Once the decision to transport the animals by sea has been made, the welfare of the animals during their journey is the paramount consideration and is the joint responsibility of all people involved. The individual responsibilities of persons involved will be described in more detail in this article. These recommendations may also be applied to the transport of animals by water within a country.

The management of animals at post-discharge facilities is outside the scope of this chapter.
Chapter 7.2.- Transport of animals by sea

1. General considerations

a) Exporters, importers, owners of animals, business or buying/selling agents, shipping companies, masters of vessels and managers of facilities are jointly responsible for the general health of the animals and their fitness for the journey, and for their overall welfare during the journey, regardless of whether duties are subcontracted to other parties during transport.

b) Exporters, shipping companies, business or buying/selling agents, and masters of vessels are jointly responsible for planning the journey to ensure the care of the animals, including:
   i) choosing appropriate vessels and ensuring that animal handlers are available to care for the animals;
   ii) developing and keeping up-to-date contingency plans to address emergencies (including adverse weather conditions) and minimise stress during transport;
   iii) correct loading of the ship, provision of appropriate food, water, ventilation and protection from adverse weather, regular inspections during the journey and for appropriate responses to problems arising;
   iv) disposal of carcasses according to international law.

c) To carry out the above mentioned responsibilities, the parties involved should be competent regarding transport regulations, equipment usage, and the humane handling and care of animals.

2. Specific considerations

a) The responsibilities of the exporters include:
   i) the organisation, carrying out and completion of the journey, regardless of whether duties are subcontracted to other parties during transport;
   ii) ensuring that equipment and medication are provided as appropriate for the species and the journey;
   iii) securing the presence of the appropriate number of animal handlers competent for the species being transported;
   iv) ensuring compliance of the animals with any required veterinary certification, and their fitness to travel;
   v) in case of animals for export, ensuring compliance with any requirements of the importing and exporting countries.

b) The responsibilities of the owners of the animals include the selection of animals that are fit to travel based on veterinary recommendations.

c) The responsibilities of the business or buying/selling agent include:
   i) selection of animals that are fit to travel based on veterinary recommendations;
   ii) availability of suitable facilities for the assembly, loading, transport, unloading and holding of animals at the start and at the end of the journey, and for emergencies.

d) The responsibilities of masters of vessels include the provision of suitable premises for animals on the vessel.

e) The responsibilities of managers of facilities during loading include:
   i) providing suitable premises for loading the animals;
   ii) providing an appropriate number of animal handlers to load the animals with minimum stress and the avoidance of injury;
   iii) minimising the opportunities for disease transmission while the animals are in the facilities;
   iv) providing appropriate facilities for emergencies;
   v) providing facilities, veterinarians or animal handlers capable of killing animals humanely when required.

f) The responsibilities of managers of facilities during unloading include:
   i) providing suitable facilities for unloading the animals onto transport vehicles for immediate movement or securely holding the animals in lairage, with shelter, water and feed, when required, for transit;
   ii) providing animal handlers to unload the animals with minimum stress and injury;
   iii) minimising the opportunities for disease transmission while the animals are in the facilities;
   iv) providing appropriate facilities for emergencies;
   v) providing facilities, and veterinarians or animal handlers capable of killing animals humanely when required.

g) The responsibilities of the animal handlers include humane handling and care of the animals, especially during loading and unloading.

h) The responsibilities of the Competent Authority of the exporting country include:
   i) establishing minimum standards for animal welfare, including requirements for inspection of animals before and during their travel, and for certification and record keeping;
   ii) approving facilities, containers, vehicles and vessels for the holding and transport of animals;
iii) setting competence standards for animal handlers and managers of facilities;
iv) implementation of the standards, including through accreditation of / interaction with other organisations and Competent Authorities;
v) monitor and evaluate health and welfare of the animals at the point of loading.

i) The responsibilities of the Competent Authority of the importing country include:
i) establishing minimum standards for animal welfare, including requirements for inspection of animals after their travel, and for certification and record keeping;
ii) approve facilities, containers, vehicles and vessels for the holding and transport of animals;
iii) setting competence standards for animal handlers and managers of facilities;
iv) implementation of the standards, including through accreditation of / interaction with other organisations and Competent Authorities;
v) ensuring that the exporting country is aware of the required standards for the vessel transporting the animals;
vi) monitor and evaluate health and welfare of the animals at the point of unloading;

j) The responsibilities of veterinarians or in the absence of a veterinarian, the animal handlers travelling on the vessel with the animals include:
i) humane handling and treatment of animals during the journey, including in emergencies, such as humane killing of the animals;
ii) possess ability to report and act independently;
iii) meet daily with the master of the vessel to obtain up-to-date information on animal health and welfare status.

k) The receiving Competent Authority should report back to the sending Competent Authority on significant animal welfare problems which occurred during the journey.

Competence

1) All people responsible for animals during journeys should be competent to carry out the relevant responsibilities listed in Article 7.2.3. Competence in areas other than animal welfare would need to be addressed separately. Competence may be gained through formal training and/or practical experience.

2) The assessment of competence of animal handlers should at a minimum address knowledge, and ability to apply that knowledge, in the following areas:
   a) planning a journey, including appropriate space allowance, feed, water and ventilation requirements;
   b) responsibilities for the welfare of animals during the journey, including loading and unloading;
   c) sources of advice and assistance;
   d) animal behaviour, general signs of disease, and indicators of poor animal welfare such as stress, pain and fatigue, and their alleviation;
   e) assessment of fitness to travel; if fitness to travel is in doubt, the animal should be examined by a veterinarian;
   f) relevant authorities and applicable transport regulations, and associated documentation requirements;
   g) general disease prevention procedures, including cleaning and disinfection;
   h) appropriate methods of animal handling during transport and associated activities such as assembling, loading and unloading;
   i) methods of inspecting animals, managing situations frequently encountered during transport such as adverse weather conditions, and dealing with emergencies, including euthanasia;
   j) species-specific aspects and age-specific aspects of animal handling and care, including feeding, watering and inspection; and
   k) maintaining a journey log and other records.

3) Assessment of competence for exporters should at a minimum address knowledge, and ability to apply that knowledge, in the following areas:
   a) planning a journey, including appropriate space allowances, and feed, water and ventilation requirements;
   b) relevant authorities and applicable transport regulations, and associated documentation requirements;
c) appropriate methods of animal handling during transport and associated activities such as cleaning and disinfection, assembling, loading and unloading;

d) species-specific aspects of animal handling and care, including appropriate equipment and medication;

e) sources of advice and assistance;

f) appropriate record keeping; and

g) managing situations frequently encountered during transport, such as adverse weather conditions, and dealing with emergencies.

Article 7.2.5.

Planning the journey

1. General considerations
   a) Adequate planning is a key factor affecting the welfare of animals during a journey.
   b) Before the journey starts, plans should be made in relation to:
      i) preparation of animals for the journey;
      ii) type of transport vessel required;
      iii) route, taking into account distance, expected weather and sea conditions;
      iv) nature and duration of journey;
      v) daily care and management of the animals, including the appropriate number of animal handlers, to help ensure the health and welfare of all the animals;
      vi) avoiding the mixing of animals from different sources in a single pen group;
      vii) provision of appropriate equipment and medication for the numbers and species carried; and
      viii) emergency response procedures.

2. Preparation of animals for the journey
   a) When animals are to be provided with a novel diet or unfamiliar methods of supplying of feed or water, they should be preconditioned.
   b) There should be planning for water and feed availability during the journey. Feed should be of appropriate quality and composition for the species, age, condition of the animals, etc.
   c) Extreme weather conditions are hazards for animals undergoing transport and require appropriate vessel design to minimise risks. Special precautions should be taken for animals that have not been acclimatised or which are unsuited to either hot or cold conditions. In some extreme conditions of heat or cold, animals should not be transported at all.
   d) Animals more accustomed to contact with humans and with being handled are likely to be less fearful of being loaded and transported. Animals should be handled and loaded in a manner that reduces their fearfulness and improves their approachability.
   e) Behaviour-modifying (such as tranquillisers) or other medication should not be used routinely during transport. Such medicines should only be administered when a problem exists in an individual animal, and should be administered by a veterinarian or other person who has been instructed in their use by a veterinarian. Treated animals should be placed in a dedicated area.

3. Control of disease
   As animal transport is often a significant factor in the spread of infectious diseases, journey planning should take into account the following:
   a) When possible and agreed by the Veterinary Authority of the importing country, animals should be vaccinated against diseases to which they are likely to be exposed at their destination.
   b) Medications used prophylactically or therapeutically should only be administered by a veterinarian or other person who has been instructed in their use by a veterinarian.
   c) Mixing of animals from different sources in a single consignment should be minimized.

4. Vessel and container design and maintenance
   a) Vessels used for the sea transport of animals should be designed, constructed and fitted as appropriate to the species, size and weight of the animals to be transported. Special attention should be paid to the avoidance of injury to animals through the use of secure smooth fittings free from sharp protrusions and the
Chapter 7.2.- Transport of animals by sea

provision of non-slippery flooring. The avoidance of injury to animal handlers while carrying out their responsibilities should be emphasised.

b) Vessels should be properly illuminated to allow animals to be observed and inspected.

c) Vessels should be designed to permit thorough cleaning and disinfection, and the management of faeces and urine.

d) Vessels and their fittings should be maintained in good mechanical and structural conditions.

e) Vessels should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported. The ventilation system should be effective when the vessel is stationary. An emergency power supply should be available to maintain ventilation in the case of primary machinery breakdown.

f) The feeding and watering system should be designed to permit adequate access to feed and water appropriate to the species, size and weight of the animals, and to minimise soiling of pens.

g) Vessels should be designed so that the faeces or urine from animals on upper levels do not soil animals on lower levels, or their feed or water.

h) Loading and stowage of feed and bedding should be carried out in such a way to ensure protection from fire hazards, the elements and sea water.

i) Where appropriate, suitable bedding, such as straw or sawdust, should be added to vessel floors to assist absorption of urine and faeces, provide better footing for animals and protect animals (especially young animals) from hard or rough flooring surfaces and adverse weather conditions.

j) The above principles apply also to containers used for the transport of animals.

5. Special provisions for transport in road vehicles on roll-on/roll-off vessels or for containers

a) Road vehicles and containers should be equipped with a sufficient number of adequately designed, positioned and maintained securing points enabling them to be securely fastened to the vessel.

b) Road vehicles and containers should be secured to the ship before the start of the sea journey to prevent them being displaced by the motion of the vessel.

c) Vessels should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported, especially where the animals are transported in a secondary vehicle/container on enclosed decks.

d) Due to the risk of limited airflow on certain decks of a vessel, a road vehicle or container may require a forced ventilation system of greater capacity than that provided by natural ventilation.

6. Nature and duration of the journey

The maximum duration of a journey should be determined taking into account factors that determine the overall welfare of animals, such as:

a) the ability of the animals to cope with the stress of transport (such as very young, old, lactating or pregnant animals);

b) the previous transport experience of the animals;

c) the likely onset of fatigue;

d) the need for special attention;

e) the need for feed and water;

f) the increased susceptibility to injury and disease;

space allowance and vessel design;

h) weather conditions;

i) vessel type used, method of propulsion and risks associated with particular sea conditions.

7. Space allowance

a) The number of animals which should be transported on a vessel and their allocation to different pens on the vessel should be determined before loading.

b) The amount of space required, including headroom, depends on the species of animal and should allow the necessary thermoregulation. Each animal should be able to assume its natural position for transport (including during loading and unloading) without coming into contact with the roof or upper deck of the vessel. When animals lie down, there should be enough space for every animal to adopt a normal lying posture.

c) Calculations for the space allowance for each animal should be carried out in reference to a relevant national or international document. The size of pens will affect the number of animals in each.

d) The same principles apply when animals are transported in containers.
8. Ability to observe animals during the journey

Animals should be positioned to enable each animal to be observed regularly and clearly by an animal handler or other responsible person, during the journey to ensure their safety and good welfare.

9. Emergency response procedures

There should be an emergency management plan that identifies the important adverse events that may be encountered during the journey, the procedures for managing each event and the action to be taken in an emergency. For each important event, the plan should document the actions to be undertaken and the responsibilities of all parties involved, including communications and record keeping.

**Article 7.2.6.**

**Documentation**

1) Animals should not be loaded until the documentation required to that point is complete.

2) The documentation accompanying the consignment should include:
   a) journey travel plan and emergency management plan;
   b) time, date and place of loading;
   c) the journey log – a daily record of inspection and important events which includes records of morbidity and mortality and actions taken, climatic conditions, food and water consumed, medication provided, mechanical defects;
   d) expected time, date and place of arrival and unloading;
   e) veterinary certification, when required;
   f) animal identification to allow traceability of animals to the premises of departure, and, where possible, to the premises of origin;
   g) details of any animals considered at particular risk of suffering poor welfare during transport (point 3e) of Article 7.2.7.);
   h) number of animal handlers on board, and their competencies; and
   i) stocking density estimate for each load in the consignment.

3) When veterinary certification is required to accompany consignments of animals, it should address:
   a) when required, details of disinfection carried out;
   b) fitness of the animals to travel;
   c) animal identification (description, number, etc.); and
   d) health status including any tests, treatments and vaccinations carried out.

**Article 7.2.7.**

**Pre-journey period**

1. General considerations
   a) Before each journey, vessels should be thoroughly cleaned and, if necessary, treated for animal and public health purposes, using chemicals approved by the Competent Authority. When cleaning is necessary during a journey, this should be carried out with the minimum of stress and risk to the animals.
   b) In some circumstances, animals may require pre-journey assembly. In these circumstances, the following points should be considered:
      i) Pre-journey rest is necessary if the welfare of the animals has become poor during the collection period because of the physical environment or the social behaviour of the animals.
      ii) When animals are to be provided with a novel diet or unfamiliar methods of supplying feed or water, they should be preconditioned.
   c) Where an animal handler believes that there is a significant risk of disease among the animals to be loaded or significant doubt as to their fitness to travel, the animals should be examined by a veterinarian.
   d) Pre-journey assembly / holding areas should be designed to:
      i) securely contain the animals;
      ii) maintain an environment safe from hazards, including predators and disease;
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iii) protect animals from exposure to adverse weather conditions;
iv) allow for maintenance of social groups; and
v) allow for rest, watering and feeding.

2. Selection of compatible groups

Compatible groups should be selected before transport to avoid adverse animal welfare consequences. The following recommendations should be applied when assembling groups of animals:

a) animals of different species should not be mixed unless they are judged to be compatible;
b) animals of the same species can be mixed unless there is a significant likelihood of aggression; aggressive individuals should be segregated (recommendations for specific species are described in detail in Article 7.2.12.). For some species, animals from different groups should not be mixed because poor welfare occurs unless they have established a social structure;
c) young or small animals may need to be separated from older or larger animals, with the exception of nursing mothers with young at foot;
d) animals with horns or antlers should not be mixed with animals lacking horns or antlers, unless judged to be compatible; and
e) animals reared together should be maintained as a group; animals with a strong social bond, such as a dam and offspring, should be transported together.

3. Fitness to travel

a) Animals should be inspected by a veterinarian or an animal handler to assess fitness to travel. If its fitness to travel is in doubt, it is the responsibility of a veterinarian to determine its ability to travel. Animals found unfit to travel should not be loaded onto a vessel.
b) Humane and effective arrangements should be made by the owner or agent for the handling and care of any animal rejected as unfit to travel.
c) Animals that are unfit to travel include, but may not be limited to:
   i) those that are sick, injured, weak, disabled or fatigued;
   ii) those that are unable to stand unaided or bear weight on each leg;
   iii) those that are blind in both eyes;
   iv) those that cannot be moved without causing them additional suffering;
   v) newborn with an unhealed navel;
   vi) females travelling without young which have given birth within the previous 48 hours;
   vii) pregnant animals which would be in the final 10% of their gestation period at the planned time of unloading;
   viii) animals with unhealed wounds from recent surgical procedures such as dehorning.
d) Risks during transport can be reduced by selecting animals best suited to the conditions of travel and those that are acclimatised to expected weather conditions.
e) Animals at particular risk of suffering poor welfare during transport and which require special conditions (such as in the design of facilities and vehicles, and the length of the journey) and additional attention during transport, may include:
   i) very large or obese individuals;
   ii) very young or old animals;
   iii) excitable or aggressive animals;
   iv) animals subject to motion sickness;
   v) animals which have had little contact with humans;
   vi) females in the last third of pregnancy or in heavy lactation.
f) Hair or wool length should be considered in relation to the weather conditions expected during transport.
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Article 7.2.8.

Loading

1. Competent supervision
   a) Loading should be carefully planned as it has the potential to be the cause of poor welfare in transported animals.
   b) Loading should be supervised by the Competent Authority and conducted by animal handler(s). Animal handlers should ensure that animals are loaded quietly and without unnecessary noise, harassment or force, and that untrained assistants or spectators do not impede the process.

2. Facilities
   a) The facilities for loading, including the collecting area at the wharf, races and loading ramps should be designed and constructed to take into account the needs and abilities of the animals with regard to dimensions, slopes, surfaces, absence of sharp projections, flooring, sides, etc.
   b) Ventilation during loading and the journey should provide for fresh air, and the removal of excessive heat, humidity and noxious fumes (such as ammonia and carbon monoxide). Under warm and hot conditions, ventilation should allow for the adequate convective cooling of each animal. In some instances, adequate ventilation can be achieved by increasing the space allowance for animals.
   c) Loading facilities should be properly illuminated to allow the animals to be easily inspected by animal handlers, and to allow the ease of movement of animals at all times. Facilities should provide uniform light levels directly over approaches to sorting pens, chutes, loading ramps, with brighter light levels inside vehicles/containers, in order to minimise baulking. Dim light levels may be advantageous for the catching of some animals. Artificial lighting may be required.

3. Goads and other aids
   When moving animals, their species-specific behaviour should be used (see Article 7.2.12.). If goads and other aids are necessary, the following principles should apply:
   a) Animals that have little or no room to move should not be subjected to physical force or goads and other aids which compel movement. Electric goads and prods should only be used in extreme cases and not on a routine basis to move animals. The use and the power output should be restricted to that necessary to assist movement of an animal and only when an animal has a clear path ahead to move. Goads and other aids should not be used repeatedly if the animal fails to respond or move. In such cases it should be investigated whether some physical or other impediment is preventing the animal from moving.
   b) The use of such devices should be limited to battery-powered goads on the hindquarters of pigs and large ruminants, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets.
   c) Useful and permitted goads include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and rattles; they should be used in a manner sufficient to encourage and direct movement of the animals without causing undue stress.
   d) Painful procedures (including whipping, tail twisting, use of nose twitches, pressure on eyes, ears or external genitalia), or the use of goads or other aids which cause pain and suffering (including large sticks, sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts), should not be used to move animals.
   e) Excessive shouting at animals or making loud noises (e.g. through the cracking of whips) to encourage them to move should not occur as such actions may make the animals agitated, leading to crowding or falling.
   f) The use of well trained dogs to help with the loading of some species may be acceptable.
   g) Animals should be grasped or lifted in a manner which avoids pain or suffering and physical damage (e.g. bruising, fractures, dislocations). In the case of quadrupeds, manual lifting by a person should only be used in young animals or small species, and in a manner appropriate to the species; grasping or lifting animals only by their wool, hair, feathers, feet, neck, ears, tails, head, horns, limbs causing pain or suffering should not be permitted, except in an emergency where animal welfare or human safety may otherwise be compromised.
   h) Conscious animals should not be thrown, dragged or dropped.
   i) Performance standards should be established in which numerical scoring is used to evaluate the use of such instruments, and to measure the percentage of animals moved with an electric instrument and the percentage of animals slipping or falling as a result of their usage.
Article 7.2.9.

Travel

1. General considerations
   a) Animal handler(s) should check the consignment immediately before departure to ensure that the animals have been loaded according to the load plan. Each consignment should be checked following any incident or situation likely to affect their welfare and in any case within 12 hours of departure.
   b) If necessary and where possible adjustments should be made to the stocking density as appropriate during the journey.
   c) Each pen of animals should be observed on a daily basis for normal behaviour, health and welfare, and the correct operation of ventilation, watering and feeding systems. There should also be a night patrol. Any necessary corrective action should be undertaken promptly.
   d) Adequate access to suitable feed and water should be ensured for all animals in each pen.
   e) Where cleaning or disinfection is necessary during travel, it should be carried out with the minimum of stress to the animals.

2. Sick or injured animals
   a) Sick or injured animals should be segregated.
   b) Sick or injured animals should be appropriately treated or humanely killed, in accordance with a predetermined emergency response plan (Article 7.2.5.). Veterinary advice should be sought if necessary. All drugs and products should be used according to recommendations from a veterinarian and in accordance with the manufacturer’s instructions.
   c) A record of treatments carried out and their outcomes should be kept.
   d) When humane killing is necessary, the animal handler must ensure that it is carried out humanely. Recommendations for specific species are described in Chapter 7.6. on killing of animals for disease control purposes. Veterinary advice regarding the appropriateness of a particular method of euthanasia should be sought as necessary.

Article 7.2.10.

Unloading and post-journey handling

1. General considerations
   a) The required facilities and the principles of animal handling detailed in Article 7.2.8. apply equally to unloading, but consideration should be given to the likelihood that the animals will be fatigued.
   b) Unloading should be carefully planned as it has the potential to be the cause of poor welfare in transported animals.
   c) A livestock vessel should have priority attention when arriving in port and have priority access to a berth with suitable unloading facilities. As soon as possible after the vessel’s arrival at the port and acceptance of the consignment by the Competent Authority, animals should be unloaded into appropriate facilities.
   d) The accompanying veterinary certificate and other documents should meet the requirements of the importing country. The veterinary inspection should be completed as quickly as possible.
   e) Unloading should be supervised by the Competent Authority and conducted by animal handler(s). The animal handlers should ensure that animals are unloaded as soon as possible after arrival but sufficient time should be allowed for unloading to proceed quietly and without unnecessary noise, harassment or force, and that untrained assistants or spectators do not impede the process.

2. Facilities
   a) The facilities for unloading including the collecting area at the wharf, races and unloading ramps should be designed and constructed to take into account of the needs and abilities of the animals with regard to dimensions, slopes, surfaces, absence of sharp projections, flooring, sides, etc.
   b) All unloading facilities should have sufficient lighting to allow the animals to be easily inspected by the animal handlers, and to allow ease of movement of animals at all times.
   c) There should be facilities to provide animals with appropriate care and comfort, adequate space, access to quality feed and clean drinking water, and shelter from extreme weather conditions.
3. Sick or injured animals

   a) An animal that has become sick, injured or disabled during a journey should be appropriately treated or humanely killed (see Chapter 7.6.). When necessary, veterinary advice should be sought in the care and treatment of these animals.

   b) In some cases, where animals are non-ambulatory due to fatigue, injury or sickness, it may be in the best welfare interests of the animal to be treated or humanely killed aboard the vessel.

   c) If unloading is in the best welfare interests of animals that are fatigued, injured or sick, there should be appropriate facilities and equipment for the humane unloading of such animals. These animals should be unloaded in a manner that causes the least amount of suffering. After unloading, separate pens and other appropriate facilities and treatments should be provided for sick or injured animals.

4. Cleaning and disinfection

   a) Vessels and containers used to carry the animals should be cleaned before re-use through the physical removal of manure and bedding, by scraping, washing and flushing vessels and containers with water until visibly clean. This should be followed by disinfection when there are concerns about disease transmission.

   b) Manure, litter and bedding should be disposed of in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.

Actions in the event of a refusal to allow the importation of a shipment

1) The welfare of the animals should be the first consideration in the event of a refusal to import.

2) When animals have been refused import, the Competent Authority of the importing country should make available suitable isolation facilities to allow the unloading of animals from a vessel and their secure holding, without posing a risk to the health of the national herd, pending resolution of the situation. In this situation, the priorities should be:

   a) The Competent Authority of the importing country should provide urgently in writing the reasons for the refusal.

   b) In the event of a refusal for animal health reasons, the Competent Authority of the importing country should provide urgent access to an OIE-appointed veterinarian(s) to assess the health status of the animals with regard to the concerns of the importing country, and the necessary facilities and approvals to expedite the required diagnostic testing.

   c) The Competent Authority of the importing country should provide access to allow continued assessment of the ongoing health and welfare situation.

   d) If the matter cannot be promptly resolved, the Competent Authorities of the exporting and importing countries should call on the OIE to mediate.

3) In the event that the animals are required to remain on the vessel, the priorities should be:

   a) The Competent Authority of the importing country should allow provisioning of the vessel with water and feed as necessary.

   b) The Competent Authority of the importing country should provide urgently in writing the reasons for the refusal.

   c) In the event of a refusal for animal health reasons, the Competent Authority of the importing country should provide urgent access to an OIE-appointed veterinarian(s) to assess the health status of the animals with regard to the concerns of the importing country, and the necessary facilities and approvals to expedite the required diagnostic testing.

   d) The Competent Authority of the importing country should provide access to allow continued assessment of the ongoing health and other aspects of the welfare of the animals, and the necessary actions to deal with any issues which arise.

   e) If the matter cannot be urgently resolved, the Competent Authorities of the exporting and importing countries should call on the OIE to mediate.

4) The OIE should utilise its informal procedure for dispute mediation to identify a mutually agreed solution which will address the animal health and welfare issues in a timely manner.
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Article 7.2.12.

Species-specific issues

Camelids of the new world in this context comprise llamas, alpacas, guanaco and vicuna. They have good eyesight and, like sheep, can negotiate steep slopes, though ramps should be as shallow as possible. They load most easily as a single animal will strive to rejoin the others. Whilst they are usually docile, they have an unnerving habit of spitting in self-defence. During transport, they usually lie down. They frequently extend their front legs forward when lying, so gaps below partitions should be high enough so that their legs are not trapped when the animals rise.

Cattle are sociable animals and may become agitated if they are singled out. Social order is usually established at about two years of age. When groups are mixed, social order has to be re-established and aggression may occur until a new order is established. Crowding of cattle may also increase aggression as the animals try to maintain personal space. Social behaviour varies with age, breed and sex; Bos indicus and B. indicus-cross animals are usually more temperamental than European breeds. Young bulls, when moved in groups, show a degree of playfulness (pushing and shoving) but become more aggressive and territorial with age. Adult bulls have a minimum personal space of six square metres. Cows with young calves can be very protective, and handling calves in the presence of their mothers can be dangerous. Cattle tend to avoid “dead end” in passages.

Goats should be handled calmly and are more easily led or driven than if they are excited. When goats are moved, their gregarious tendencies should be exploited. Activities which frighten, injure or cause agitation to animals should be avoided. Bullying is particularly serious in goats. Housing strange goats together could result in fatalities, either through physical violence, or subordinate goats being refused access to food and water.

Horses in this context include all solipeds, donkeys, mules, hinnies and zebra. They have good eyesight and a very wide angle of vision. They may have a history of loading resulting in good or bad experiences. Good training should result in easier loading, but some horses can prove difficult, especially if they are inexperienced or have associated loading with poor transport conditions. In these circumstances, two experienced animal handlers can load an animal by linking arms or using a strap below its rump. Blindfolding may even be considered. Ramps should be as shallow as possible. Steps are not usually a problem when horses mount a ramp, but they tend to jump a step when descending, so steps should be as low as possible. Horses benefit from being individually stalled, but may be transported in compatible groups. When horses are to travel in groups, their shoes should be removed.

Pigs have poor eyesight, and may move reluctantly in unfamiliar surroundings. They benefit from well-lit loading bays. Since they negotiate ramps with difficulty, these should be as level as possible and provided with secure footholds. Ideally, a hydraulic lift should be used for greater heights. Pigs also negotiate steps with difficulty. A good ‘rule-of-thumb’ is that no step should be higher than the pig’s front knee. Serious aggression may result if unfamiliar animals are mixed. Pigs are highly susceptible to heat stress.

Sheep are sociable animals with good eyesight and tend to “flock together”, especially when they are agitated. They should be handled calmly and their tendency to follow each other should be exploited when they are being moved. Sheep may become agitated if they are singled out for attention and will strive to rejoin the group. Activities which frighten, injure or cause agitation to sheep should be avoided. They can negotiate steep ramps.
CHAPTER 7.3.

TRANSPORT OF ANIMALS BY LAND

Preamble: These recommendations apply to the following live domesticated animals: cattle, buffaloes, camels, sheep, goats, pigs, poultry and equines. They will also be largely applicable to some other animals, e.g. deer, other camelids and ratites. Wild animals and feral animals may need different conditions.

Article 7.3.1.

The amount of time animals spend on a journey should be kept to the minimum.

Article 7.3.2.

1. Animal behaviour

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

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

Most domestic livestock are kept in groups and follow a leader by instinct. Animals which are likely to harm each other in a group situation should not be mixed.

The desire of some animals to control their personal space should be taken into account in designing loading and unloading facilities, transport vessels and containers.

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

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

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

Although domestic animals have a highly sensitive sense of smell, they may react differently to the smells encountered during travel. Smells which cause negative responses should be taken into consideration when managing animals.

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

2. Distractions and their removal

Design of new loading and unloading facilities or modification of existing facilities should aim to minimise the potential for distractions that may cause approaching animals to stop, baulk or turn back. Below are examples of common distractions and methods for eliminating them:

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

b) dark entrances – illuminate with indirect lighting which does not shine directly into the eyes of approaching animals;
c) *animals* seeing moving people or equipment up ahead – install solid sides on chutes and races or install shields;

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

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

f) uneven floors or a sudden drop in floor levels – avoid uneven floor surfaces or install a solid false floor to provide an illusion of a solid and continuous walking surface;

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

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

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

An example of a flight zone (cattle)

![Flight Zone Diagram](image)

Handler movement pattern to move cattle forward
Responsibilities

Once the decision to transport the animals has been made, the welfare of the animals during their journey is the paramount consideration and is the joint responsibility of all people involved. The individual responsibilities of persons involved will be described in more detail in this article.

The roles of each of those responsible are defined below:

1) The owners and managers of the animals are responsible for:
   a) the general health, overall welfare and fitness of the animals for the journey;
   b) ensuring compliance with any required veterinary or other certification;
   c) the presence of an animal handler competent for the species being transported during the journey with the authority to take prompt action; in case of transport by individual trucks, the truck driver may be the sole animal handler during the journey;
   d) the presence of an adequate number of animal handlers during loading and unloading;
   e) ensuring that equipment and veterinary assistance are provided as appropriate for the species and the journey.

2) Business agents or buying/selling agents are responsible for:
   a) selection of animals that are fit to travel;
   b) availability of suitable facilities at the start and at the end of the journey for the assembly, loading, transport, unloading and holding of animals, including for any stops at resting points during the journey and for emergencies.

3) Animal handlers are responsible for the humane handling and care of the animals, especially during loading and unloading, and for maintaining a journey log. To carry out their responsibilities, they should have the authority to take prompt action. In the absence of a separate animal handler, the driver is the animal handler.

4) Transport companies, vehicle owners and drivers are responsible for planning the journey to ensure the care of the animals; in particular they are responsible for:
   a) choosing appropriate vehicles for the species transported and the journey;
   b) ensuring that properly trained staff are available for loading/unloading of animals;
   c) ensuring adequate competency of the driver in matters of animal welfare for the species being transported in case a separate animal handler is not assigned to the truck;
   d) developing and keeping up-to-date contingency plans to address emergencies (including adverse weather conditions) and minimise stress during transport;
   e) producing a journey plan which includes a loading plan, journey duration, itinerary and location of resting places;
   f) loading only those animals which are fit to travel, for their correct loading into the vehicle and their inspection during the journey, and for appropriate responses to problems arising; if its fitness to travel is in doubt, the animal should be examined by a veterinarian in accordance with point 3(a) of Article 7.3.7.;
   g) welfare of the animals during the actual transport.

5) Managers of facilities at the start and at the end of the journey and at resting points are responsible for:
   a) providing suitable premises for loading, unloading and securely holding the animals, with water and feed when required, and with protection from adverse weather conditions until further transport, sale or other use (including rearing or slaughter);
   b) providing an adequate number of animal handlers to load, unload, drive and hold animals in a manner that causes minimum stress and injury; in the absence of a separate animal handler, the driver is the animal handler;
   c) minimising the opportunities for disease transmission;
   d) providing appropriate facilities, with water and feed when required;
   e) providing appropriate facilities for emergencies;
   f) providing facilities for washing and disinfecting vehicles after unloading;
   g) providing facilities and competent staff to allow the humane killing of animals when required;
   h) ensuring proper rest times and minimal delay during stops.

6) The responsibilities of Competent Authorities include:
   a) establishing minimum standards for animal welfare, including requirements for inspection of animals before, during and after their travel, defining ‘fitness to travel’ and appropriate certification and record keeping;
Chapter 7.3. - Transport of animals by land

b) setting standards for facilities, containers and vehicles for the transport of animals;
c) setting standards for the competence of animal handlers, drivers and managers of facilities in relevant issues in animal welfare;
d) ensuring appropriate awareness and training of animal handlers, drivers and managers of facilities in relevant issues in animal welfare;
e) implementation of the standards, including through accreditation of interaction with other organisations;
f) monitoring and evaluating the effectiveness of standards of health and other aspects of welfare;
g) monitoring and evaluating the use of veterinary medications;
h) giving animal consignments priority at frontiers in order to allow them to pass without unnecessary delay.

7) All individuals, including veterinarians, involved in transporting animals and the associated handling procedures should receive appropriate training and be competent to meet their responsibilities.
8) The receiving Competent Authority should report back to the sending Competent Authority on significant animal welfare problems which occurred during the journey.

Article 7.3.4.

Competence
1) All people responsible for animals during journeys should be competent according to their responsibilities listed in Article 7.3.3. Competence may be gained through formal training and/or practical experience.
2) The assessment of the competence of animal handlers should at a minimum address knowledge, and ability to apply that knowledge, in the following areas:
   a) planning a journey, including appropriate space allowance, and feed, water and ventilation requirements;
   b) responsibilities for animals during the journey, including loading and unloading;
   c) sources of advice and assistance;
   d) animal behaviour, general signs of disease, and indicators of poor animal welfare such as stress, pain and fatigue, and their alleviation;
   e) assessment of fitness to travel; if fitness to travel is in doubt, the animal should be examined by a veterinarian;
   f) relevant authorities and applicable transport regulations, and associated documentation requirements;
   g) general disease prevention procedures, including cleaning and disinfection;
   h) appropriate methods of animal handling during transport and associated activities such as assembling, loading and unloading;
   i) methods of inspecting animals, managing situations frequently encountered during transport such as adverse weather conditions, and dealing with emergencies, including humane killing;
   j) species-specific aspects and age-specific aspects of animal handling and care, including feeding, watering and inspection; and
   k) maintaining a journey log and other records.

Article 7.3.5.

Planning the journey

1. General considerations
   a) Adequate planning is a key factor affecting the welfare of animals during a journey.
   b) Before the journey starts, plans should be made in relation to:
      i) preparation of animals for the journey;
      ii) choice of road, rail, roll-on roll-off vessels or containers;
      iii) nature and duration of the journey;
      iv) vehicle design and maintenance, including roll-on roll-off vessels;
      v) required documentation;
      vi) space allowance;
      vii) rest, water and feed;
      viii) observation of animals en route;
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ix) control of disease;

x) emergency response procedures;

xi) forecast weather conditions (e.g. conditions being too hot or too cold to travel during certain periods of the day);

xii) transfer time when changing mode of transport, and

xiii) waiting time at frontiers and inspection points.

c) Regulations concerning drivers (for example, maximum driving periods) should take into account animal welfare whenever possible.

2. Preparation of animals for the journey
   a) When animals are to be provided with a novel diet or method of water provision during transport, an adequate period of adaptation should be planned. For all animals it is essential that the rest stops during long journeys are long enough to fulfil each animal’s need for feed and water. Species-specific short period of feed deprivation prior to loading may be desirable

b) Animals more accustomed to contact with humans and with being handled are likely to be less fearful of being loaded and transported. Animal handlers should handle and load animals in a manner that reduces their fearfulness and improves their approachability.

c) Behaviour-modifying compounds (such as tranquillisers) or other medication should not be used routinely during transport. Such compounds should only be administered when a problem exists in an individual animal, and should be administered by a veterinarian or other person who has been instructed in their use by a veterinarian.

3. Nature and duration of the journey
   The maximum duration of a journey should be determined according to factors such as:
   a) the ability of the animals to cope with the stress of transport (such as very young, old, lactating or pregnant animals);
   b) the previous transport experience of the animals;
   c) the likely onset of fatigue;
   d) the need for special attention;
   e) the need for feed and water;
   f) the increased susceptibility to injury and disease;
   g) space allowance, vehicle design, road conditions and driving quality;
   h) weather conditions;
   i) vehicle type used, terrain to be traversed, road surfaces and quality, skill and experience of the driver.

4. Vehicle and container design and maintenance
   a) Vehicles and containers used for the transport of animals should be designed, constructed and fitted as appropriate for the species, size and weight of the animals to be transported. Special attention should be paid to avoid injury to animals through the use of secure smooth fittings free from sharp protrusions. The avoidance of injury to drivers and animal handlers while carrying out their responsibilities should be emphasised.

b) Vehicles and containers should be designed with the structures necessary to provide protection from adverse weather conditions and to minimise the opportunity for animals to escape.

c) In order to minimise the likelihood of the spread of infectious disease during transport, vehicles and containers should be designed to permit thorough cleaning and disinfection, and the containment of faeces and urine during a journey.

d) Vehicles and containers should be maintained in good mechanical and structural condition.

e) Vehicles and containers should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported; the ventilation system (natural or mechanical) should be effective when the vehicle is stationary, and the airflow should be adjustable.

f) Vehicles should be designed so that the faeces or urine from animals on upper levels do not soil animals on lower levels, nor their feed and water. This condition is not applicable for poultry. They are generally transported in plastic crates which are designed to let air flow through in all directions to obtain a better ventilation.

g) When vehicles are carried on board ferries, facilities for adequately securing them should be available.

h) If feeding or watering while the vehicle is moving is required, adequate facilities on the vehicle should be available.
i) When appropriate, suitable bedding should be added to vehicle floors to assist absorption of urine and faeces, to minimise slipping by animals, and protect animals (especially young animals) from hard flooring surfaces and adverse weather conditions.

5. Special provisions for transport in vehicles (road and rail) on roll-on/roll-off vessels or for containers
   a) Vehicles and containers should be equipped with a sufficient number of adequately designed, positioned and maintained securing points enabling them to be securely fastened to the vessel.
   b) Vehicles and containers should be secured to the vessel before the start of the sea journey to prevent them being displaced by the motion of the vessel.
   c) Roll-on/roll-off vessels should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported, especially where the animals are transported in a secondary vehicle/container on enclosed decks.

6. Space allowance
   a) The number of animals which should be transported on a vehicle or in a container and their allocation to compartments should be determined before loading.
   b) The space required on a vehicle or in a container depends upon whether or not the animals need to lie down (for example, cattle, sheep, pigs, camels and poultry), or to stand (horses). Animals which will need to lie down often stand when first loaded or when the vehicle is driven with too much lateral movement or sudden braking.
   c) When animals lie down, they should all be able to adopt a normal lying posture, without being on top of one another, and allowing necessary thermoregulation.
   d) When animals are standing, they should have sufficient space to adopt a balanced position as appropriate to the climate and species transported.
   e) The amount of headroom necessary depends on the species of animal. Each animal should be able to assume its natural standing position for transport (including during loading and unloading) without coming into contact with the roof or upper deck of the vehicle, and there should be sufficient headroom to allow adequate airflow over the animals. These conditions will not normally apply to poultry except for one day-old chicks. However, under tropical and subtropical conditions (under study) poultry benefit from having adequate head room to allow head cooling.
   f) Calculations for the space allowance for each animal should be carried out using the figures given in a relevant national or international document. The number and size of pens on the vehicle should be varied to where possible accommodate already established groups of animals while avoiding group sizes which are too large.
   g) Other factors which may influence space allowance include:
      i) vehicle/container design;
      ii) length of journey;
      iii) need to provide feed and water on the vehicle;
      iv) quality of roads;
      v) expected weather conditions;
      vi) category and sex of the animals.

7. Rest, water and feed
   a) Suitable water and feed should be available as appropriate and needed for the species, age, and condition of the animals, as well as the duration of the journey, climatic conditions, etc.
   b) Animals should be allowed to rest at resting points at appropriate intervals during the journey. The type of transport, the age and species of the animals being transported, and climatic conditions should determine the frequency of rest stops and whether the animals should be unloaded. Water and feed should be available during rest stops.

8. Ability to observe animals during the journey
   a) Animals should be positioned to enable each animal to be observed regularly during the journey to ensure their safety and good welfare. The condition will not normally apply to poultry. However, efforts should be made to observe the general conditions within the crates.
   b) If the animals are in crates or on multi-tiered vehicles which do not allow free access for observation, for example where the roof of the tier is too low, animals cannot be inspected adequately, and serious injury or disease could go undetected. In these circumstances, a shorter journey duration should be allowed, and the
maximum duration will vary according to the rate at which problems arise in the species and under the conditions of transport.

9. Control of disease

As animal transport is often a significant factor in the spread of infectious diseases, journey planning should take the following into account:

a) mixing of animals from different sources in a single consignment should be minimised;
b) contact at resting points between animals from different sources should be avoided;
c) when possible, animals should be vaccinated against diseases to which they are likely to be exposed at their destination;
d) medications used prophylactically or therapeutically should be approved by the Veterinary Authority of the exporting country and the importing country and should only be administered by a veterinarian or other person who has been instructed in their use by a veterinarian.

10. Emergency response procedures

There should be an emergency management plan that identifies the important adverse events that may be encountered during the journey, the procedures for managing each event and the action to be taken in an emergency. For each important event, the plan should document the actions to be undertaken and the responsibilities of all parties involved, including communications and record keeping.

11. Other considerations

a) Extreme weather conditions are hazardous for animals undergoing transport and require appropriate vehicle design to minimise risks. Special precautions should be taken for animals that have not been acclimatised or which are unsuited to either hot or cold conditions. In some extreme conditions of heat or cold, animals should not be transported at all.
b) In some circumstances, transportation during the night may reduce thermal stress or the adverse effects of other external stimuli.

Article 7.3.6.

Documentation

1) Animals should not be loaded until the documentation required to that point is complete.

2) The documentation accompanying the consignment should include:

a) journey travel plan and emergency management plan;
b) date, time and place of loading and unloading;
c) veterinary certification, when required;
d) animal welfare competencies of the driver (under study);
e) animal identification to allow animal traceability to the premises of departure and, where possible, to the premises of origin;
f) details of any animals considered at particular risk of suffering poor welfare during transport (point 3(e) of Article 7.3.7.);
g) documentation of the period of rest, and access to feed and water, prior to the journey;
h) stocking density estimate for each load in the consignment;
i) the journey log - daily record of inspection and important events, including records of morbidity and mortality and actions taken, climatic conditions, rest stops, travel time and distance, feed and water offered and estimates of consumption, medication provided, and mechanical defects.

3) When veterinary certification is required to accompany consignments of animals, it should address:

a) fitness of animals to travel;
b) animal identification (description, number, etc.);
c) health status including any tests, treatments and vaccinations carried out;
d) when required, details of disinfection carried out.

At the time of certification, the veterinarian should notify the animal handler or the driver of any factors affecting the fitness of animals to travel for a particular journey.
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Article 7.3.7.

Pre-journey period

1. General considerations
   a) Pre-journey rest is necessary if the welfare of animals has become poor during the collection period because of the physical environment or the social behaviour of the animals. The need for rest should be judged by a veterinarian or other competent person.
   b) Pre-journey assembly/holding areas should be designed to:
      i) securely hold the animals;
      ii) maintain a safe environment from hazards, including predators and disease;
      iii) protect animals from exposure to severe weather conditions;
      iv) allow for maintenance of social groups;
      v) allow for rest, and appropriate water and feed.
   c) Consideration should be given to the previous transport experience, training and conditioning of the animals, if known, as these may reduce fear and stress in animals.
   d) Feed and water should be provided pre-journey if the journey duration is greater than the normal inter-feeding and drinking interval for the animal. Recommendations for specific species are described in detail in Article 7.3.12.
   e) When animals are to be provided with a novel diet or method of feed or water provision during the journey, an adequate period of adaptation should be allowed.
   f) Before each journey, vehicles and containers should be thoroughly cleaned and, if necessary, treated for animal health and public health purposes, using methods approved by the Competent Authority. When cleaning is necessary during a journey, this should be carried out with the minimum of stress and risks to the animals.
   g) Where an animal handler believes that there is a significant risk of disease among the animals to be loaded or significant doubt as to their fitness to travel, the animals should be examined by a veterinarian.

2. Selection of compatible groups
   Compatible groups should be selected before transport to avoid adverse animal welfare consequences. The following recommendations should be applied when assembling groups of animals:
   a) Animals reared together should be maintained as a group; animals with a strong social bond, such as a dam and offspring, should be transported together.
   b) Animals of the same species can be mixed unless there is a significant likelihood of aggression; aggressive individuals should be segregated (recommendations for specific species are described in detail in Article 7.3.12.). For some species, animals from different groups should not be mixed because poor welfare occurs unless they have established a social structure.
   c) Young or small animals should be separated from older or larger animals, with the exception of nursing mothers with young at foot.
   d) Animals with horns or antlers should not be mixed with animals lacking horns or antlers unless judged to be compatible.
   e) Animals of different species should not be mixed unless they are judged to be compatible.

3. Fitness to travel
   a) Each animal should be inspected by a veterinarian or an animal handler to assess fitness to travel. If its fitness to travel is in doubt, the animal should be examined by a veterinarian. Animals found unfit to travel should not be loaded onto a vehicle, except for transport to receive veterinary attention.
   b) Humane and effective arrangements should be made by the owner and the agent for the handling and care of any animal rejected as unfit to travel.
   c) Animals that are unfit to travel include, but may not be limited to:
      i) those that are sick, injured, weak, disabled or fatigued;
      ii) those that are unable to stand unaided and bear weight on each leg;
      iii) those that are blind in both eyes;
      iv) those that cannot be moved without causing them additional suffering;
      v) newborn with an unhealed navel;
vi) pregnant animals which would be in the final 10% of their gestation period at the planned time of unloading;

vii) females travelling without young which have given birth within the previous 48 hours;

viii) those whose body condition would result in poor welfare because of the expected climatic conditions.

d) Risks during transport can be reduced by selecting animals best suited to the conditions of travel and those that are acclimatised to expected weather conditions.

e) Animals at particular risk of suffering poor welfare during transport and which require special conditions (such as in the design of facilities and vehicles, and the length of the journey) and additional attention during transport, may include:

i) large or obese individuals;

ii) very young or old animals;

iii) excitable or aggressive animals;

iv) animals which have had little contact with humans;

v) animals subject to motion sickness;

vi) females in late pregnancy or heavy lactation, dam and offspring;

vii) animals with a history of exposure to stressors or pathogenic agents prior to transport;

viii) animals with unhealed wounds from recent surgical procedures such as dehorning.

4. Specific-species requirements

Transport procedures should be able to take account of variations in the behaviour of the species. Flight zones, social interactions and other behaviour vary significantly among species and even within species. Facilities and handling procedures that are successful with one species are often ineffective or dangerous with another.

Recommendations for specific species are described in detail in Article 7.3.12.

Article 7.3.8.

Loading

1. Competent supervision

a) Loading should be carefully planned as it has the potential to be the cause of poor welfare in transported animals.

b) Loading should be supervised and/or conducted by animal handlers. The animals are to be loaded quietly and without unnecessary noise, harassment or force. Untrained assistants or spectators should not impede the process.

c) When containers are loaded onto a vehicle, this should be carried out in such a way to avoid poor animal welfare.

2. Facilities

a) The facilities for loading including the collecting area, races and loading ramps should be designed and constructed to take into account the needs and abilities of the animals with regard to dimensions, slopes, surfaces, absence of sharp projections, flooring, etc.

b) Loading facilities should be properly illuminated to allow the animals to be observed by animal handler(s), and to allow the ease of movement of the animals at all times. Facilities should provide uniform light levels directly over approaches to sorting pens, chutes, loading ramps, with brighter light levels inside vehicles/containers, in order to minimise baulking. Dim light levels may be advantageous for the catching of poultry and some other animals. Artificial lighting may be required. Loading ramps and other facilities should have a non-slippery flooring.

c) Ventilation during loading and the journey should provide for fresh air, the removal of excessive heat, humidity and noxious fumes (such as ammonia and carbon monoxide), and the prevention of accumulations of ammonia and carbon dioxide. Under warm and hot conditions, ventilation should allow for the adequate convective cooling of each animal. In some instances, adequate ventilation can be achieved by increasing the space allowance for animals.
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3. **Goads and other aids**

   When moving animals, their species-specific behaviour should be used (see Article 7.3.12.). If goads and other aids are necessary, the following principles should apply:
   
   a) **Animals** that have little or no room to move should not be subjected to physical force or goads and other aids which compel movement. Electric goads and prods should only be used in extreme cases and not on a routine basis to move animals. The use and the power output should be restricted to that necessary to assist movement of an animal and only when an animal has a clear path ahead to move. Goads and other aids should not be used repeatedly if the animal fails to respond or move. In such cases it should be investigated whether some physical or other impediment is preventing the animal from moving.
   
   b) The use of such devices should be limited to battery-powered goads on the hindquarters of pigs and large ruminants, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets.
   
   c) Useful and permitted goads include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and rattles; they should be used in a manner sufficient to encourage and direct movement of the animals without causing undue stress.
   
   d) Painful procedures (including whipping, tail twisting, use of nose twitches, pressure on eyes, ears or external genitalia), or the use of goads or other aids which cause pain and suffering (including large sticks, sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts), should not be used to move animals.
   
   e) Excessive shouting at animals or making loud noises (e.g. through the cracking of whips) to encourage them to move should not occur, as such actions may make the animals agitated, leading to crowding or falling.
   
   f) The use of well trained dogs to help with the loading of some species may be acceptable.
   
   g) **Animals** should be grasped or lifted in a manner which avoids pain or suffering and physical damage (e.g. bruising, fractures, dislocations). In the case of quadrupeds, manual lifting by a person should only be used in young animals or small species, and in a manner appropriate to the species; grasping or lifting animals only by their wool, hair, feathers, feet, neck, ears, tails, head, horns, limbs causing pain or suffering should not be permitted, except in an emergency where animal welfare or human safety may otherwise be compromised.
   
   h) Conscious animals should not be thrown, dragged or dropped.
   
   i) Performance standards should be established in which numerical scoring is used to evaluate the use of such instruments, and to measure the percentage of animals moved with an electric instrument and the percentage of animals slipping or falling as a result of their usage.

Article 7.3.9.

**Travel**

1. **General considerations**
   
   a) Drivers and animal handlers should check the load immediately before departure to ensure that the animals have been properly loaded. Each load should be checked again early in the trip and adjustments made as appropriate. Periodic checks should be made throughout the trip, especially at rest or refuelling stops or during meal breaks when the vehicle is stationary.
   
   b) Drivers should utilise smooth, defensive driving techniques, without sudden turns or stops, to minimise uncontrolled movements of the animals.

2. **Methods of restraining or containing animals**
   
   a) Methods of restraining animals should be appropriate to the species and age of animals involved and the training of the individual animal.
   
   b) Recommendations for specific species are described in detail in Article 7.3.12.

3. **Regulating the environment within vehicles or containers**
   
   a) **Animals** should be protected against harm from hot or cold conditions during travel. Effective ventilation procedures for maintaining the environment within vehicles or containers will vary according to whether conditions are cold, hot and dry or hot and humid, but in all conditions a build-up of noxious gases should be prevented.
   
   b) The environment within vehicles or containers in hot and warm weather can be regulated by the flow of air produced by the movement of the vehicle. In warm and hot weather, the duration of journey stops should be minimised and vehicles should be parked under shade, with adequate and appropriate ventilation.
c) To minimise slipping and soiling, and maintain a healthy environment, urine and faeces should be removed from floors when necessary and disposed of in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.

4. Sick, injured or dead animals
   a) A driver or an animal handler finding sick, injured or dead animals should act according to a predetermined emergency response plan.
   b) Sick or injured animals should be segregated.
   c) Ferries (roll-on roll-off) should have procedures to treat sick or injured animals during the journey.
   d) In order to reduce the likelihood that animal transport will increase the spread of infectious disease, contact between transported animals, or the waste products of the transported animals, and other farm animals should be minimised.
   e) During the journey, when disposal of a dead animal becomes necessary, this should be carried out in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.
   f) When killing is necessary, it should be carried out as quickly as possible and assistance should be sought from a veterinarian or other person(s) competent in humane killing procedures. Recommendations for specific species are described in Chapter 7.6. on killing of animals for disease control purposes.

5. Water and feed requirements
   a) If journey duration is such that feeding or watering is required or if the species requires feed or water throughout, access to suitable feed and water for all the animals (appropriate for their species and age) carried in the vehicle should be provided. There should be adequate space for all animals to move to the feed and water sources and due account taken of likely competition for feed.
   b) Recommendations for specific species are described in detail in Article 7.3.12.

6. Rest periods and conditions
   a) Animals that are being transported should be rested at appropriate intervals during the journey and offered feed and water, either on the vehicle or, if necessary, unloaded into suitable facilities.
   b) Suitable facilities should be used en route, when resting requires the unloading of the animals. These facilities should meet the needs of the particular animal species and should allow access of all animals to feed and water.

7. In-transit observations
   a) Animals being transported by road should be observed soon after a journey is commenced and whenever the driver has a rest stop. After meal breaks and refuelling stops, the animals should be observed immediately prior to departure.
   b) Animals being transported by rail should be observed at each scheduled stop. The responsible rail transporter should monitor the progress of trains carrying animals and take all appropriate action to minimise delays.
   c) During stops, it should be ensured that the animals continue to be properly confined, have appropriate feed and water, and their physical condition is satisfactory.

Unloading and post-journey handling

1. General considerations
   a) The required facilities and the principles of animal handling detailed in Article 7.3.8. apply equally to unloading, but consideration should be given to the likelihood that the animals will be fatigued.
   b) Unloading should be supervised and/or conducted by an animal handler with knowledge and experience of the behavioural and physical characteristics of the species being unloaded. Animals should be unloaded from the vehicle into appropriate facilities as soon as possible after arrival at the destination but sufficient time should be allowed for unloading to proceed quietly and without unnecessary noise, harassment or force.
   c) Facilities should provide all animals with appropriate care and comfort, adequate space and ventilation, access to feed (if appropriate) and water, and shelter from extreme weather conditions.
   d) For details regarding the unloading of animals at a slaughterhouse, see Chapter 7.5. on slaughter of animals for human consumption.
2. Sick or injured animals
   a) An animal that has become sick, injured or disabled during a journey should be appropriately treated or humanely killed (see Chapter 7.6. on killing of animals for disease control purposes). If necessary, veterinary advice should be sought in the care and treatment of these animals. In some cases, where animals are non-ambulatory due to fatigue, injury or sickness, it may be in the best welfare interests of the animal to be treated or killed aboard the vehicle. Assistance should be sought from a veterinarian or other person(s) competent in humane killing procedures.
   b) At the destination, the animal handler or the driver during transit should ensure that responsibility for the welfare of sick, injured or disabled animals is transferred to a veterinarian or other suitable person.
   c) If treatment or humane killing is not possible aboard the vehicle, there should be appropriate facilities and equipment for the humane unloading of animals that are non-ambulatory due to fatigue, injury or sickness. These animals should be unloaded in a manner that causes the least amount of suffering. After unloading, separate pens and other appropriate facilities should be available for sick or injured animals.
   d) Feed, if appropriate, and water should be available for each sick or injured animal.

3. Addressing disease risks
   The following should be taken into account in addressing the greater risk of disease due to animal transport and the possible need for segregation of transported animals at the destination:
   a) increased contact among animals, including those from different sources and with different disease histories;
   b) increased shedding of pathogens and increased susceptibility to infection related to stress and impaired defences against disease, including immunosuppression;
   c) exposure of animals to pathogens which may contaminate vehicles, resting points, markets, etc.

4. Cleaning and disinfection
   a) Vehicles, crates, containers, etc. used to carry the animals should be cleaned before re-use through the physical removal of manure and bedding by scraping, washing and flushing with water and detergent. This should be followed by disinfection when there are concerns about disease transmission.
   b) Manure, litter, bedding and the bodies of any animals which die during the journey should be disposed of in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.
   c) Establishments like livestock markets, slaughterhouses, resting sites, railway stations, etc. where animals are unloaded should be provided with appropriate areas for the cleaning and disinfection of vehicles.

Actions in the event of a refusal to allow the completion of the journey

1) The welfare of the animals should be the first consideration in the event of a refusal to allow the completion of the journey.

2) When the animals have been refused import, the Competent Authority of the importing country should make available suitable isolation facilities to allow the unloading of animals from a vehicle and their secure holding, without posing a risk to the health of national herd or flock, pending resolution of the situation. In this situation, the priorities should be:
   a) the Competent Authority of the importing country should provide urgently in writing the reasons for the refusal;
   b) in the event of a refusal for animal health reasons, the Competent Authority of the importing country should provide urgent access to a veterinarian, where possible an OIE veterinarian(s) appointed by the Director General, to assess the health status of the animals with regard to the concerns of the importing country, and the necessary facilities and approvals to expedite the required diagnostic testing;
   c) the Competent Authority of the importing country should provide access to allow continued assessment of the health and other aspects of the welfare of the animals;
   d) if the matter cannot be promptly resolved, the Competent Authorities of the exporting and importing countries should call on the OIE to mediate.

3) In the event that a Competent Authority requires the animals to remain on the vehicle, the priorities should be:
   a) to allow provisioning of the vehicle with water and feed as necessary;
   b) to provide urgently in writing the reasons for the refusal;
c) to provide urgent access to an independent veterinarian(s) to assess the health status of the animals, and the necessary facilities and approvals to expedite the required diagnostic testing in the event of a refusal for animal health reasons;

d) to provide access to allow continued assessment of the health and other aspects of the welfare of the animals, and the necessary actions to deal with any animal issues which arise.

4) The OIE should utilise its informal procedure for dispute mediation to identify a mutually agreed solution which will address animal health and any other welfare issues in a timely manner.

Article 7.3.12.

Species-specific issues

Camelids of the new world in this context comprise llamas, alpacas, guanaco and vicuna. They have good eyesight and, like sheep, can negotiate steep slopes, though ramps should be as shallow as possible. They load most easily in a bunch as a single animal will strive to rejoin the others. Whilst they are usually docile, they have an unnerving habit of spitting in self-defence. During transport, they usually lie down. They frequently extend their front legs forward when lying, so gaps below partitions should be high enough so that their legs are not trapped when the animals rise.

Cattle are sociable animals and may become agitated if they are singled out. Social order is usually established at about two years of age. When groups are mixed, social order has to be re-established and aggression may occur until a new order is established. Crowding of cattle may also increase aggression as the animals try to maintain personal space. Social behaviour varies with age, breed and sex; *Bos indicus* and *B. indicus-cross* animals are usually more temperamental than European breeds. Young bulls, when moved in groups, show a degree of playfulness (pushing and shoving) but become more aggressive and territorial with age. Adult bulls have a minimum personal space of six square metres. Cows with young calves can be very protective, and handling calves in the presence of their mothers can be dangerous. Cattle tend to avoid “dead end” in passages.

Goats should be handled calmly and are more easily led or driven than if they are excited. When goats are moved, their gregarious tendencies should be exploited. Activities which frighten, injure or cause agitation to animals should be avoided. Bullying is particularly serious in goats and can reflect demands for personal space. Housing strange goats together could result in fatalities, either through physical violence, or subordinate goats being refused access to food and water.

Horses in this context include donkeys, mules and hinnies. They have good eyesight and a very wide angle of vision. They may have a history of loading resulting in good or bad experiences. Good training should result in easier loading, but some horses can prove difficult, especially if they are inexperienced or have associated loading with poor transport conditions. In these circumstances, two experienced animal handlers can load an animal by linking arms or using a strop below its rump. Blindfolding may even be considered. Ramps should be as shallow as possible. Steps are not usually a problem when horses mount a ramp, but they tend to jump a step when descending, so steps should be as low as possible. Horses benefit from being individually stalled, but may be transported in compatible groups. When horses are to travel in groups, their shoes should be removed. Horses are prone to respiratory disease if they are restricted by period by tethers that prevent the lowering and lifting of their heads.

Pigs have poor eyesight, and may move reluctantly in unfamiliar surroundings. They benefit from well-lit loading bays. Since they negotiate ramps with difficulty, these should be as level as possible and provided with secure footholds. Ideally, a hydraulic lift should be used for greater heights. Pigs also negotiate steps with difficulty. A good ‘rule-of-thumb’ is that no step should be higher than the pig’s front knee. Serious aggression may result if unfamiliar animals are mixed. Pigs are highly susceptible to heat stress. Pigs are susceptible to motion sickness when in transit. Feed deprivation prior to loading may be beneficial to prevent motion sickness.

Sheep are sociable animals with good eyesight, a relatively subtle and undemonstrative behaviour and a tendency to “flock together”, especially when they are agitated. They should be handled calmly and their tendency to follow each
other should be exploited when they are being moved. Crowding of sheep may lead to damaging aggressive and submissive behaviours as animals try to maintain personal space. Sheep may become agitated if they are singled out for attention, or kept alone, and will strive to rejoin the group. Activities which frighten, injure or cause agitation to sheep should be avoided. They can negotiate steep ramps.
CHAPTER 7.4.
TRANSPORT OF ANIMALS BY AIR

Preamble: These recommendations apply to the following live domesticated animals: cattle, buffaloes, camels, sheep, goats, pigs, poultry and equines. They will also be largely applicable to some other animals, e.g. deer, other camelids and ratites. Wild animals and feral animals may need different conditions.

Article 7.4.1.

Livestock containers

1. Design
   a) General principles of design
      The container should:
      - conform to the size of the standard pallet of the aircraft that will be used to transport animals;
      - not be constructed of material that could be harmful to the animals health or welfare;
      - allow observation of the animals and be marked on opposite sides with the International Air Transport Association (IATA) symbols which indicate animals and the upright position;
      - allow emergency access to animals;
      - allow the animal to stand in its normal position without touching the roof of the container or, in the case of open containers, the restraining nets, and provide at least 10 cm (4 in.) clearance above the animal's head when standing in its normal position; in the case of horses, provide sufficient space above the horses head (21 cm, 8 in. recommended) to allow for the movement required to maintain the horses balance;
      - protect the animals from adverse weather;
      - ensure animals stand on a suitable floor to prevent slipping or injury;
      - have adequate strength to ensure the safety of the animals and to prevent the animals from escaping;
      - ensure doors can be opened and closed easily, but be secured so that they cannot be opened accidentally;
      - be free of any nails, bolts and other protrusions or sharp edges that could cause injuries;
      - be designed to minimise the risk of any opening or space entrapping any portion of the animals body;
      - if reusable, crates should be constructed of impermeable material that is easily cleaned and disinfected;
      - ensure faeces and urine cannot escape from the crate; this requires a minimum upturn of 20 cm but it should not block any ventilation openings;
      - if designated for stacking be stable, not block any ventilation space and prevent urine and faeces from leaking into the containers below when stacked;
      - allow for a facility for provision of water and possibly food during transportation of longer than six hours duration.
   b) Ventilation
      The container design should:
      - provide adequate ventilation taking into consideration the species stocking densities, maximum temperature and humidity of the points of departure, destination, and any interim technical stops;
      - allow the normal resting or sleeping position to be assumed for certain species and juvenile animals;
      - ensure there is no dead air space in the container;
      - provide ventilation openings on the walls equal to at least 16 percent of the wall area; this may be reduced if the container has an open top;
      - in the case of two-tiered containers, ventilation in the sides should be for cattle equivalent to not less than 20 percent of the floor area of each deck, and for pigs and sheep up to 40 percent of the floor area of each deck;
Chapter 7.4.- Transport of animals by air

- have ventilation openings on all four sides of the crate except that two walls may have reduced ventilation space and the other walls have increased space where required by the positioning of the crates during transportation and/or the ventilation pattern of the aircraft;
- ensure that any internal supports or dividers do not block the cross ventilation;
- not have a solid wall above the height of the animal's head in normal resting position;
- in those species where the mouth is normally held near the floor, have at least 25 cm (10 in.) of ventilation space at the level of the animal's head; this opening should be divided in two with a maximum height for any opening of 13 cm; in all containers, there should be a sufficiently large ventilation opening at a height of 25 cm to 30 cm (10 to 11 in.) above floor level on all four sides to allow for circulation;
- have some physical means of ensuring the ventilation space is not blocked, such as the use of cleats (wedges) or allowing space between the outside of the container and the pallet.

2. Species requirements

In general, fractious animals or animals in late pregnancy should not be transported by air (see Article 7.4.2.).

a) Horses

Should be transported in containers and be separated from each other if they are more than 145 cm (57 in.) in height.

Crates used to transport horses should:
- be strong enough to prevent unruly horses from breaking or escaping from the container under any circumstances;
- in the case of multi-horse containers, have partitions of sufficient strength and size to separate the horses and to support each horse's weight;
- adjust to allow mare and foal to travel together;
- provide the same percentage of open space for ventilation as required in point 1 above, divided between the two side walls; however, if the access doors are constructed in such a manner that they may be left open during the flight, the door space may be included in the ventilation space;
- be constructed to minimise noise;
- allow access to the head during the flight;
- have the front end notched and padded to accept the neck of the animal;
- have a secure point for attaching restraining devices;
- have a front and rear barrier that will restrict the movement of the horse and will ensure that liquids are deflected into the container;
- ensure horses cannot bite other animals;
- be constructed to resist kicking;
- have no fittings or projections in the area likely to be kicked, metal plates should be covered with a protective material;
- ramps shall be non-skid in nature, have foot battens, and be of a maximum slope of 25 degrees when the container is on a standard 50 cm (20 in.) dolly;
- not have a step up or down of more than 25 cm (10 in.).

b) Swine

- Crate design and shipment planning should recognize that swine are extremely susceptible to high heat and humidity and that they normally carry their head near the floor.
- In the use of multi-tiered crates, special attention should be paid to ensure air can move through the crate, in accordance with the aircraft's ventilation pattern and capacity to remove heat.
- Crate construction should take into consideration the tendency for mature swine to chew.
- Litter should be dust-free, shavings or other non-toxic materials may be used but not sawdust.
- Containers for immature swine should only be constructed when flight is imminent, since rapid growth can result in undersized containers if the flight is delayed.
- In order to reduce fighting, swine shipped in group pens should be housed together as a group prior to shipment and not be mixed with other swine before loading on the aircraft.
- Mature boars and incompatible females should be shipped in individual crates.
- Individual crates should be 20 cm (8 in.) longer than the body, 15 cm (6 in.) higher than the loin of the pig and of sufficient width, to allow the pigs to lie on their side.
Chapter 7.4.- Transport of animals by air

c) Cattle

Crates used to transport cattle should:
- if multi-tiered or roofed, have at least 30 percent of the roof and four walls as open space;
- have at least one ventilation opening 20–25 cm (8-10 in.) above the floor which is of such width that it will not cause injuries to the feet.

Adult bulls should be transported separately unless they have been accustomed to each other. Cattle with and without horns should be separated from each other.

d) Poultry

The most current container requirement published by IATA should be adhered to.

Crates/containers containing poultry should be handled and carried carefully with no unnecessary tilting.

The majority of birds transported by air will be newly hatched chicks. These animals are very vulnerable to sudden changes in temperature.

e) Other species

- Animals that normally exhibit a herding instinct, including buffalo and deer, can be shipped in group containers providing the mental and physical characteristics of the species are taken into consideration.
- All crates used to move such animals should have a roof or other method of preventing the animals from escaping.
- Animals in which the horns or antler cannot be removed, should be transported individually.
- Deer should not be transported in velvet nor in rut.

Article 7.4.2.

Recommendations for pregnant animals

Heavily pregnant animals should not be carried except under exceptional circumstances. Pregnant animals should not be accepted when the last service or exposure to a male prior to departure has exceeded the following time given here for guidance only:

<table>
<thead>
<tr>
<th>Females</th>
<th>Maximum number of days since the last service</th>
</tr>
</thead>
<tbody>
<tr>
<td>Horses</td>
<td>300</td>
</tr>
<tr>
<td>Cows</td>
<td>250</td>
</tr>
<tr>
<td>Deer (axis, fallow and sika)</td>
<td>170</td>
</tr>
<tr>
<td>Deer (red deer and reindeer)</td>
<td>185</td>
</tr>
<tr>
<td>Ewes</td>
<td>115</td>
</tr>
<tr>
<td>Nannies (goats)</td>
<td>115</td>
</tr>
<tr>
<td>Sows (pigs)</td>
<td>90</td>
</tr>
</tbody>
</table>

Where service dates or date of last exposure to a male are not available, the animals should be examined by a veterinarian to ensure that pregnancy is not so advanced that animals are likely to give birth during transport or suffer unnecessarily.

Any animal showing udder engorgement and slackening of the pelvic ligament should be refused.

Article 7.4.3.

Stocking density

The current stocking densities agreed by the International Air Transport Association (IATA) should continue to be accepted. However, the graphs giving the space requirements should be extended to take into account animals larger and smaller than those dealt with currently.
1. **General considerations**

When calculating stocking rates, the following should be taken into account:

a) it is essential that accurate weights of *animals* are obtained in view of the limitations imposed by the load capabilities of the aircraft and the space required per *animal*;

b) in narrow bodied aircraft, there is a loss of floor area in the upper tier of two-tier penning due to the contours of the aircraft;

c) space available should be calculated on the inside measurements of the crates or penning system used, not on the floor space of the aircraft;

d) multi-tiered crates, high outdoor temperatures at departure, arrival or stopover points, or extreme length of the trip will require an increase in the amount of space per *animal*; a 10 percent decrease in *stocking density* is recommended for trips in excess of 24 hours;

e) special attention should be paid to the transport of sheep in heavy wool which require an increase in space allotted per *animal* and to pigs which have limited ability to dissipate heat;

f) *animals* confined in groups, especially in pens, should be stocked at a high enough density to prevent injuries at take-off, during turbulence and at landing, but not to the extent that individual *animals* cannot lie down and rise without risk of injury or crushing;

g) in multi-tiered shipments, it should be recognized that the ventilation and cooling capacity of the aircraft is the limiting factor, especially in narrow bodied aircraft. Ventilation capacity varies on each individual aircraft and between aircraft of the same model.

2. **Recommendations for stocking densities**

The following table gives *stocking density* recommendations for different domestic species. The values are expressed in kilograms and metres.

<table>
<thead>
<tr>
<th>Species</th>
<th>Weight</th>
<th>Density</th>
<th>Space/animal</th>
<th>No. of animals per 10 m²</th>
<th>Animals per single tier pallet</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>kg</td>
<td>kg/m²</td>
<td>m²</td>
<td>214x264 cm</td>
<td>214x308 cm</td>
</tr>
<tr>
<td>Calves</td>
<td>50</td>
<td>220</td>
<td>0.23</td>
<td>43</td>
<td>24</td>
</tr>
<tr>
<td></td>
<td>70</td>
<td>246</td>
<td>0.28</td>
<td>35/6</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>80</td>
<td>268</td>
<td>0.30</td>
<td>33</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>90</td>
<td>280</td>
<td>0.32</td>
<td>31</td>
<td>17</td>
</tr>
<tr>
<td>Cattle</td>
<td>300</td>
<td>344</td>
<td>0.84</td>
<td>11-12</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>500</td>
<td>393</td>
<td>1.27</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>600</td>
<td>408</td>
<td>1.45</td>
<td>6-7</td>
<td>3-4</td>
</tr>
<tr>
<td></td>
<td>700</td>
<td>400</td>
<td>1.63</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Sheep</td>
<td>25</td>
<td>147</td>
<td>0.17</td>
<td>59</td>
<td>32</td>
</tr>
<tr>
<td></td>
<td>70</td>
<td>196</td>
<td>0.36</td>
<td>27/8</td>
<td>15</td>
</tr>
<tr>
<td>Pigs</td>
<td>25</td>
<td>172</td>
<td>0.15</td>
<td>67</td>
<td>37</td>
</tr>
<tr>
<td></td>
<td>100</td>
<td>196</td>
<td>0.51</td>
<td>20</td>
<td>10</td>
</tr>
</tbody>
</table>

### Article 7.4.4.

**Preparation for air transport of livestock**

1. **Health and customs requirements**

The legal requirements including animal health, *welfare* and species conservation, should be ascertained from the country of destination and any in *transit countries* before the *animals* are assembled or the transportation is arranged.

Contact the *Veterinary Authorities* in the country of origin regarding veterinary certification.

Planning of the transportation should take into account weekends, holidays and airport closures.

Verify that any proposed intransit stops or alternates will not jeopardise the importing or in *transit countries* health requirements.

Waiting time at customs (cargo handling and clearance) should be reduced as much as possible to avoid *welfare* problems.
2. Environment

Animals are affected by extremes of temperature. This is especially true of high temperature when compounded by high humidity. Temperature and humidity should therefore be taken into consideration when planning the shipment.

Times of arrival, departure and stopovers should be planned so that the aircraft lands during the coolest hours. At outside temperatures of below 25°C at the landing point, the aircraft doors should be opened to ensure adequate ventilation. Confirmation should be received from government authorities that animal health legislation does not prevent opening of aircraft doors.

When outside temperatures at any landing point exceed 25°C, prior arrangements should be made to have an adequate air-conditioning unit available when the plane lands.

3. Facilities and equipment

Specific arrangements should be made to ensure that holding and loading facilities including ramps, trucks, and air-conditioning units are available at departure, all in transit and arrival airports. This should include identification of specific staff who are responsible and the method of contacting them, e.g. telephone number and address.

Specific notification should be given to all those responsible for providing facilities or equipment at the destination and in transit stops immediately before departure.

Containers should be loaded so as to ensure access can be made to the animals at all times.

4. Preparation of animals

Vaccination should be done far enough in advance of the departure date to allow for immunity to develop. Veterinary certification and serological testing should be arranged several weeks in advance of livestock shipment. Many animals require acclimatisation before they are transported. Animals such as swine and wild herbivores should be separated and held in the groups that will occupy containers. Mixing of such animals immediately before or during transport is extremely stressing and should be avoided.

Incompatible animals should be transported singly.

Disinfection and disinfestation

1. Disinfection

a) Those parts of the interior of the aircraft destined for the carriage of animals should be thoroughly cleaned of all foreign matters using methods acceptable to aircraft management before being loaded.

b) These parts should be sprayed with a disinfectant:

   i) suitable for the diseases which could be carried by the animals;

   ii) that does not cause problems with the aircraft;

   iii) that will not leave a residue hazardous to the animals being transported.

If in doubt, the airline should be consulted on the suitability of the disinfectant. A mechanical nebuliser should be used to minimise the amount of disinfectant used.

Suggested disinfectants currently in use are:

   iv) 4 percent sodium carbonate and 0.1 percent sodium silicate;

   v) 0.2 percent citric acid.

c) All removeable equipment, penning and containers including loading ramps should be thoroughly cleaned and disinfected in accordance with the requirements of both the exporting and importing countries.

d) After disinfection, all equipment to be replaced in the aircraft should be washed with clean water to remove any traces of disinfectant to avoid any damage to the aircraft structures.

2. Disinfestation

Where disinfestation is required, the country requesting the action should be consulted for appropriate procedures. The World Health Organisation (WHO) Recommendations on the Disinsectisation of Aircraft (WHO Weekly Epidem. Rec., No. 7, 1985) are recognised as standard.
Article 7.4.6.

Radiation

Radioactive materials should be separated from live animals by a distance of at least 0.5 metre for journeys not exceeding 24 hours, and by a distance of at least 1.0 metre for journeys longer than 24 hours (reference: Technical instructions on storage and loading-separation of the International Civil Aviation Organisation). Special care should be taken with regard to pregnant animals, semen and embryos/ova.

Article 7.4.7.

Tranquilization

Experience has shown that there is considerable risk in sedating animals transported by air. Tranquilizers reduce the ability of the animals to respond to stress during transportation. In addition, the reaction of various species to tranquilization cannot always be foreseen. For these reasons, routine tranquilization is not recommended. Tranquilizers should only be used when a specific problem exists, and should be administered by a veterinarian or by a person who has been instructed in their use. Persons using these drugs should understand the full implications of the effects of the drug in air transport, e.g. certain animals such as horses and elephants should not go down in containers. Drugs should only be administered during the flight with the knowledge and consent of the captain.

In all cases, when tranquilizers are used, a note should be attached to the container stating the weight of the individual animal, the generic name of the drug used, the dose, the method and time of administration.

Article 7.4.8.

Destruction of carcasses

In the event of any animal death on board, the competent authority of the airport of destination should be notified in advance of landing.

Carcasses should be disposed of under the supervision of and to the satisfaction of the Veterinary Authority of the country the aircraft is in.

The method of disposal should be based on the risk of introducing a controlled disease.

For carcasses which represent a high risk of introducing disease, the following is recommended:
1) destruction by incineration, rendering or deep burial under the supervision of the Veterinary Authority;
2) if removed from the airport site, transportation in a closed, leakproof container.

Article 7.4.9.

Emergency killing

Emergency killing of animals in aircraft should, in general, only occur when the safety of the aircraft, crew or other animals are involved.

Every aircraft transporting animals should have a method of killing the animals with minimum pain and someone trained in that method.

In all cases when horses or other large animals are to be carried, the method of killing should be discussed with the airline during the planning stages. Suitable methods are:

1. Captive bolt stunner, followed by an injection of a lethal chemical
   a) Operator should be trained to use the captive bolt stunner on the species or type of animal being transported.
   b) An expert should determine that the type of captive bolt pistol and cartridge power is adequate for all the animals being transported.
   c) Some airlines and countries may prohibit the carriage of captive bolt pistols.
   d) The user should recognize that the noise associated with the captive bolt may excite other animals.
e) The requirement that the captive bolt pistol is accurately positioned may be difficult to achieve with an excited animal.

2. Injection of a chemical
   a) Various chemicals may be used to sedate, immobilize or kill animals.
   b) Central nervous system depressants such as barbiturate euthanasia solutions should be injected directly into a vein to be effective. This is not normally practical for anyone but an experienced veterinarian or an especially trained and experienced attendant, where the animal is sufficiently fractious to require euthanasia.
   c) Sedatives such as promazine and its derivatives may make the animal more fractious (see Article 7.4.7.).
   d) Immobilizing solutions such as succinylcholine are not humane.

3. Firearms
   Airlines do not permit the use of firearms which discharge a free bullet because of the danger to the aircraft.

Article 7.4.10.

Handling of food and waste material

Waste material which contains anything of animal origin including food, litter, manure, or animal feed should be handled, collected and disposed of in a manner that ensures it will not be fed to livestock. It should be collected in specified areas, and stored and transported in closed, leakproof containers.

Some importing countries legislation may prohibit or restrict the use of hay or straw during the transportation period. Unloading of hay, straw, other animal feed and litter may be restricted or prohibited by in transit countries.

Article 7.4.11.

Disposal of food and waste material

Recommended methods of disposal are:

1) incineration to an ash;
2) heating at an internal temperature of at least of 100°C for 30 minutes, then disposal in a land fill site;
3) controlled burial in a land fill site.
General principles

1. Object

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

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

2. Personnel

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

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

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

3. Animal behaviour

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

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

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

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

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

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

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

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

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

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

4. Distractions and their removal

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

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

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

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

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

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

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

An example of a flight zone (cattle)
Article 7.5.2.

Moving and handling animals

1. General considerations

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

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

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

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

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

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

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

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

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

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

ii) The use of such devices should be limited to battery-powered goads on the hindquarters of pigs and large ruminants, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets.
iii) Useful and permitted goads include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and metallic rattles; they should be used in a manner sufficient to encourage and direct movement of the animals without causing undue stress.

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

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

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

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

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

2. Specific considerations for poultry

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

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

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

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

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

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

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

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

3. Provisions relevant to animals delivered in containers

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

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

c) Animals which have been transported in containers should be slaughtered as soon as possible; mammals and ruminants which are not taken directly upon arrival to the place of slaughter should have drinking water available to them from appropriate facilities at all times. Delivery of poultry for slaughter should be scheduled such that they are not deprived of water at the premises for longer than 12 hours. Animals which have not been slaughtered within 12 hours of their arrival should be fed, and should subsequently be given moderate amounts of food at appropriate intervals.
4. Provisions relevant to restraining and containing animals
a) Provisions relevant to restraining animals for stunning or slaughter without stunning, to help maintain animal welfare, include:
   i) provision of a non-slippery floor;
   ii) avoidance of excessive pressure applied by restraining equipment that causes struggling or vocalisation in animals;
   iii) equipment engineered to reduce noise of air hissing and clanging metal;
   iv) absence of sharp edges in restraining equipment that would harm animals;
   v) avoidance of jerking or sudden movement of restraining device.

b) Methods of restraint causing avoidable suffering should not be used in conscious animals because they cause severe pain and stress:
   i) suspending or hoisting animals (other than poultry) by the feet or legs;
   ii) indiscriminate and inappropriate use of stunning equipment;
   iii) mechanical clamping of the legs or feet of the animals (other than shackles used in poultry and ostriches) as the sole method of restraint;
   iv) breaking legs, cutting leg tendons or blinding animals in order to immobilise them;
   v) severing the spinal cord, for example using a puntilla or dagger, to immobilise animals using electric currents to immobilise animals, except for proper stunning.

Article 7.5.3.

Lairage design and construction

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

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

   The following recommendations may help to achieve this.

2. Design of lairage
   a) The lairage should be designed to allow a one-way flow of animals from unloading to the point of slaughter, with a minimum number of abrupt corners to negotiate.
   b) In red meat slaughterhouses, pens, passageways and races should be arranged in such a way as to permit inspection of animals at any time, and to permit the removal of sick or injured animals when considered to be appropriate, for which separate appropriate accommodation should be provided.
   c) Each animal should have room to stand up and lie down and, when confined in a pen, to turn around, except where the animal is reasonably restrained for safety reasons (e.g. fractious bulls). Fractious animals should be slaughtered as soon as possible after arrival at the slaughterhouse to avoid welfare problems. The lairage should have sufficient accommodation for the number of animals intended to be held. Drinking water should always be available to the animals, and the method of delivery should be appropriate to the type of animal held. Troughs should be designed and installed in such a way as to minimise the risk of fouling by faeces, without introducing risk of bruising and injury in animals, and should not hinder the movement of animals.
   d) Holding pens should be designed to allow as many animals as possible to stand or lie down against a wall. Where feed troughs are provided, they should be sufficient in number and feeding space to allow adequate access of all animals to feed. The feed trough should not hinder the movement of animals.
   e) Where tethers, ties or individual stalls are used, these should be designed so as not to cause injury or distress to the animals and should also allow the animals to stand, lie down and access any food or water that may need to be provided.
   f) Passageways and races should be either straight or consistently curved, as appropriate to the animal species. Passageways and races should have solid sides, but when there is a double race, the shared partition should allow adjacent animals to see each other. For pigs and sheep, passageways should be wide enough to enable two or more animals to walk side by side for as long as possible. At the point where passageways are reduced in width, this should be done by a means which prevents excessive bunching of the animals.
Chapter 7.5.- Slaughter of animals

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

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

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

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

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

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

**Article 7.5.4.**

Care of animals in lairages

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

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

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

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

4) Animals should be kept securely in the lairage, and care should be taken to prevent them from escaping and from predators.
5) Suitable drinking water should be available to the animals on their arrival and at all times to animals in lairages unless they are to be slaughtered without delay.

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

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

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

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

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

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

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

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

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

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

Recommendations for specific species are described in detail in Articles 7.5.5. to 7.5.9.

Article 7.5.5.

Management of foetuses during slaughter of pregnant animals

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

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

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

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

If there is any doubt about consciousness, the foetus should be killed with a captive bolt of appropriate size or a blow to the head with a suitable blunt instrument.
The above recommendations do not refer to foetal rescue. Foetal rescue, the practice of attempting to revive foetuses found alive at the evisceration of the dam, should not be attempted during normal commercial slaughter as it may lead to serious welfare complications in the newborn animal. These include impaired brain function resulting from oxygen shortage before rescue is completed, compromised breathing and body heat production because of foetal immaturity, and an increased incidence of infections due to a lack of colostrum.

Article 7.5.6.

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

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<td>Proper design and operation of equipment</td>
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### Article 7.5.7.

#### Stunning methods

1. **General considerations**

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

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

   a) the animal is adequately restrained;

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

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

   d) the equipment is applied correctly;

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

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

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

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

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<td>Stress of resisting restraint; prolonged restraint, animal temperament; bruising. Keep restraint as short as possible.</td>
<td>Competent animal handlers</td>
<td>Sheep, goats, small camelids, pigs</td>
<td></td>
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</tbody>
</table>
2. Mechanical stunning
A mechanical device should be applied usually to the front of the head and perpendicular to the bone surface. For a more detailed explanation on the different methods for mechanical stunning, see Chapter 7.6. and Articles 7.6.6., 7.6.7. and 7.6.8. The following diagrams illustrate the proper application of the device for certain species.

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

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

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

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

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

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

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

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

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<th>Species</th>
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<tr>
<td>Calves (bovines of less than 6 month of age)</td>
<td>1.0 amps</td>
</tr>
<tr>
<td>Pigs</td>
<td>1.25 amps</td>
</tr>
<tr>
<td>Sheep and goats</td>
<td>1.0 amps</td>
</tr>
<tr>
<td>Lambs</td>
<td>0.7 amps</td>
</tr>
<tr>
<td>Ostriches</td>
<td>0.4 amps</td>
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</table>

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

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

Birds should be hung on shackles by both legs.

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

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

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

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

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

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

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

Birds should receive the current for at least 4 seconds.

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

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

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

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

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

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Current (milliamperes per bird)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Broilers</td>
<td>100</td>
</tr>
<tr>
<td>Layers (spent hens)</td>
<td>100</td>
</tr>
<tr>
<td>Turkeys</td>
<td>150</td>
</tr>
<tr>
<td>Ducks and geese</td>
<td>130</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Frequency (Hz)</th>
<th>Minimum current (milliamperes per bird)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chickens</td>
</tr>
<tr>
<td>From 50 to 200 Hz</td>
<td>100 mA</td>
</tr>
<tr>
<td>From 200 to 400 Hz</td>
<td>150 mA</td>
</tr>
<tr>
<td>From 400 to 1500 Hz</td>
<td>200 mA</td>
</tr>
</tbody>
</table>

4. **Gas stunning (under study)**

a) Stunning of pigs by exposure to carbon dioxide (CO₂)

The concentration of CO₂ for stunning should be preferably 90 percent by volume but in any case no less than 80 percent by volume. After entering the stunning chamber, the animals should be conveyed to the point of maximum concentration of the gas as rapidly as possible and be kept until they are dead or brought into a
Chapter 7.5.- Slaughter of animals

State of insensibility which lasts until death occur due to bleeding. Ideally, pigs should be exposed to this concentration of CO₂ for 3 minutes. Sticking should occur as soon as possible after exit from the gas chamber. In any case, the concentration of the gas should be such that it minimises as far as possible all stress of the animal prior to loss of consciousness.

The chamber in which animals are exposed to CO₂ and the equipment used for conveying them through it shall be designed, constructed and maintained in such a way as to avoid injury or unnecessary stress to the animals. The animal density within the chamber should be such to avoid stacking animals on top of each other.

The conveyor and the chamber shall be adequately lit to allow the animals to see their surroundings and, if possible, each other. It should be possible to inspect the CO₂ chamber whilst it is in use, and to have access to the animals in emergency cases.

The chamber shall be equipped to continuously measure and display register at the point of stunning the CO₂ concentration and the time of exposure, and to give a clearly visible and audible warning if the concentration of CO₂ falls below the required level.

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

b) Inert gas mixtures for stunning pigs

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

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

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

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

c) Gas stunning of poultry

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

Live poultry contained within transport modules or crates may be exposed to gradually increasing concentrations of CO₂ until the birds are properly stunned. No bird should recover consciousness during bleeding.

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

Live poultry should be conveyed into the gas mixtures either in transport crates or on conveyor belts. The following gas procedures have been properly documented for chickens and turkeys but do not necessarily apply for other domestic birds. In any case the procedure should be designed as to ensure that all animals are properly stunned without unnecessary suffering. Some monitoring points for gas stunning could be the following:

- ensure smooth entry and passage of crates or birds through the system;
- avoid crowding of birds in crates or conveyors;
- monitor and maintain gas concentrations continuously during operation;
- provide visible and audible alarm systems if gas concentrations are inappropriate to the species;
- calibrate gas monitors and maintain verifiable records;
- ensure that duration of exposure is adequate to prevent recovery of consciousness;
- make provision to monitor and deal with recovery of consciousness;
- ensure that blood vessels are cut to induce death in unconscious birds;
- ensure that all birds are dead before entering scalding tank;
- provide emergency procedures in the event of system failure.

i) Gas mixtures used for stunning poultry include:

- a minimum of 2 minutes exposure to 40 percent carbon dioxide, 30 percent oxygen and 30 percent nitrogen, followed by a minimum of one minute exposure to 80 percent carbon dioxide in air; or
– a minimum of 2 minutes exposure to any mixture of argon, nitrogen or other inert gases with atmospheric air and carbon dioxide, provided that the carbon dioxide concentration does not exceed 30 percent by volume and the residual oxygen concentration does not exceed 2 percent by volume; or

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

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

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

ii) Requirements for effective use are as follows:

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

– Gas mixtures should be humidified.

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

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

5. Bleeding

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

<table>
<thead>
<tr>
<th>Stunning method</th>
<th>Maximum–stun stick interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrical methods and non-penetrating captive bolt</td>
<td>20 seconds</td>
</tr>
<tr>
<td>CO₂</td>
<td>60 seconds (after leaving the chamber)</td>
</tr>
</tbody>
</table>

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

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

After incision of the blood vessels, no scalding carcass treatment or dressing procedures should be performed on the animals for at least 30 seconds, or in any case until all brain-stem reflexes have ceased.
Figure 1. The optimum position for cattle is at the intersection of two imaginary lines drawn from the rear of the eyes to the opposite horn buds.

Cattle

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

Figure 2. The optimum position for pigs is on the midline just above eye level, with the shot directed down the line of the spinal cord.

Pigs

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

Figure 3. The optimum position for hornless sheep and goats is on the midline.

Sheep

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).
Figure 4. The optimum position for heavily horned sheep and horned goats is behind the poll, aiming towards the angle of the jaw.

**Goats**

![Diagram of Goats](image1)

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

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

**Horses**

![Diagram of Horses](image2)

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

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

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

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

3) normal rhythmic breathing stops; and

4) the eyelid is open with the eyeball facing straight ahead and is not rotated.
Captive bolts powered by cartridges, compressed air or spring can be used for poultry. The optimum position for poultry species is at right angles to the frontal surface.

Firing of a captive bolt according to the manufacturers’ instructions should lead to immediate destruction of the skull and the brain and, as a result, immediate death.
### Summary analysis of stunning methods and the associated animal welfare issues

<table>
<thead>
<tr>
<th>Method</th>
<th>Specific method</th>
<th>Animal welfare concerns/implications</th>
<th>Key animal welfare requirements applicable</th>
<th>Species</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanical</td>
<td>Free bullet</td>
<td>In accurate targeting and inappropriate ballistics</td>
<td>Operator competence; achieving outright kill with first shot</td>
<td>Cattle, calves, buffalo, deer, horses, pigs (boars and sows)</td>
<td>Personnel safety</td>
</tr>
<tr>
<td>Captive bolt – penetrating</td>
<td>Inaccurate targeting, velocity and diameter of bolt</td>
<td>Competent operation and maintenance of equipment; restraint; accuracy</td>
<td>Cattle, calves, buffalo, sheep, goats, deer, horses, pigs, camelids, ratites, poultry</td>
<td>(Unsuitable for specimen collection from TSE suspects). A back-up gun should be available in the event of an ineffective shot</td>
<td></td>
</tr>
<tr>
<td>Captive bolt – non-penetrating</td>
<td>Inaccurate targeting, velocity of bolt, potentially higher failure rate than penetrating captive bolt</td>
<td>Competent operation and maintenance of equipment; restraint; accuracy</td>
<td>Cattle, calves, sheep, goats, deer, pigs, camelids, ratites, poultry</td>
<td>Presently available devices are not recommended for young bulls and animals with thick skull. This method should only be used for cattle and sheep when alternative methods are not available.</td>
<td></td>
</tr>
<tr>
<td>Manual percussive blow</td>
<td>Inaccurate targeting; insufficient power; size of instrument</td>
<td>Competent animal handlers; restraint; accuracy. Not recommended for general use</td>
<td>Young and small mammals, ostriches and poultry</td>
<td>Mechanical devices potentially more reliable. Where manual percussive blow is used, unconsciousness should be achieved with single sharp blow delivered to central skull bones</td>
<td></td>
</tr>
<tr>
<td>Electrical</td>
<td>Split application: 1. across head then head to chest; 2. across head then across chest</td>
<td>Accidental pre-stun electric shocks; electrode positioning; application of a current to the body while animal conscious; inadequate current and voltage</td>
<td>Competent operation and maintenance of equipment; restraint; accuracy</td>
<td>Cattle, calves, sheep, goats and pigs, ratites, poultry</td>
<td>Systems involving repeated application of head-only or head-to-leg with short current durations (&lt;1 second) in the first application should not be used.</td>
</tr>
<tr>
<td>Single application: 1. head only; 2. head to body; 3. head to leg</td>
<td>Accidental pre-stun electric shocks; inadequate current and voltage; wrong electrode positioning; recovery of consciousness</td>
<td>Competent operation and maintenance of equipment; restraint; accuracy</td>
<td>Cattle, calves, sheep, goats, pigs, ratites, poultry</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Waterbath</td>
<td>Restraint, accidental pre-stun electric shocks; inadequate current and voltage; recovery of consciousness</td>
<td>Competent operation and maintenance of equipment</td>
<td>Poultry only</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CO₂ / O₂ mixture; CO₂ inert gas mixture</td>
<td>Aversiveness of high CO₂; respiratory distress; inadequate exposure</td>
<td>Concentration; duration of exposure; design, maintenance and operation of equipment; stocking density management</td>
<td>Pigs, poultry</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Article 7.5.9.

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

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

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

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

3) The slaughter method of brain stem severance by piercing through the eye socket or skull bone without prior stunning is not acceptable in any species.
CHAPTER 7.6.
KILLING OF ANIMALS FOR DISEASE CONTROL PURPOSES

Article 7.6.1.

General principles

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

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

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

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

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

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

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

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

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

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

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

Article 7.6.2.

Organisational structure

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

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

The operational activities should be led by an official Veterinarian who has the authority to appoint the personnel in the specialist teams and ensure that they adhere to the required animal welfare and biosecurity standards. When appointing the personnel, he/she should ensure that the personnel involved have the required competencies.
Chapter 7.6.- Killing of animals for disease control purposes

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

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

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

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

Article 7.6.3.

Responsibilities and competencies of the specialist team

1. Team leader
   a) Responsibilities
      i) plan overall operations on affected premises;
      ii) determine and address requirements for animal welfare, operator safety and biosecurity;
      iii) organise, brief and manage team of people to facilitate humane killing of the relevant animals on the premises in accordance with national regulations and these recommendations;
      iv) determine logistics required;
      v) monitor operations to ensure animal welfare, operator safety and biosecurity requirements are met;
      vi) report upwards on progress and problems;
      vii) provide a written report at the conclusion of the killing, describing the practices adopted and their effect on the animal welfare, operator safety and biosecurity outcomes.
   b) Competencies
      i) appreciation of normal animal husbandry practices;
      ii) appreciation of animal welfare and the underpinning behavioural, anatomical and physiological processes involved in the killing process;
      iii) skills to manage all activities on premises and deliver outcomes on time;
      iv) awareness of psychological effects on farmer, team members and general public;
      v) effective communication skills;
      vi) appreciation of the environmental impacts caused by their operation.

2. Veterinarian
   a) Responsibilities
      i) determine and supervise the implementation of the most appropriate killing method to ensure that animals are killed without avoidable pain and distress;
      ii) determine and implement the additional requirements for animal welfare, including the order of killing;
      iii) ensure that confirmation of the death of the animals is carried out by competent persons at appropriate times after the killing procedure;
      iv) minimise the risk of disease spread within and from the premises through the supervision of biosecurity procedures;
      v) continuously monitor animal welfare and biosecurity procedures;
      vi) in cooperation with the leader, prepare a written report at the conclusion of the killing, describing the practices adopted and their effect on animal welfare.
   b) Competencies
      i) ability to assess animal welfare, especially the effectiveness of stunning and killing and to correct any deficiencies;
      ii) ability to assess biosecurity risks.
3. Animal handlers
   a) Responsibilities
      i) review on-site facilities in terms of their appropriateness;
      ii) design and construct temporary animal handling facilities, when required;
      iii) move and restrain animals;
      iv) continuously monitor animal welfare and biosecurity procedures.
   b) Competencies
      i) animal handling in emergency situations and in close confinement is required;
      ii) an appreciation of biosecurity and containment principles.

4. Animal killing personnel
   a) Responsibilities
      Humane killing of the animals through effective stunning and killing should be ensured.
   b) Competencies
      i) when required by regulations, licensed to use necessary equipment;
      ii) competent to use and maintain relevant equipment;
      iii) competent to use techniques for the species involved;
      iv) competent to assess effective stunning and killing.

5. Carcass disposal personnel
   a) Responsibilities
      An efficient carcass disposal (to ensure killing operations are not hindered) should be ensured.
   b) Competencies
      The personnel should be competent to use and maintain available equipment and apply techniques for the species involved.

6. Farmer/owner/manager
   a) Responsibilities
      i) assist when requested.
   b) Competencies
      i) specific knowledge of his/her animals and their environment.

Article 7.6.4.

Considerations in planning the humane killing of animals

Many activities will need to be conducted on affected premises, including the humane killing of animals. The team leader should develop a plan for humanely killing animals on the premises which should include consideration of:
1) minimising handling and movement of animals;
2) killing the animals on the affected premises; however, there may be circumstances where the animals may need to be moved to another location for killing; when the killing is conducted at an abattoir, the recommendations in Chapter on the slaughter of animals should be followed;
3) the species, number, age and size of animals to be killed, and the order of killing them;
4) methods of killing the animals, and their cost;
5) housing, husbandry, location of the animals as well as accessibility of the farm;
6) the availability and effectiveness of equipment needed for killing of the animals, as well as the time necessary to kill the required number of animals using such methods;
7) the facilities available on the premises that will assist with the killing including any additional facilities that may need to be brought on and then removed from the premises;
8) biosecurity and environmental issues;
9) the health and safety of personnel conducting the killing;
10) any legal issues that may be involved, for example where restricted veterinary drugs or poisons may be used, or where the process may impact on the environment;
11) the presence of other nearby premises holding animals;
12) possibilities for removal, disposal and destruction of carcasses.

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

Competences and skills of the personnel handling and killing animals.

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

Article 7.6.5.

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

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Age range</th>
<th>Procedure</th>
<th>Restraint necessary</th>
<th>Animal welfare concerns with inappropriate application</th>
<th>Article reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cattle</td>
<td>all</td>
<td>free bullet</td>
<td>no</td>
<td>non-lethal wounding</td>
<td>Article 7.6.6.</td>
</tr>
<tr>
<td></td>
<td>all except neonates</td>
<td>penetrating captive bolt - followed by pithing or bleeding</td>
<td>yes</td>
<td>ineffective stunning</td>
<td>Article 7.6.7.</td>
</tr>
<tr>
<td></td>
<td>adults only</td>
<td>non-penetrating captive bolt, followed by bleeding</td>
<td>yes</td>
<td>ineffective stunning, regaining of consciousness before killing</td>
<td>Article 7.6.8.</td>
</tr>
<tr>
<td></td>
<td>calves only</td>
<td>electrical, two-stage application</td>
<td>yes</td>
<td>pain associated with cardiac arrest after ineffective stunning</td>
<td>Article 7.6.10.</td>
</tr>
<tr>
<td></td>
<td>calves only</td>
<td>electrical, single application (method 1)</td>
<td>yes</td>
<td>ineffective stunning</td>
<td>Article 7.6.11.</td>
</tr>
<tr>
<td></td>
<td>all</td>
<td>injection with barbiturates and other drugs</td>
<td>yes</td>
<td>non-lethal dose, pain associated with injection site</td>
<td>Article 7.6.15.</td>
</tr>
<tr>
<td>Sheep and goats</td>
<td>all</td>
<td>free bullet</td>
<td>no</td>
<td>non-lethal wounding</td>
<td>Article 7.6.6.</td>
</tr>
<tr>
<td></td>
<td>all except neonates</td>
<td>penetrating captive bolt, followed by pithing or bleeding</td>
<td>yes</td>
<td>ineffective stunning, regaining of consciousness before death</td>
<td>Article 7.6.7.</td>
</tr>
<tr>
<td></td>
<td>all except neonates</td>
<td>non-penetrating captive bolt, followed by bleeding</td>
<td>yes</td>
<td>ineffective stunning, regaining of consciousness before death</td>
<td>Article 7.6.8.</td>
</tr>
<tr>
<td></td>
<td>neonates</td>
<td>non-penetrating captive bolt</td>
<td>yes</td>
<td>non-lethal wounding</td>
<td>Article 7.6.8.</td>
</tr>
<tr>
<td></td>
<td>all</td>
<td>electrical, two-stage application</td>
<td>yes</td>
<td>pain associated with cardiac arrest after ineffective stunning</td>
<td>Article 7.6.10.</td>
</tr>
<tr>
<td></td>
<td>all</td>
<td>electrical, single application (method 1)</td>
<td>yes</td>
<td>ineffective stunning</td>
<td>Article 7.6.11.</td>
</tr>
<tr>
<td></td>
<td>neonates only</td>
<td>CO₂ / air mixture</td>
<td>yes</td>
<td>slow induction of unconsciousness, aversiveness of induction</td>
<td>Article 7.6.12.</td>
</tr>
</tbody>
</table>
### Chapter 7.6. - Killing of animals for disease control purposes

<table>
<thead>
<tr>
<th>Species</th>
<th>Age range</th>
<th>Procedure</th>
<th>Restraint necessary</th>
<th>Animal welfare concerns with inappropriate application</th>
<th>Article reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sheep and goats</td>
<td>neonates only</td>
<td>nitrogen and/or inert gas mixed with CO₂</td>
<td>yes</td>
<td>slow induction of unconsciousness, aversiveness of induction</td>
<td>Article 7.6.13.</td>
</tr>
<tr>
<td></td>
<td>neonates only</td>
<td>nitrogen and/or inert gases</td>
<td>yes</td>
<td>slow induction of unconsciousness</td>
<td>Article 7.6.14.</td>
</tr>
<tr>
<td></td>
<td>all</td>
<td>injection of barbiturates and other drugs</td>
<td>yes</td>
<td>non-lethal dose, pain associated with injection site</td>
<td>Article 7.6.15.</td>
</tr>
<tr>
<td>Pigs</td>
<td>all, except neonates</td>
<td>free bullet</td>
<td>no</td>
<td>non-lethal wounding</td>
<td>Article 7.6.6.</td>
</tr>
<tr>
<td></td>
<td>all except neonates</td>
<td>penetrating captive bolt, followed by pithing or bleeding</td>
<td>yes</td>
<td>ineffective stunning, regaining of consciousness before death</td>
<td>Article 7.6.7.</td>
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<tr>
<td></td>
<td>neonates only</td>
<td>non-penetrating captive bolt</td>
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<td>non-lethal wounding</td>
<td>Article 7.6.8.</td>
</tr>
<tr>
<td></td>
<td>all</td>
<td>electrical, two-stage application</td>
<td>yes</td>
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<td></td>
<td>all</td>
<td>electrical, single application (method 1)</td>
<td>yes</td>
<td>ineffective stunning</td>
<td>Article 7.6.11.</td>
</tr>
<tr>
<td></td>
<td>neonates only</td>
<td>CO₂ / air mixture</td>
<td>yes</td>
<td>slow induction of unconsciousness, aversiveness of induction</td>
<td>Article 7.6.12.</td>
</tr>
<tr>
<td></td>
<td>neonates only</td>
<td>nitrogen and/or inert gas mixed with CO₂</td>
<td>yes</td>
<td>slow induction of unconsciousness, aversiveness of induction</td>
<td>Article 7.6.13.</td>
</tr>
<tr>
<td></td>
<td>neonates only</td>
<td>nitrogen and/or inert gases</td>
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<td>slow induction of unconsciousness</td>
<td>Article 7.6.14.</td>
</tr>
<tr>
<td></td>
<td>all</td>
<td>injection with barbiturates and other drugs</td>
<td>yes</td>
<td>non-lethal dose, pain associated with injection site</td>
<td>Article 7.6.15.</td>
</tr>
<tr>
<td>Poultry</td>
<td>adults only</td>
<td>non-penetrating captive bolt</td>
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<td>ineffective stunning</td>
<td>Article 7.6.8.</td>
</tr>
<tr>
<td></td>
<td>day-olds and eggs only</td>
<td>maceration</td>
<td>no</td>
<td>non-lethal wounding, non-immediacy</td>
<td>Article 7.6.9.</td>
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<tr>
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<td>adults only</td>
<td>electrical, single application (method 2)</td>
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<td>ineffective stunning</td>
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<tr>
<td></td>
<td>adults only</td>
<td>electrical, single application, followed by killing (method 3)</td>
<td>yes</td>
<td>ineffective stunning, regaining of consciousness before death</td>
<td>Article 7.6.11.</td>
</tr>
<tr>
<td></td>
<td>all</td>
<td>CO₂ / air mixture Method 1 Method 2</td>
<td>yes</td>
<td>slow induction of unconsciousness, aversiveness of induction</td>
<td>Article 7.6.12.</td>
</tr>
<tr>
<td></td>
<td>all</td>
<td>nitrogen and/or inert gas mixed with CO₂</td>
<td>yes</td>
<td>slow induction of unconsciousness, aversiveness of induction</td>
<td>Article 7.6.13.</td>
</tr>
<tr>
<td></td>
<td>all</td>
<td>nitrogen and/or inert gases</td>
<td>yes</td>
<td>slow induction of unconsciousness</td>
<td>Article 7.6.14.</td>
</tr>
<tr>
<td></td>
<td>all</td>
<td>injection of barbiturates and other drugs</td>
<td>yes</td>
<td>non-lethal dose, pain associated with injection site</td>
<td>Article 7.6.15.</td>
</tr>
</tbody>
</table>
Chapter 7.6.- Killing of animals for disease control purposes

Article 7.6.6.

1. **Introduction**
   a) A free bullet is a projectile fired from a shot gun, rifle, handgun or purpose-made humane killer.
   b) The most commonly used firearms for close range use are:
      i) humane killers (specially manufactured/adapted single-shot weapons);
      ii) shotguns (12, 16, 20, 28 bore and .410);
      iii) rifles (.22 rimfire);
      iv) handguns (various calibres from .32 to .45).
   c) The most commonly used firearms for long range use are rifles (.22, .243, .270 and .308).
   d) A free bullet used from long range should be aimed to penetrate the skull or soft tissue at the top of the neck of the animals (high neck shot) and to cause irreversible concussion and death and should only be used by properly trained and competent marksmen.

2. **Requirements for effective use**
   a) The marksman should take account of human safety in the area in which he/she is operating. Appropriate vision and hearing protective devices should be worn by all personnel involved.
   b) The marksman should ensure that the animal is not moving and in the correct position to enable accurate targeting and the range should be as short as possible (5–50 cm for a shotgun) but the barrel should not be in contact with the head of the animals.
   c) The correct cartridge, calibre and type of bullet for the different species age and size should be used. Ideally, the ammunition should expand upon impact and dissipate its energy within the cranium.
   d) Shot animals should be checked to ensure the absence of brain stem reflexes.

3. **Advantages**
   a) Used properly, a free bullet provides a quick and effective method for killing.
   b) It requires minimal or no restraint and can be use to kill from a distance by properly trained and competent marksmen.
   c) It is suitable for killing agitated animals in open spaces.
4. **Disadvantages**

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

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

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

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

e) Legal requirements may preclude or restrict use.

f) There is a limited availability of competent personnel.

5. **Conclusion**

The method is suitable for cattle, sheep, goats and pigs, including large *animals* in open spaces.

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

![Figure 1](image1.png)

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

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

![Figure 2](image2.png)

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).
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Figure 3. The optimum shooting position for heavily horned sheep and horned goats is behind the poll aiming towards the angle of the jaw.

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

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

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

Article 7.6.7.

Penetrating captive bolt

1. Introduction

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

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

2. Requirements for effective use

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

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

c) More than one gun may be necessary to avoid overheating, and a back-up gun should be available in the event of an ineffective shot.
Chapter 7.6.- Killing of animals for disease control purposes

3. Advantages
   a) Mobility of cartridge powered equipment reduces the need to move animals.
   b) The method induces an immediate onset of a sustained period of unconsciousness.

4. Disadvantages
   a) Poor gun maintenance and misfiring, and inaccurate gun positioning and orientation may result in poor animal welfare.
   b) Post stun convulsions may make pithing difficult and hazardous.
   c) The method is difficult to apply in agitated animals.
   d) Repeated use of a cartridge powered gun may result in over-heating.
   e) Leakage of bodily fluids may present a biosecurity risk.
   f) Destruction of brain tissue may preclude diagnosis of some diseases.

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

Article 7.6.8.

Non-penetrating captive bolt

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

   The gun should be placed on the front of the skull to deliver a percussive blow which produces unconsciousness in cattle (adults only), sheep, goats and pigs, and death in poultry and neonate sheep, goats and pigs. Bleeding should be performed as soon as possible after the blow to ensure the death of the animal.

2. Requirements for effective use
   a) For cartridge powered and compressed air guns, the bolt velocity should be appropriate to the species and type of animal, in accordance with the recommendations of the manufacturer.
   b) Captive bolt guns should be frequently cleaned and maintained in good working condition.
   c) More than one gun may be necessary to avoid overheating, and a back-up gun should be available in the event of an ineffective shot.
   d) Animals should be restrained; at a minimum mammals should be penned for cartridge powered guns and in a race for compressed air guns; birds should be restrained in cones, shackles, crushes or by hand.
   e) The operator should ensure that the head of the animal is accessible.
   f) The operator should fire the captive bolt at right angles to the skull in the optimal position (figures 1–4).
   g) To ensure death in non-neonate mammals, bleeding should be performed as soon as possible after stunning.
   h) Animals should be monitored continuously after stunning until death to ensure the absence of brain stem reflexes.
Chapter 7.6. - Killing of animals for disease control purposes

3. Advantages
   a) The method induces an immediate onset of unconsciousness, and death in birds and neonates.
   b) Mobility of equipment reduces the need to move animals.

4. Disadvantages
   a) As consciousness can be regained quickly in non-neonate mammals, they should be bled as soon as possible after stunning.
   b) Laying hens in cages have to be removed from their cages and most birds have to be restrained.
   c) Poor gun maintenance and misfiring, and inaccurate gun positioning and orientation may result in poor animal welfare.
   d) Post stun convulsions may make bleeding difficult and hazardous.
   e) Difficult to apply in agitated animals; such animals may be sedated in advance of the killing procedure.
   f) Repeated use of a cartridge powered gun may result in over-heating.
   g) Bleeding may present a biosecurity risk.

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

Maceration

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

2. Requirements
   a) Maceration requires specialised equipment which should be kept in excellent working order.
   b) The rate of introducing the birds should not allow the equipment to jam, birds to rebound from the blades or the birds to suffocate before they are macerated.

3. Advantages
   a) Procedure results in immediate death.
   b) Large numbers can be killed quickly.

4. Disadvantages
   a) Specialised equipment is required.
   b) Macerated tissues may present biosecurity or human health risks.
   c) The cleaning of the equipment can be a source of contamination.

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

Article 7.6.10.

Electrical – two-stage application

1. Introduction
   A two-stage application of electric current comprises firstly an application of current to the head by scissor-type tongs, immediately followed by an application of the tongs across the chest in a position that spans the heart. The application of sufficient electric current to the head will induce ‘tonic/clonic’ epilepsy and unconsciousness. Once the animal is unconscious, the second stage will induce ventricular fibrillation (cardiac arrest) resulting in death. The second stage (the application of low frequency current across the chest) should only be applied to unconscious animals to prevent unacceptable levels of pain.
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2. Requirements for effective use

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

<table>
<thead>
<tr>
<th>Animal</th>
<th>Minimum voltage (V)</th>
<th>Minimum current (A)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cattle</td>
<td>220</td>
<td>1.5</td>
</tr>
<tr>
<td>Sheep</td>
<td>220</td>
<td>1.0</td>
</tr>
<tr>
<td>Pigs over 6 weeks of age</td>
<td>220</td>
<td>1.3</td>
</tr>
<tr>
<td>Pigs less than 6 weeks of age</td>
<td>125</td>
<td>0.5</td>
</tr>
</tbody>
</table>

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

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

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

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

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

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

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

3. Advantages

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

b) Non-invasive technique minimises biosecurity risk.

4. Disadvantages

a) The method requires a reliable supply of electricity.

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

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

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

5. Conclusion

The method is suitable for calves, sheep and goats, and especially for pigs (over one week of age).
Article 7.6.11.

Electrical – single application

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

   a) Requirements for effective use
      i) The stunner control device should generate a low frequency (30–60 Hz) current with a minimum voltage of 250 volts true RMS under load.
      ii) Appropriate protective clothing (including rubber gloves and boots) should be worn.
      iii) *Animals* should be individually and mechanically restrained close to an electrical supply as the maintenance of physical contact between the stunning electrodes and the animal is necessary for effective use.
      iv) The rear electrode should be applied to the back, above or behind the heart, and then the front electrode in a position that is forward of the eyes, with current applied for a minimum of 3 seconds.
      v) Electrodes should be cleaned regularly between *animals* and after use, to enable optimum electrical contact to be maintained.
      vi) Water or saline may be necessary to improve electrical contact with sheep.
      vii) An effective stun and kill should be verified by the absence of brain stem reflexes.

   b) Advantages
      i) Method 1 stuns and kills simultaneously.
      ii) It minimises post-stun convulsions and therefore is particularly effective with pigs.
      iii) A single team member only is required for the application.
      iv) Non-invasive technique minimises biosecurity risk.

   c) Disadvantages
      i) Method 1 requires individual mechanical animal restraint.
      ii) The electrodes should be applied and maintained in the correct positions to produce an effective stun and kill.
      iii) Method 1 requires a reliable supply of electricity.

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

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

   a) Requirements for effective use
      i) A mobile waterbath stunner and a short loop of processing line are required.
ii) A low frequency (50–60 Hz) current applied for a minimum of 3 seconds is necessary to stun and kill the birds.

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

iv) The required minimum currents to stun and kill dry birds are:
   - Quails – 100 mA/bird
   - Chickens – 160 mA/bird
   - Ducks & geese – 200 mA/bird
   - Turkeys – 250 mA/bird.

A higher current is required for wet birds.

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

b) Advantages

i) Method 2 stuns and kills simultaneously.

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

iii) This non-invasive technique minimises biosecurity risk.

c) Disadvantages

i) Method 2 requires a reliable supply of electricity.

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

d) Conclusion

Method 2 is suitable for large numbers of poultry.

3. Method 3

Method 3 comprises the single application of sufficient electrical current to the head of poultry in a position that spans the brain, causing unconsciousness; this is followed by a killing method (see Article 7.6.17.).

a) Requirements for effective use

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

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

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

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

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

b) Advantages

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

c) Disadvantages

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

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

iii) Birds should be individually restrained.

iv) It should be followed by a killing method.

d) Conclusion

Method 3 is suitable for small numbers of poultry.

Article 7.6.12.

CO₂ / air mixture

1. Introduction

Controlled atmosphere killing is performed by exposing animals to a predetermined gas mixture, either by placing them in a gas-filled container or apparatus (Method 1) or by placing transport modules or crates containing birds in a gas tight container and introducing a gas mixture (Method 2) or by the gas being introduced into a poultry house (Method 3). Method 3 should be used whenever possible, as it eliminates welfare issues resulting from the need
Chapter 7.6.- Killing of animals for disease control purposes

To manually remove live birds. Although Method 2 requires handling and crating of the birds, it benefits bird welfare overall in comparison with Method 1 as it reduces the risk of death by smothering or suffocation.

Inhalation of carbon dioxide (CO₂) induces respiratory and metabolic acidosis and hence reduces the pH of cerebrospinal fluid (CSF) and neurones thereby causing unconsciousness and, after prolonged exposure, death. Exposure to carbon dioxide does not induce immediate loss of consciousness, therefore the aversive nature of gas mixtures containing high concentrations of CO₂ and the respiratory distress occurring during the induction phase are important considerations for animal welfare.

2. **Method 1**

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

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

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

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

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

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

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

   b) **Advantages**

      i) CO₂ is readily available.

      ii) Application methods are simple.

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

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

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

      vi) Metal containers can be readily cleansed and disinfected.

   c) **Disadvantages**

      i) The need for properly designed container or apparatus.

      ii) The aversive nature of high CO₂ concentrations.

      iii) No immediate loss of consciousness.

      iv) The risk of suffocation due to overcrowding.

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

   d) **Conclusion**

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

3. **Method 2**

   In this method, the crates or modules holding the birds are loaded into a chamber into which gas is introduced. As illustrated in the example below, a containerised gassing unit (CGU) typically comprises a gas-tight chamber designed to accommodate poultry transport crates or a single module. The chamber is fitted with gas lines and diffusers, with silencers that are connected via a system of manifolds and gas regulators to gas cylinders. There is a hole at the top to permit displaced air to escape when the container is filling with gas.

   The procedures for the operation of CGU include (a) position the container on level, solid, open ground; (b) connect the gas cylinder to the container (c) load birds into the container (d) shut and secure the door, (e) deliver the gas until a concentration of 45 percent by volume of carbon dioxide has been achieved at the top of the container, (f) allow time for the birds to become unconscious and die (g) open the door and allow gas to be dispersed in the air.
Chapter 7.6.- Killing of animals for disease control purposes

(h) remove the module (i) check each drawer for survivors (j) humanely kill any survivors; and (k) dispose of carcasses appropriately.

a) Requirements for effective use of containerised gassing units (CGU)
   i) The birds should be caught gently and placed in crates or modules of appropriate size and at appropriate stocking densities to allow all birds to sit down.
   ii) The crates or module full of birds should be placed inside the container and the door shut only when the operator is ready to administer the gas.
   iii) Ensure the container door is locked and administer the gas until a minimum concentration of 45 percent carbon dioxide is achieved at the top of the crates.
   iv) An appropriate gas meter should be used to ensure the appropriate concentration of carbon dioxide is achieved and maintained until it can be confirmed that the birds have been killed.
   v) Sufficient exposure time should be allowed for birds to die before the door is opened. In the absence of a viewing window that allows direct observation of birds during killing, cessation of vocalisation and convulsive wing flapping sounds, which can be listened to by standing near the container, can be used to determine that the birds are unconscious and that death is imminent. Remove the crates or modules from the container and leave them in the open air.
   vi) Each crate or module should be examined and birds checked to ensure they are dead. Dilated pupils and absence of breathing indicate death.
   vii) Any survivors should be humanely killed.
   viii) Ducks and geese are resilient to the effects of carbon dioxide and therefore require a minimum of 80 percent CO₂ and a longer period of exposure to die.

b) Advantages
   i) The gas is introduced quickly and quietly resulting in less turbulence and disturbance to the birds.
   ii) Gradual increase in the concentration of CO₂ minimises the aversive nature of this method for inducing unconsciousness.
   iii) The use of transport crates or modules to move birds minimises handling. Birds should be handled by trained, experienced catching teams at the time of depopulation of the poultry house.
   iv) The modules are loaded mechanically into the CGU and a lethal mixture of gas is rapidly introduced into the chamber immediately after sealing.
   v) CO₂ is readily available.
   vi) Birds are exposed to gas more uniformly and they do not smother each other when compared with Method 1.
   vii) The volume of gas required can be readily calculated.
   viii) As the units are operated outdoors, the gas is dispersed quickly at the end of each cycle by opening the door, improving operator’s health and safety.
   ix) The system uses skilled catching teams and equipment in daily use by the industry.
   x) Metal containers can be readily cleansed and disinfected.

c) Disadvantages
   i) Requires trained operators, trained catchers, transport modules and fork lift. However, this equipment and suitable areas with hard surfaces are usually available.
   ii) The main limiting factors are speed of catching birds.
   iii) In the absence of a viewing window, visual confirmation of death while the birds are still in the container is difficult. However, cessation of vocalisation and convulsive wing flapping sounds can be used to determine onset of death.

d) Conclusion
   i) Method 2 is suitable for use in a wide range of poultry systems, providing there is access to vehicles to carry the containers and equipment.
   ii) Birds should be introduced into the container or apparatus, which is then sealed and filled as quickly as possible with the required gas concentrations, i.e. more than 40 percent CO₂. Birds are held in this atmosphere until death is confirmed.
   iii) Method 2 is suitable for use in poultry, and neonatal sheep, goats and pigs. However, CO₂ is likely to cause a period of distress in the animals before they lose consciousness.
4. **Method 3**

The gas is introduced into a poultry house.

a) Requirements for effective use in a poultry house

i) Prior to introduction of the CO₂, the poultry house should be appropriately sealed to allow control over the gas concentration. The interval between sealing and gas administration should be kept to the minimum so as to avoid overheating.

   Forced ventilation systems, where fitted, should only be switched off immediately prior to gas administration.

   The main water supply to the poultry house may have to be turned off and water drained to avoid freezing and bursting of water pipes.

   Feeders and water troughs should be lifted to avoid obstruction of the gas entry and prevent injury to birds.

ii) Gas delivery pipes or lancets should be positioned appropriately such that birds are not hit directly by very cold gas delivered at high pressures. It may be necessary to exclude birds from the area in front of the delivery pipes, for a distance of about 20 meters, by partitioning the house with nets, wire mesh or similarly perforated materials.

iii) The house should be gradually filled with CO₂ so that all birds are exposed to a concentration of >40 percent until they are dead; a vaporiser may be required to prevent freezing.

iv) Devices should be used to accurately measure the gas concentration at the maximum height accommodation of birds.

b) Advantages

i) Applying gas to birds *in situ* eliminates the need to manually remove live birds.

ii) CO₂ is readily available.

iii) Gradual raising of CO₂ concentration minimises the aversiveness of the induction of unconsciousness.

c) Disadvantages

i) It is difficult to determine volume of gas required to achieve adequate concentrations of CO₂ in some poultry houses.

ii) It is difficult to verify death while the birds are in the poultry house.

   The extremely low temperature of liquid CO₂ entering the house and formation of solid CO₂ (dry ice) may cause concern for bird welfare.

d) Conclusion

Method 3 is suitable for use in poultry in closed-environment sheds. This method could be developed for killing pigs. However, CO₂ is likely to cause a period of distress in the birds before they lose consciousness.

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**Nitrogen and/or inert gas mixed with CO₂**

1. **Introduction**

CO₂ may be mixed in various proportions with nitrogen or an inert gas (e.g. argon), and the inhalation of such mixtures leads to hypercapnic-hypoxia and death when the oxygen concentration by volume is <2 percent, or <5 percent for chickens. Various mixtures of CO₂ and nitrogen or an inert gas can be administered to kill birds using Methods 1 and 2 described under Article 7.6.12. Whole house gassing with mixtures of CO₂ and nitrogen, or an inert gas, has not been tested owing to the complex issues presented by mixing gases in large quantities. Such mixtures however do not induce immediate loss of consciousness, therefore the aversiveness of various gas mixtures containing high concentrations of CO₂ and the respiratory distress occurring during the induction phase, are important animal welfare considerations.

   Pigs and poultry appear not to find low concentrations of CO₂ strongly aversive, and a mixture of nitrogen or argon with ≤30 percent CO₂ by volume and ≤2 percent O₂ by volume can be used for killing poultry, neonatal sheep, goats and pigs.

2. **Method 1**

The animals are placed in a gas-filled container or apparatus.
Chapter 7.6.- Killing of animals for disease control purposes

a) Requirements for effective use
   i) Containers or apparatus should allow the required gas concentrations to be maintained, and the O₂ and CO₂ concentrations accurately measured during the killing procedure.
   ii) When animals are exposed to the gases individually or in small groups in a container or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the animals and allow them to be observed.
   iii) Animals should be introduced into the container or apparatus after it has been filled with the required gas concentrations (with <2 percent O₂), and held in this atmosphere until death is confirmed.
   iv) Team members should ensure that there is sufficient time allowed for each batch of animals to die before subsequent ones are introduced into the container or apparatus.
   v) Containers or apparatus should not be overcrowded and measures are needed to avoid animals suffocating by climbing on top of each other.

b) Advantages
   Low concentrations of CO₂ cause little aversiveness and, in combination with nitrogen or an inert gas, produces a fast induction of unconsciousness.

c) Disadvantages
   i) A properly designed container or apparatus is needed.
   ii) It is difficult to verify death while the animals are in the container or apparatus.
   iii) There is no immediate loss of consciousness.
   iv) Exposure times required to kill are considerable.

d) Conclusion
   The method is suitable for poultry, and for neonatal sheep, goats and pigs.

3. Method 2
   In this method, the crates or modules holding the birds are loaded into a container and gas is introduced into the container (refer to Figures under Article 7.6.12.). As shown in the example below, each containerised gassing unit (CGU) typically comprises a gas-tight chamber designed to accommodate poultry transport crates or a module. The container or chamber is fitted with gas lines and diffusers, with silencers, which in turn are connected via a system of manifolds and gas regulators to gas cylinders. There is a hole at the top of the unit to permit displaced air to escape when filling the container with gas.

   Procedures involved in the operation of CGU includes (a) position the container on a level, solid, open ground; (b) connect gas cylinder to the container; (c) load a module of birds into the container; (d) shut and secure the door; (e) deliver the gas to the point where less than 2 percent by volume of oxygen is found at the top of the container, (f) allow time for the birds to become unconscious and die, (g) open the door and allow the gas to be dispersed in air, (h) remove the module, (i) check each drawer for survivors; (j) humanely kill survivors, if any; and (k) dispose carcasses appropriately.

a) Requirements for effective use of containerised gassing units (CGU)
   i) The birds should be caught gently and placed in crates or modules of appropriate size and at appropriate stocking densities to allow all birds to sit down.
   ii) The crates or module of birds should be placed inside the container and the door shut only when the operator is ready to administer the gas mixture.
   iii) Ensure the container door is locked and administer the gas mixture until <2 percent residual oxygen is achieved at the top of the crates.
   iv) An appropriate gas meter should be used to ensure a concentration of oxygen <2 percent is achieved and maintained until it can be confirmed that the birds have been killed.
   v) Sufficient exposure time should be allowed for birds to die before the door is opened. In the absence of a viewing window, which allows direct observation of birds during killing, cessation of vocalisation and wing flapping sounds can be observed by standing close to the container and used to determine the onset of death in birds. Remove the crates or modules from the container and leave them in the open air.
   vi) Each crate or module should be examined and birds checked to ensure they are dead. Dilated pupils and absence of breathing movements indicate death.
   vii) Any survivors should be humanely killed.
viii) Ducks and geese do not appear to be resilient to the effects of a mixture of 20 percent carbon dioxide and 80 percent nitrogen or argon.

b) Advantages

i) The gas mixture is introduced quickly and quietly resulting in less turbulence and disturbance to the birds.

ii) The use of transport crates or modules to move birds minimises handling. Birds should be handled by trained, experienced catching teams at the time of depopulation of the poultry house.

iii) The modules are loaded mechanically into the CGU and a lethal mixture of gas is rapidly introduced into the chamber immediately after sealing.

iv) Mixtures containing up to 20 percent carbon dioxide in argon are readily available as welding gas cylinders.

v) Birds are exposed to gas in a more uniform manner and they do not smother each other when compared with Method 1.

vi) Two CGU can be operated in tandem and throughputs of up to 4,000 chickens per hour are possible.

vii) The volume of gas required can be readily calculated.

viii) As the units are operated outdoor the gas is dispersed quickly at the end of each cycle by opening the door, improving operators' health and safety.

ix) The system uses skilled catching teams and equipment in daily use by the industry.

x) Metal containers can be readily cleansed and disinfected.

c) Disadvantages

i) Requires trained operators, trained catchers, transport modules and a fork lift. However, such equipment and suitable outdoor areas with a hard surface are usually available.

ii) The main limiting factors are speed of catching birds and availability of gas mixtures.

iii) In the absence of a viewing window, visual confirmation of death while the birds are still in the container is difficult. However, cessation of vocalisation and convulsive wing flapping can be used to determine the onset of death.

iv) CGU could be used to kill poultry on small to medium farms, e.g. up to 25 thousand birds on a single farm.

d) Conclusion

i) Method 2 is suitable for use in poultry and in neonatal sheep, goats and pigs.

ii) Method 2 is suitable for use in poultry in a wide range of poultry systems providing that these have access to vehicles to carry containers and equipment.

iii) Animals should be introduced into the container or apparatus, which is then sealed and filled as quickly as possible with the gas mixture. A residual oxygen concentration of less than 2 percent should be achieved and maintained and birds should be held in this atmosphere until death is confirmed.
Chapter 7.6.- Killing of animals for disease control purposes

Figure source: Department of Clinical Veterinary Science, University of Bristol, United Kingdom.
Nitrogen and/or inert gases

1. Introduction
   This method involves the introduction of animals into a container or apparatus containing nitrogen or an inert gas such as argon. The controlled atmosphere produced leads to unconsciousness and death from hypoxia. Research has shown that hypoxia is not aversive to pigs and poultry, and it does not induce any signs of respiratory distress prior to loss of consciousness.

2. Requirements for effective use
   a) Containers or apparatus should allow the required gas concentrations to be maintained, and the O₂ concentration accurately measured.
   b) When animals are exposed to the gases individually or in small groups in a container or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the animals and allow them to be observed.
   c) Animals should be introduced into the container or apparatus after it has been filled with the required gas concentrations (with <2 percent O₂), and held in this atmosphere until death is confirmed.
   d) Team members should ensure that there is sufficient time allowed for each batch of animals to die before subsequent ones are introduced into the container or apparatus.
   e) Containers or apparatus should not be overcrowded, and measures are needed to avoid animals suffocating by climbing on top of each other.

3. Advantages
   Animals are unable to detect nitrogen or inert gases, and the induction of hypoxia by this method is not aversive to animals.

4. Disadvantages
   a) A properly designed container or apparatus is needed.
   b) It is difficult to verify death while the animals are in the container or apparatus.
   c) There is no immediate loss of consciousness.
   d) Exposure times required to kill are considerable.

5. Conclusion
   The method is suitable for poultry and neonatal sheep, goats and pigs.

Lethal injection

1. Introduction
   A lethal injection using high doses of anaesthetic and sedative drugs causes CNS depression, unconsciousness and death. In practice, barbiturates in combination with other drugs are commonly used.

2. Requirements for effective use
   a) Doses and routes of administration that cause rapid loss of consciousness followed by death should be used.
   b) Prior sedation may be necessary for some animals.
   c) Intravenous administration is preferred, but intraperitoneal or intramuscular administration may be appropriate, especially if the agent is non-irritating.
   d) Animals should be restrained to allow effective administration.
   e) Animals should be monitored to ensure the absence of brain stem reflexes.

3. Advantages
   a) The method can be used in all species.
   b) Death can be induced smoothly.
4. Disadvantages
   a) Restraint and/or sedation may be necessary prior to injection.
   b) Some combinations of drug type and route of administration may be painful, and should only be used in unconscious animals.
   c) Legal requirements and skill/training required may restrict use to veterinarians.
   d) Contaminated carcasses may present a risk to other wild animals or domestic animals.

5. Conclusion
   The method is suitable for killing small numbers of cattle, sheep, goats, pigs and poultry.

Article 7.6.16.

Addition of anaesthetics to feed or water

1. Introduction
   An anaesthetic agent which can be mixed with poultry feed or water may be used to kill poultry in houses. Poultry which are only anaesthetised need to be killed by another method such as cervical dislocation.

2. Requirements for effective use
   a) Sufficient quantities of anaesthetic need to be ingested rapidly for effective response.
   b) Intake of sufficient quantities is facilitated if the birds are fasted or water is withheld.
   c) Should be followed by killing (see Article 7.6.17.) if birds are anaesthetised only.

3. Advantages
   a) Handling is not required until birds are anaesthetised.
   b) There may be biosecurity advantages in the case of large numbers of diseased birds.

4. Disadvantages
   a) Non-target animals may accidentally access the medicated feed or water when provided in an open environment.
   b) Dose taken is unable to be regulated and variable results may be obtained.
   c) Animals may reject adulterated feed or water due to illness or adverse flavour.
   d) The method may need to be followed by killing.
   e) Care is essential in the preparation and provision of treated feed or water, and in the disposal of uneaten treated feed/water and contaminated carcasses.

5. Conclusion
   The method is suitable for killing large numbers of poultry in houses. However, a back-up method should be available to kill birds that are anaesthetized but not killed.

Article 7.6.17.

Cervical dislocation and decapitation

1. Cervical dislocation (manual and mechanical)
   a) Introduction
      Unconscious poultry may be killed by either manual or mechanical cervical dislocation (stretching the neck). This method results in death from cerebral anoxia due to cessation of breathing and/or blood supply to the brain.
      When the number of birds to be killed is small, and other methods of killing are not available, conscious birds of less than 3 kilograms may be killed using cervical dislocation in such a way that the blood vessels of the neck are severed and death is instantaneous.
b) Requirements for effective use
   i) Killing should be performed either by manually or mechanically stretching the neck to sever the spinal cord with consequent major damage to the spinal cord.
   ii) Consistent results require strength and skill so team members should be rested regularly to ensure consistently reliable results.
   iii) Birds should be monitored continuously until death to ensure the absence of brain stem reflexes.

c) Advantages
   i) It is a non-invasive killing method.
   ii) It can be performed manually on small birds.

d) Disadvantages
   i) Operator fatigue.
   ii) The method is more difficult in larger birds.
   iii) Requires trained personnel to perform humanely.
   iv) Human health and safety concerns due to handling of the birds.
   v) Additional stress to the animals from handling.

2. Decapitation
   a) Introduction
      Decapitation results in death by cerebral ischaemia using a guillotine or knife.
   b) Requirements for effective use
      The required equipment should be kept in good working order.
   c) Advantages
      The technique is effective and does not require monitoring.
   d) Disadvantages
      i) The working area is contaminated with body fluids, which increases biosecurity risks.
      ii) Pain if consciousness is not lost immediately.

Pithing and bleeding

1. Pithing
   a) Introduction
      Pithing is a method of killing animals which have been stunned by a penetrating captive bolt, without immediate death. Pithing results in the physical destruction of the brain and upper regions of the spinal cord, through the insertion of a rod or cane through the bolt hole.
   b) Requirements for effective use
      i) Pithing cane or rod is required.
      ii) An access to the head of the animal and to the brain through the skull is required.
      iii) Animals should be monitored continuously until death to ensure the absence of brain stem reflexes.
   c) Advantages
      The technique is effective in producing immediate death.
   d) Disadvantages
      i) A delayed and/or ineffective pithing due to convulsions may occur.
      ii) The working area is contaminated with body fluids, which increases biosecurity risks.
2. **Bleeding**
   a) **Introduction**
   Bleeding is a method of killing animals through the severance of the major blood vessels in the neck or chest that results in a rapid fall in blood pressure, leading to cerebral ischaemia and death.

   b) **Requirements for effective use**
      i) A sharp knife is required.

      ii) An access to the neck or chest of the animal is required.

      iii) Animals should be monitored continuously until death to ensure the absence of brain stem reflexes.

   c) **Advantages**
      The technique is effective in producing death after an effective stunning method which does not permit pithing.

   d) **Disadvantages**
      i) A delayed and/or ineffective bleeding due to convulsions may occur.

      ii) The working area is contaminated with body fluids, which increases biosecurity risks.

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1 The only preclusion against the use of this method for neonates is the design of the stunning tongs that may not facilitate their application across such a small-sized head/body.
CHAPTER 7.7.

STRAY DOG POPULATION CONTROL

Preamble: The scope of these recommendations is to deal with stray and feral dogs, which pose serious human health, animal health and welfare problems and have a socio-economic, environmental, political and religious impact in many countries. Human health, including the prevention of zoonotic diseases, notably rabies, is a priority. Dog population management is an integral part of rabies control programmes. Furthermore, the OIE recognises the importance of controlling dog populations without causing unnecessary animal suffering. Veterinary Services should play a lead role in preventing zoonotic diseases and ensuring animal welfare and should be involved in dog population control, coordinating their activities with other competent public institutions and/or agencies.

Article 7.7.1.

Guiding principles

The following recommendations are based on those laid down in Chapter 7.1. Some additional principles are relevant to these recommendations:

1) The promotion of responsible dog ownership can significantly reduce the numbers of stray dogs and the incidence of zoonotic diseases.

2) Because dog ecology is linked with human activities, control of dog populations has to be accompanied by changes in human behaviour to be effective.

Article 7.7.2.

Definitions

Carrying capacity: means the upper limit of the dog population density that could be supported by the habitat based on the availability of resources (food, water, shelter), and human acceptance.

Dog population control programme: means a programme with the aim of reducing a stray dog population to a particular level and/or maintaining it at that level and/or managing it in order to meet a predetermined objective (see Article 7.7.3.).

Person: this can include more than one individual, and could comprise family/household members or an organisation.

Article 7.7.3.

Dog population control programme objectives

The objectives of a programme to control the dog population may include the following:

1) improve health and welfare of owned and stray dog population;

2) reduce numbers of stray dogs to an acceptable level;

3) promote responsible ownership;

4) assist in the creation and maintenance of a rabies immune or rabies free dog population;

5) reduce the risk of zoonotic diseases other than rabies;

6) manage other risks to human health (e.g. parasites);

7) prevent harm to the environment and other animals;

8) prevent illegal trade and trafficking.
Chapter 7.7.- Stray dog population control

Article 7.7.4.

Responsibilities and competencies

1. Veterinary Authority

The Veterinary Authority is responsible for the implementation of animal health and animal welfare legislation, in coordination with other competent government agencies and institutions. Control of endemic zoonotic diseases such as rabies and parasitic infections (e.g. Echinococcus spp.) would require technical advice from the Veterinary Authority, as animal health and some aspects of public health are within this Authority’s competence but organising and/or supervising dog control schemes can be the responsibility of non-governmental organisations and governmental agencies other than the Veterinary Authority.

2. Other government agencies

The responsibilities of other government agencies will depend on the risk being managed and the objective/nature of the dog population control measures employed.

The ministry or other agency responsible for public health would normally play a leadership role and may have legislative authority in dealing with zoonotic diseases. Control of stray dogs with regard to other human health risks (e.g. stray dogs on roads; dog attacks within communities) may fall within the responsibility of the public health agency but is more likely to be the responsibility of the local government authorities or other agencies for public safety/security operating at the state/provincial or municipal level.

Environment protection agencies may take responsibility for control problems associated with stray dogs when they present a hazard to the environment (e.g. control of feral dogs in national parks; prevention of dog attacks on wildlife or transmission of diseases to wildlife) or where a lack of environmental controls is giving rise to stray dog populations that threaten human health or access to amenities. For example, environmental protection agencies may regulate and enforce measures to prevent dogs from accessing waste or human sewage.

3. Private sector veterinarians

The private sector veterinarian is responsible for providing advice to dog owners or handlers consulting the veterinarian for advice or treatment of a dog. The private sector veterinarian can play an important role in disease surveillance because he/she might be the first to see a dog suffering from a notifiable disease such as rabies. It is necessary that the private sector veterinarian follow the procedure established by the Veterinary Authority for responding to and reporting a suspected rabies case or a dog that is suffering from any other notifiable disease. Private sector veterinarians also play an important role (often in liaison with the police and/or local authorities) in dealing with cases of neglect that can lead to problems with stray and mismanaged dogs.

The private veterinarian has competence and will normally be involved in dog health programmes and population control measures, including health testing, vaccination, identification, kennelling during the absence of the owner, sterilisation and euthanasia. Two-way communication between the private sector veterinarian and Veterinary Authority, often via the medium of a veterinary professional organisation, is very important and the Veterinary Authority is responsible for setting up appropriate mechanisms for this action.

4. Non-governmental organisations

Non-governmental organisations (NGOs) are potentially important partners of the Veterinary Services in contributing to public awareness and understanding and helping to obtain resources to contribute in a practical way to the design and successful implementation of dog control programmes. NGOs can supply local knowledge on dog populations and features of ownership, as well as expertise in handling and kennelling dogs and the implementation of sterilisation programmes. NGOs can also contribute, together with veterinarians and the authorities in educating the public in responsible dog ownership.

5. Local government authorities

Local government authorities are responsible for many services and programmes that relate to health, safety and public good within their jurisdiction. In many countries the legislative framework gives authority to local government agencies in regard to aspects of public health, environmental health/hygiene and inspection/compliance activities.

In many countries local government agencies are responsible for the development and enforcement of legislation relating to dog ownership (e.g. registration, microchipping, vaccination, leash laws, abandonment), the control of stray dogs (e.g. dog catching and shelters) and the alleviation of the problems stray dogs cause in their jurisdiction. This would normally be done with advice from a higher level (national or state/provincial) authority with specialised expertise in regard to public health and animal health. Collaboration with the private sector veterinarians (e.g. in programmes to sterilise and vaccinate stray dogs) and NGOs is a common feature of dog control programmes. Regardless of the legislative basis, it is essential to have the co-operation of local government authorities in the control of stray dogs.
6. **Dog owners**

When a person takes on the ownership of a dog, there should be an immediate acceptance of responsibility for that dog, and for any offspring it may produce, for the duration of its life or until a subsequent owner is found. The owner should ensure that the welfare of the dog, including behavioural needs, are respected and the dog is protected, as far as possible, from infectious diseases (e.g. through vaccination and parasite control) and from unwanted reproduction (e.g. through contraception or sterilisation). Owners should ensure that the dog’s ownership is clearly identified (preferably with permanent identification such as a tattoo or microchip) and, where required by legislation, registered on a centralised database. All reasonable steps should be taken to ensure that the dog does not roam out of control in a manner that would pose a problem to the community and/or the environment.

**Article 7.7.5.**

In the development of a dog population control programme it is recommended that the authorities establish an advisory group, which should include veterinarians, experts in dog ecology, dog behaviour and zoonotic diseases, and representatives of relevant stakeholders (local authorities, human health services/authorities, environmental control services/authorities, NGOs and the public). The main purpose of this advisory group would be to analyse and quantify the problem, identify the causes, obtain public opinion on dogs and propose the most effective approaches to use in the short and long term.

Important considerations are as follows:

1. **Identifying the sources of stray dogs**
   a) **Owned dogs** that roam freely;
   b) dogs that have been abandoned by their owner, including puppies resulting from uncontrolled breeding of owned dogs;
   c) unowned dogs that reproduce successfully.

2. **Estimating the existing number, distribution and ecology**

   Practical tools that are available include registers of dogs, population estimates, and surveys of dogs, owners, dog shelters and veterinarians. The important factors relevant to the dog carrying capacity of the environment include food, shelter, water and human attitudes and behaviour.

   A methodology could be established to make an estimate of the total dog population. An overview of appropriate methodologies may be found in Article 7.7.8. The same methodology could be used at appropriate intervals to assess population trends.

3. **Regulatory framework**

   A regulatory framework that would help authorities establish successful dog control programmes could include the following key elements:
   a) registration and identification of dogs and licensing of dog breeders;
   b) vaccination against rabies and other preventive measures against zoonotic diseases, as appropriate;
   c) veterinary procedures (e.g. surgical procedures);
   d) control of dog movement (national and international);
   e) control of dangerous dogs;
   f) regulations on the breeding and sale of dogs;
   g) environmental controls (e.g. abattoirs, rubbish dumps, dead stock facilities);
   h) regulations for dog shelters;
   i) **animal welfare** obligations of owners and authorities.

4. **Resources available to authorities**
   a) Human resources;
   b) financial resources;
   c) technical tools;
   d) infrastructure;
   e) cooperative activities;
   f) public-private-NGO partnerships;
Chapter 7.7.- Stray dog population control

Control measures

The following control measures could be implemented according to the national context and local circumstances. Measures may be used in combination. Euthanasia of dogs, used alone, is not an effective control measure. If used, it should be done humanely (see point 11 of Article 7.7.6.) and in combination with other measures to achieve effective long term control. It is also important that authorities gain an understanding of people’s attitudes towards dog ownership so that they can develop a cooperative approach to the control of dog populations.

1. **Education and legislation for responsible ownership**

   Encouraging dog owners to be more responsible will reduce the number of dogs allowed to roam, improve the health and welfare of dogs, and minimise the risk that dogs pose to the community. The promotion of responsible dog ownership through legislation and education is a necessary part of a dog population control programme. Collaboration with local government authorities, animal welfare NGOs, kennel clubs, private veterinarians and veterinary organisations will assist Veterinary Authorities in establishing and maintaining programmes.

   Education on responsible dog ownership (for the currently owned dog and any offspring it produces) should address the following elements:

   a) the importance of proper selection for behaviour and care to ensure the welfare of the dog and any offspring; the latter may include preparing the dog to cope with its environment through attention to socialisation and training;
   b) registration and identification of dogs (see point 2 of Article 7.7.6.);
   c) disease prevention, in particular zoonotic diseases, e.g. through regular vaccination in rabies endemic areas;
   d) preventing negative impacts of dogs on the community, via pollution (e.g. faeces and noise), risks to human health through biting or traffic accidents and risks to other dogs, wildlife, livestock and other companion animal species;
   e) control of dog reproduction.

   In order to achieve a shift towards responsible ownership, a combination of legislation, public awareness, education, and promotion of these elements will be required. It may also be necessary to improve access to resources supporting responsible ownership, such as veterinary care, identification and registration services and measures for control of zoonotic diseases.

2. **Registration and identification of dogs (licensing)**

   A core component of dog population control by the Competent Authorities is the registration and identification of owned dogs. This may include granting licences to owners and breeders. Registration and identification may be emphasized as part of responsible dog ownership and are often linked to animal health programmes, for example, mandatory rabies vaccination and traceability.

   Registration of animals in a centralised database can be used to support the enforcement of legislation and the reuniting of lost animals with owners. The control of dog reproduction by sterilisation can be encouraged through financial incentives presented by differential licensing fees.

3. **Reproductive control**

   Controlling reproduction in dogs prevents the birth of unwanted puppies and can help address the balance between demand for dogs and the size of the population. It is advisable to focus efforts to control reproduction on those individuals or groups in the dog population identified as the most productive and the most likely to be the sources of unwanted and stray dogs, to ensure best use of resources. Methods of controlling reproduction will require direct veterinary input to individual animals. Involvement of both private and public veterinary sectors may be required to meet demand for services. Subsidisation of sterilisation programmes by government or other organisations may be considered to encourage uptake. The control of reproduction is essentially the responsibility of owners and can be incorporated into education on responsible ownership (see point 1 of Article 7.7.6.). Methods for controlling reproduction in dogs include:

   a) surgical sterilisation;
   b) chemical sterilisation;
   c) chemical contraception;
d) separation of female dogs during oestrus from unsterilised males. Surgical sterilisation should be carried out by a veterinarian and include appropriate anaesthesia and pain management.

Any chemicals or drugs used in controlling reproduction should be shown to have appropriate safety, quality and efficacy for the function required and used according to the manufacturer’s and Competent Authority’s regulations. In the case of chemical sterilants and contraceptives, research and field trials may need to be completed before use.

4. Removal and handling

The Competent Authority should collect dogs that are not under direct supervision and verify their ownership. Capture, transport, and holding of the dogs should be done humanely. The Competent Authority should develop and implement appropriate legislation and training to regulate these activities. Capture should be achieved with the minimum force required and equipment should be used that supports humane handling. Uncovered wire loops should not be used for capture.

5. Capture and return, rehoming or release

Competent Authorities have the responsibility to develop minimum standards for the housing (physical facilities) and care of these dogs. There should be provision for holding the dogs for a reasonable period of time to allow for reunion with the owner and, as appropriate, for rabies observation.

a) Minimum standards for housing should include the following provisions:
   i) site selection: access to drainage, water and electricity are essential and environmental factors such as noise and pollution should be taken into account;
   ii) kennel size, design and occupancy taking exercise into account;
   iii) disease control measures including isolation and quarantine facilities.

b) Management should address:
   i) adequate fresh water and nutritious food;
   ii) regular hygiene and cleaning;
   iii) routine inspection of the dogs;
   iv) monitoring of health and provision of required veterinary treatments;
   v) policies and procedures for rehoming (adoption), sterilisation and euthanasia;
   vi) training of staff in safe and appropriate handling of dogs;
   vii) record keeping and reporting to authorities.

Dogs that are removed from a community may be reunited with the owner or offered to new owners for rehoming. This provides an opportunity to promote responsible ownership and good animal health care (including rabies vaccination). Prior to rehoming, authorities may consider sterilisation of dogs as a population control measure. The suitability of new owners to adopt dogs should be assessed and owners matched with available animals. The effectiveness of rehoming may be limited due to the suitability and number of dogs.

Dogs that are removed from a community may in some cases be provided with health care (including rabies vaccination), sterilised, and released to their local community at or near the place of capture. This method is more likely to be accepted in the situation where the presence of stray dogs is considered to be inevitable and is well tolerated by the local community.

This method is not applicable in all situations and may be illegal in countries or regions where legislation prohibits the abandonment of dogs. Problems caused by dogs, such as noise, faecal pollution, bite injuries and traffic accidents, would not be alleviated as dogs are returned to the local community and their movements are not restricted. If the local community has owned dogs, and sterilised dogs are released, consideration should be given to the risk that this could encourage abandonment of unwanted dogs. In the situation where many dogs are owned, a population control programme that focuses on neutering and responsible ownership may be more appropriate.

It is recommended that before adopting this approach, a cost-benefit analysis is conducted. Factors such as the monetary costs, impact on culture of ownership and public safety should be assessed as well as the benefits for disease control and animal welfare as well as any societal benefits.

b) If this method is adopted, the following factors should be addressed:
   i) raising awareness of the programme within the local community to ensure understanding and support;
   ii) use of humane methods for catching, transporting and holding dogs;
   iii) correct surgical technique, anaesthesia and analgesia, followed by post-operative care;
   iv) disease control may include blanket vaccination (e.g. rabies) and treatments and testing for diseases (e.g. leishmaniasis) followed, as appropriate by treatment or euthanasia of the dog;
v) behavioural observation may be used to assess if dogs are suitable for release; if not suitable for release or rehoming, *euthanasia* should be considered;

vi) permanent marking (e.g. tattoo or microchip) to indicate that the *animal* has been sterilised; individual identification also allows for tracking of *vaccination* status and treatment history and identification of a level of ‘ownership’ by the organisation/authority responsible for carrying out this intervention; a visible identification (e.g. collar) may also be used to prevent unnecessary recapture;

vii) the dog should be returned to a place that is as near as possible to the place of capture;

viii) the welfare of dogs after release should be monitored and action taken if required.

Dogs that are removed from a community may be too numerous or may be unsuitable for any rehoming scheme. If *euthanasia* of these unwanted *animals* is the only option, the procedure should be conducted in accordance with the regulations of the *Competent Authority* (see point 11 of Article 7.7.6.).

6. Environmental controls
   
   Steps should be taken to exclude dogs from sources of food (e.g. rubbish dumps and *abattoirs*, and installing animal-proof rubbish containers).

   This should be linked to a reduction in the dog population by other methods, to avoid *animal welfare* problems.

7. Control of dog movement – international (export/import)
   
   Chapter 8.11. provides recommendations on the international movement of dogs, with respect to provisions for rabies.

8. Control of dog movements – within country (e.g. leash laws, roaming restrictions)
   
   Measures for the control of dog movement in a country are generally invoked for the following reasons:

   a) for rabies control when the *disease* is present in a country;
   
   b) for public safety reasons;
   
   c) for the safety of ‘owned dogs’ in an area or locality when a *stray dog* control programme is in place;
   
   d) to protect wildlife and livestock.

   It is necessary to have a regulatory framework and a national or local infrastructure comprising organisation, administration, staff and resources to encourage the finders of *stray dogs* to report to the *Competent Authority*.

9. Regulation of commercial dog dealers
   
   Dog breeders and dealers should be encouraged to form or join an appropriate association. Such associations should encourage a commitment to the raising and selling of physically and psychologically healthy dogs, as unhealthy dogs may be more likely to be abandoned to become part of the stray population. They should encourage breeders and dealers to provide advice on proper care to all new owners of dogs. Regulations covering commercial dog breeders and dealers should include specific requirements for accommodation, provision of suitable food, drink and bedding, adequate exercise, veterinary care and *disease* control and may require breeders and dealers to allow regular inspection, including veterinary inspection.

10. Reduction in dog bite incidence
    
    The most effective means of reducing prevalence of dog bites are education and placing responsibility on the owner. Dog owners should be educated in principles of *responsible dog ownership* as described in point 1 of Article 7.7.6.) Legal mechanisms that enable the *Competent Authorities* to impose penalties or otherwise deal with irresponsible owners are necessary. Mandatory registration and identification schemes will facilitate the effective application of such mechanisms. Young children are the group at highest risk for dog bites. Public education programmes focussed on appropriate dog-directed behaviour have been demonstrated to be effective in reducing dog bite prevalence and these programmes should be encouraged. Authorities should seek advice from dog behaviour experts in developing dog safety education programmes.
11. Euthanasia

When euthanasia is practised, the general principles in the Terrestrial Code should be followed, with the emphasis on using the most practical, rapid and humane methods and ensuring operator safety. Regardless of the method used, it is important to minimise distress, anxiety and pain by ensuring that operators are appropriately trained.

Table 1 shows a summary analysis of methods for the euthanasia of dogs.

Comments on methods for the euthanasia of dogs:

a) Restrains
When a dog needs to be restrained for any procedure, including euthanasia, this should always be done with full regard for operator security and animal welfare. Some euthanasia methods should be used in association with sedation or anaesthesia in order to be considered humane.

b) Special equipment
When special equipment is needed to perform euthanasia (e.g. gas chamber), the system should be designed for the purpose and regularly maintained in order to achieve operator security and animal welfare.

c) The following methods, procedures and practices are unacceptable on animal welfare grounds:

i) Chemical methods:
- Embutramide + Mebezonium + Tetracaine without sedation or by other than IV injection
- Chloral hydrate
- Nitrous oxide: may be used with other inhalants to speed the onset of anaesthesia, but alone it does not induce anaesthesia in dogs
- Ether
- Chloroform
- Cyanide
- Strychnine
- Neuromuscular blocking agents (nicotine, magnesium sulphate, potassium chloride, all curariform agents): when used alone, respiratory arrest occurs before loss of consciousness, so the dog may perceive pain
- Formalin
- Household products and solvents.

ii) Mechanical methods:
- Air embolism on conscious animal
- Burning
- Exsanguination of conscious animal
- Decompression: expansion of gas trapped in body cavities may be very painful
- Drowning
- Hypothermia, rapid freezing
- Stunning: stunning is not a euthanasia method, it should always be followed by a method which ensures death
- Kill-trapping
- Electrocoagulation of conscious animal.

Because neonatal animals and adults with impaired breathing or low blood pressure are resistant to hypoxia, methods that depend upon achieving a hypoxic state (e.g. CO₂, CO, N₂, Ar) should not be used. These methods should not be used in animals aged less than 2 months, except to produce loss of consciousness and should be followed by another method to cause death. Concussion and cervical dislocation may be used in very small neonatal dogs and only in cases of emergency.

Operators should be well trained in the use of physical techniques to ensure that they are correctly and humanely carried out. The dog should be exsanguinated immediately after concussion or cervical dislocation.

d) Confirmation of death
For all methods of euthanasia used, death should be confirmed before animals are disposed of or left unattended. If an animal is not dead, another method of euthanasia should be performed.
e) Carcass disposal
Carcasses should be disposed of in a manner that complies with legislation. Attention should be paid to the risk of residues occurring in the carcass. Incineration is generally the safest way of carcass disposal.

Table 1. Summary analysis of methods for the euthanasia of dogs.

<table>
<thead>
<tr>
<th>Euthanasia method</th>
<th>Specific method</th>
<th>Animal welfare concerns/implications</th>
<th>Key animal welfare requirements</th>
<th>Considerations relating to operator security</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical via infection</td>
<td>Barbiturates</td>
<td>Correct restraint is needed. IP is slow and may be irritant. IC injection is a painful procedure.</td>
<td>Recommend to use IV injection. When using IP injection, the solution may be diluted or local anaesthetic agent used in conjunction. IC should only be performed on unconscious animal and by skilled operator.</td>
<td>Correct restraint is needed. Administered under veterinary supervision and requires trained personnel.</td>
<td>Speed of action generally depends on the dose, concentration, route and rate of injection. Barbiturates induce euthanasia smoothly, with minimal discomfort to the animal. Barbiturates are less expensive than many other euthanasia agents.</td>
<td>These drugs persist in the carcass and may cause sedation or death in animals that consume the cadaver.</td>
</tr>
<tr>
<td>Embutramide + Mebezonium + Tetracaine</td>
<td>Muscle paralysis may occur before loss of consciousness if injection given rapidly.</td>
<td>Use slow IV injection with sedation to permit slow rate of injection.</td>
<td>Correct restraint is needed. To be administered under veterinary supervision and by trained personnel.</td>
<td>Quite low cost.</td>
<td>Unavailable/unlicensed in some countries.</td>
<td></td>
</tr>
<tr>
<td>Anaesthetic agent overdose (thiopentone or propofenol)</td>
<td>Underdosing may lead to recovery.</td>
<td>IV injection of a sufficient dose.</td>
<td>Correct restraint is needed. To be administered under veterinary supervision and by trained personnel.</td>
<td>Generally quick action and minimal discomfort to animal.</td>
<td>Large volume required (cost implications).</td>
<td></td>
</tr>
<tr>
<td>Potassium chloride (KCl)</td>
<td>K+ is cardiotoxic and very painful if used without anaesthetic agent.</td>
<td>Only use on anaesthetised animals. IV injection.</td>
<td>Requires trained personnel.</td>
<td>Readily available without veterinary control.</td>
<td>Prior need for anaesthetic (cost and availability implications).</td>
<td></td>
</tr>
<tr>
<td>Mechanical</td>
<td>Free bullet</td>
<td>Can be inhumane if shot is inaccurate and dog is only wounded; dog may also escape.</td>
<td>Skilled operator essential.</td>
<td>Risk of injury to operators and spectators.</td>
<td>Not necessary to handle or capture dog.</td>
<td>Brain tissue may be unavailable for rabies diagnosis. Risk of injury to bystanders. Legal constraints on use of firearms.</td>
</tr>
<tr>
<td>Penetrating captive bolt followed by pithing where necessary to ensure death</td>
<td>Can be inhumane if shot is inaccurate and dog is only wounded.</td>
<td>Skilled operator essential.</td>
<td>Animal should be restrained. Skilled operator essential.</td>
<td>No risk to operator (see free bullet) unless risk of dog infected with rabies, due to potential contact with brain tissue.</td>
<td>Brain tissue may be unavailable for rabies diagnosis. Legal constraints on use of firearms. May raise aesthetic objections.</td>
<td></td>
</tr>
<tr>
<td>Exsanguination</td>
<td>Onset of hypovolaemia may cause dog to become anxious.</td>
<td>Only use on unconscious animal.</td>
<td>Danger to operator through use of sharp instrument.</td>
<td>Material requirements minimal.</td>
<td>Need to render animal unconscious. Aesthetically objectionable.</td>
<td></td>
</tr>
<tr>
<td>Euthanasia method</td>
<td>Specific method</td>
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<tr>
<td>Gaseous</td>
<td>Carbon monoxide (CO)</td>
<td>Inadequate concentration of CO is not lethal and can cause suffering. Signs of distress (convulsions, vocalization and agitation) may occur.</td>
<td>Compressed CO in cylinders should be used to achieve and maintain adequate concentration, which should be monitored. Note: fumes from gasoline engines are an irritant and this source of CO is not recommended.</td>
<td>Very hazardous for operator - gas is odourless and causes toxicity at both acute high levels and chronic low levels.</td>
<td>Dog dies quite rapidly if concentration of 4 to 6% used. No odour (therefore no aversive effect). Gas is not flammable or explosive except at concentration greater than 10%.</td>
<td></td>
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<tr>
<td></td>
<td>Carbon dioxide (CO₂)</td>
<td>Gas is aversive. Inadequate concentration of CO₂ is not lethal and can cause suffering. CO₂ is heavier than air, so when incomplete filling of the chamber occurs, dogs may raise their head and avoid exposure. Few studies on adequate concentration and animal welfare.</td>
<td>Compressed CO₂ gas chamber is the only acceptable method because the concentration can be monitored and regulated.</td>
<td>Minimal hazard to operator when properly designed equipment used.</td>
<td>Gas is not flammable or explosive and causes quite rapid anaesthesia when correct concentrations used. Low cost. Readily available as compressed gas.</td>
<td>Unconsciousness can occur in minutes, but death may take some time. Likelihood of suffering before unconsciousness.</td>
</tr>
<tr>
<td></td>
<td>Inert gas (nitrogen, N₂, argon, Ar)</td>
<td>Loss of consciousness is preceded by hypoxemia and ventilatory stimulation, which may be distressing to the dog. Re-establishing a low concentration of O₂ (i.e. greater than or equal to 6%) in the chamber before death will allow immediate recovery.</td>
<td>Concentration above 98% should be achieved rapidly and maintained. Properly designed equipment should be used.</td>
<td>Minimal hazard to operator when properly designed equipment used.</td>
<td>Gas is not flammable or explosive and is odourless. Readily available as compressed gas.</td>
<td>High cost. Little data on animal welfare implications in dogs.</td>
</tr>
<tr>
<td></td>
<td>Anaesthetic gas overdose (halothane or enflurane)</td>
<td>Animal may struggle and become anxious during induction. Vapours may be irritating and can induce excitement.</td>
<td>Supplementation with air or O₂ required to avoid hypoxemia during induction phase.</td>
<td>Some gases may be hazardous, especially for pregnant women. General recommendation: avoid human exposure to greater than or equal to 2 ppm to avoid narcosis.</td>
<td>Gas is not flammable or explosive. Valuable for use with small animals (&lt;7 kgs) and animals that are already anaesthetised with gas.</td>
<td>High cost. Anaesthetic and euthanasia properties of the gas used should be known. Isoflurane has a pungent odour. Methoxyflurane’s action is slow and dog may become agitated.</td>
</tr>
</tbody>
</table>
Chapter 7.7.- Stray dog population control

Article 7.7.7.

Monitoring and evaluation of dog population control programmes

1) Monitoring and evaluation allows for comparison of important indicators against the baselines measured during initial assessment (see Article 7.7.5.). The three main reasons for carrying out monitoring and evaluation are:
   a) to help improve performance, by highlighting both problems and successful elements of interventions;
   b) for accountability, to demonstrate that the programme is achieving its aims;
   c) assuming methods are standardised, to compare the success of strategies used in different locations and situations.

2) Monitoring is a continuous process that aims to check the programme progress against targets and allows for regular adjustments. Evaluation is a periodic assessment, usually carried out at particular milestones to check the programme is having the desired and stated impact. These procedures involve the measurement of ‘indicators’ that are chosen because they reflect important components of the programme at different stages. Selection of suitable indicators requires clear planning of what the programme is aiming to achieve, the best selection of indicators will be one that reflects the interest of all relevant stakeholders. Standardised methodology will facilitate comparison of data from subsequent evaluations and performance between different projects. Indicators can be direct measurements of an area targeted to change (e.g. population of free roaming dogs on public property) or indirect measures that reflect change in a targeted area.

3) Elements that should generally be monitored and evaluated include:
   a) dog population size, separated into sub-populations according to ownership and restriction of movement (i.e. roaming unrestricted or restricted by an owner);

<table>
<thead>
<tr>
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<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrical</td>
<td>Electrocution</td>
<td>Cardiac fibrillation occurs before onset of unconsciousness, causing severe pain if dog is conscious. Pain can also be caused by violent extension of the limbs, head and neck. Method may not be effective if insufficient current applied.</td>
<td>Only use on unconscious dogs. This can be accomplished by electrical stunning (current passed through the brain to produce an instantaneous stun) or anaesthesia. Electrodes should span the brain in order that the current passed through the brain in order to achieve an effective stun. Death would result from current passed through the heart of an unconscious animal. Proper equipment and trained operator is essential.</td>
<td>May be hazardous for operator, who should use protective equipment (boots and gloves).</td>
<td>Low cost.</td>
<td>Need to render animal unconscious. May raise aesthetic objections.</td>
</tr>
</tbody>
</table>

KEY to abbreviations used in Table 1:

IV: intravenous
IP: intraperitoneal
IC: intracardiac
b) dog welfare, in the target population (e.g. body condition score, skin conditions and injuries or lameness) and as a result of the programme (if interventions involve direct handling of dogs, the welfare of the dogs as result of this handling should be monitored);

c) prevalence of zoonotic diseases, such as rabies, in both the animal and human population;

d) responsible animal ownership, including measures of attitudes and understanding of responsible ownership and evidence that this is translating into responsible behaviour.

4) There are many sources of information for monitoring and evaluation purposes, including:

a) feedback from the local community (e.g. through the use of structured questionnaires, focus groups or ‘open format’ consultation processes);

b) records and opinions obtained from relevant professionals (e.g. veterinarians, medical doctors, law enforcement agencies, educators);

c) animal based measurements (e.g. direct observation surveys of population size and welfare status).

5) The output of activities against budget should be carefully recorded in order to evaluate the effort (or cost) against the outcomes and impact (or benefit) that are reflected in the results of monitoring and evaluation.

Article 7.7.8.

An overview of appropriate methods for estimating the size of dog populations

Population estimates are necessary for making realistic plans for dog population management and zoonosis control, and for monitoring the success of such interventions. However, for designing effective management plans, data on population sizes alone are insufficient. Additional information is required, such as degrees of supervision of owned dogs, the origin of ownerless dogs, accessibility, etc.

The term ‘owned’ may be restricted to a dog that is registered with licensing authorities, or it may be expanded to unregistered animals that are somewhat supervised and receive shelter and some form of care in individual households. Owned dogs may be well supervised and restrained at all times, or they may be left without control for various time periods and activities. Dogs without owners that claim responsibility may still be accepted or tolerated in the neighbourhood, and individuals may provide food and protection. Such animals are sometimes called ‘community owned dogs’ or ‘neighbourhood dogs’. For an observer it is frequently impossible to decide if a free roaming dog belongs to someone or not.

The choice of methods for assessing the size of a dog population depends on the ratio of owned versus ownerless dogs, which may not always easy to judge. For populations with a large proportion of owned dogs it may be sufficient to consult dog registration records or to conduct household surveys. These surveys should establish the number of owned dogs and the dog to human ratio in the area. In addition, questions on dog reproduction and demographics, care provided, zoonosis prevention, dog bite incidence, etc. may be asked. Standard polling principles should be applied.

If the proportion of ownerless dogs is high or difficult to assess, then one should resort to more experimental approaches. Methods borrowed from wildlife biology can be applied. Being generally diurnal and tolerant to human proximity, dogs lend themselves to direct observation and the application of mark-recapture techniques. Nevertheless, a number of caveats and limitations have to be taken into account. Firstly, the risk of zoonotic disease transmission is increased through close physical contact. Also, the methods are relatively labour intensive, they require some understanding of statistics and population biology, and most importantly, they are difficult to apply to very large areas. One should take into account that dog distribution is non-random, that their populations are not static, and that individual dogs are fairly mobile.

Counting of dogs visible in a defined area is the simplest approach to getting information on population size. One has to take into account that the visibility of dogs depends on the physical environment, but also on dog and human activity patterns. The visibility of animals changes with the time of the day and with seasons as a function of food availability, shelter (shade), disturbance, etc. Repeated standardized counting of dogs visible within defined geographical localities (e.g. wards) and specific times will provide indications of population trends. Direct counting is most reliable if it is applied to small and relatively confined dog populations, e.g. in villages, where it might be possible to recognize individual dogs based on their physical appearance.

Methods using mark-recapture procedures are often considered more reliable. However, they also produce trustworthy results only when a number of preconditions are met. Mortality, emigration and recruitment into the population should be minimal during the census period. One may be able to incorporate corrective factors into the calculations.

It is therefore important that the recommended census procedures are applied at times of low dispersal and that one selects study plots of shape and size that minimize the effect of dog movements in and out of the observation area.
Census surveys should be completed within a few days to a maximum of two weeks in order to reduce demographic changes. In addition, all individuals in the population should have an equal chance of being counted. This is a highly improbable condition for dogs, whose visibility depends on ownership status and degrees of supervision. It is therefore recommended that the investigator determines what fraction of the total population he/she might cover with an observational method and how much this part overlaps with the owned dog segment that he/she assesses with household surveys.

There are essentially two ways to obtain a population estimate if it is possible, in a defined area and within a few days, to tag a large number of dogs with a visible mark, e.g. a distinctive collar or a paint smudge. The first method requires that the capture (marking) effort remains reasonably constant for the whole length of the study. By plotting the daily number of dogs marked against the accumulated total of marked dogs for each day one can extrapolate the value representing the total number of dogs in the area. More commonly used in wildlife studies are mark recapture methods. Dogs are marked (tagged) and released back into the population. The population is subsequently sampled by direct observation. The number of marked and unmarked dogs is recorded. One multiplies the number of dogs that were initially marked and released by the number of subsequently observed dogs divided by the number of dogs seen as marked during the re-observation to obtain a total population estimate.

Since the dog populations of entire countries, states, provinces or even cities are much too large for complete assessment, it is necessary to apply the methods summarized above to sample areas. These should be selected (using common sense) so that results can be extrapolated to larger areas.
CHAPTER 7.8.

USE OF ANIMALS
IN RESEARCH AND EDUCATION

Preamble: The purpose of this chapter is to provide advice and assistance for Member Countries to follow when formulating regulatory requirements, or other form of oversight, for the use of live animals in research and education. Wherever the term "research" is used, it includes basic and applied research, testing and the production of biological materials; "education" includes teaching and training. A system of animal use oversight should be implemented in each country. The system will, in practice, vary from country to country and according to cultural, economic, religious and social factors. However, the OIE recommends that Member Countries address all the essential elements identified in this chapter in formulating a regulatory framework that is appropriate to their local conditions. This framework may be delivered through a combination of national, regional and institutional jurisdictions and both public sector and private sector responsibilities should be clearly defined.

The OIE recognises the vital role played by the use of live animals in research and education. The OIE Guiding Principles for Animal Welfare state that such a use makes a major contribution to the wellbeing of people and animals and emphasise the importance of the Three Rs (see Article 7.8.3.). Most scientists and members of the public agree that the animals should only be used when necessary; ethically justified (thereby avoiding unnecessary duplication of animal-based research); and when no other alternative methods, not using live animals, are available; that the minimum number of animals should be used to achieve the scientific or educational goals; and that such use of animals should cause as little pain and/or distress as possible. In addition, animal suffering is often recognised separately from pain and distress and should be considered alongside any lasting harm which is expected to be caused to animals.

The OIE emphasises the need for humane treatment of animals and that good quality science depends upon good animal welfare. It is the responsibility of all involved in the use of animals to ensure that they give due regard to these recommendations. In keeping with the overall approach to animal welfare detailed in the Guiding Principles, the OIE stresses the importance of standards based on outcomes for the animal.

The OIE recognises the significant role of veterinarians in animal-based research. Given their unique training and skills, they are essential members of a team including scientists and animal care technicians. This team approach is based on the concept that everyone involved in the use of animals has an ethical responsibility for the animals' welfare. The approach also ensures that animal use leads to high quality scientific and educational outcomes and optimum welfare for the animals used.

The OIE recognises that the use of live animals in research and education is a legitimate activity and, as a consequence, domestic and international transport of animals is essential to maintaining progress in advancing human and animal health. Such a transport should be conducted in a legal manner, ensuring the safety of the animal and applying humane principles.

The OIE recommends that records on animal use should be maintained at an institutional level, as appropriate to the institution and project proposals and species used. Key events and interventions should be recorded to aid decision making and promote good science and welfare. A summary of these records may be gathered on a national basis and be published to provide a degree of public transparency, without compromising personnel or animal safety, or releasing proprietary information.

Article 7.8.1.

Definitions

Biocontainment: means the system and procedures designed to prevent the accidental release of biological material including allergens.

Bioexclusion: means the prevention of the unintentional transfer of adventitious organisms with subsequent infection of animals, resulting in adverse effects on their health or suitability for research.

Biosecurity: means a continuous process of risk assessment and risk management designed to minimise or eliminate microbiological infection with adventitious organisms that can cause clinical disease in the infected animals or humans, or make animals unsuitable for biomedical research.
Cloned animal: means a genetic copy of another living or dead animal produced by somatic cell nuclear transfer or other reproductive technology.

Distress: means the state of an animal, that has been unable to adapt to stressors, and that manifests as abnormal physiological or behavioural responses. It can be acute or chronic and may result in pathological conditions.

Endangered species: means a population of organisms which is at risk of becoming extinct because it is either few in numbers, or threatened by changing environmental or predation parameters.

Environmental enrichment: means increasing the complexity (e.g. with toys, cage furniture, foraging opportunities, social housing, etc.) in a captive animal's environment to foster the expression of non-injurious species-typical behaviours and reduce the expression of maladaptive behaviours, as

as provide cognitive stimulation.

Ethical review: means consideration of the validity and justification for using animals including: an assessment and weighing of the potential harms for animals and likely benefits of the use and how these balance (see harm-benefit analysis below); and consideration of experimental design; implementation of the Three Rs; animal husbandry and care and other related issues such as personnel training. Ethical judgements are influenced by prevailing societal attitudes.

Harm-benefit analysis: means the process of weighing the likely adverse effects (harms) to the animals against the benefits likely to accrue as a result of the proposed project.

Humane endpoint: means the point in time at which an experimental animal's pain and/or distress is avoided, terminated, minimised or reduced, by taking actions such as giving treatment to relieve pain and/or distress, terminating a painful procedure, removing the animal from the study, or humanely killing the animal.

Laboratory animal: means an animal that is intended for use in research. In most cases, such animals are purpose-bred to have a defined physiological, metabolic, genetic or pathogen free status.

Operant conditioning: means the association that an animal makes between a particular response (such as pressing a bar) and a particular reinforcement that may be positive (for example, a food reward) or negative (e.g. a mild electric shock). As a result of this association, the occurrence of a specific behaviour of the animal can be modified (e.g. increased or decreased in frequency or intensity).

Pain: means an unpleasant sensory and emotional experience associated with actual or potential tissue damage. It may elicit protective actions, result in learned avoidance and distress and may modify species-specific traits of behaviour, including social behaviour.

Project proposal (sometimes called protocol): means a written description of a study or experiment, programme of work, or other activities that includes the goals of the work, characterises the use of the animals, and includes ethical considerations.

Suffering: means an unpleasant, undesired state of being that is the outcome of the impact on an animal of a variety of noxious stimuli and/or the absence of important positive stimuli. It is the opposite of good welfare.

Article 7.8.2.

Scope

This chapter applies to animals as defined in the Terrestrial Code (excluding bees) bred, supplied and/or used in research (including testing) and higher education. Animals to be used for production of biologicals and/or humanely killed for harvesting their cells, tissues and organs for scientific purposes are also covered. Member Countries should consider both the species and the developmental stage of the animal in implementing these standards.

Article 7.8.3.

The Three Rs

The internationally accepted tenet, the ‘Three Rs’, comprises the following alternatives:

1) replacement refers to the use of methods utilizing cells, tissues or organs of animals (relative replacement), as well as those that do not require the use of animals to achieve the scientific aims (absolute replacement);
2) reduction refers to the use of methods that enable researchers to obtain comparable levels of information from fewer animals or to obtain more information from the same number of animals;

3) refinement refers to the use of methods that prevent, alleviate or minimise pain, suffering, distress or lasting harm and/or enhance welfare for the animals used. Refinement includes the appropriate selection of relevant species with a lesser degree of structural and functional complexity in their nervous systems and a lesser apparent capacity for experiences that derive from this complexity. Opportunities for refinement should be considered and implemented throughout the lifetime of the animal and include, for example, housing and transportation as well as procedures and euthanasia.

Article 7.8.4.

The oversight framework

The role of a Competent Authority is to implement a system (governmental or other) for verification of compliance by institutions. This usually involves a system of authorisation (such as licensing or registering of institutions, scientists, and/or projects) and compliance which may be assessed at the institutional, regional and/or national level.

The oversight framework encompasses both ethical review of animal use and considerations related to animal care and welfare. This may be accomplished by a single body or distributed across different groups. Different systems of oversight may involve animal welfare officers, regional, national or local committees or bodies. An institution may utilise a local committee (often referred to as Animal Care and Use Committee, Animal Ethics Committee, Animal Welfare Body or Animal Care Committee) to deliver some or all of this oversight framework. It is important that the local committee reports to senior management within the institution to ensure it has appropriate authority, resources and support. Such a committee should undertake periodic review of its own policies, procedures and performance.

Ethical review of animal use may be undertaken by regional, national or local ethical review bodies or committees. Consideration should be given to ensuring the impartiality and independence of those serving on the committees.

In providing this oversight and ensuring the implementation of the Three Rs, the following expertise should be included as a minimum:

1) one scientist with experience in animal research, whose role is to ensure that protocols are designed and implemented in accordance with sound science;

2) one veterinarian, with the necessary expertise to work with research animals, whose specific role is to provide advice on the care, use and welfare of such animals;

3) one public member, where appropriate, to represent general community interests who is independent of the science and care of the animals and is not involved in the use of animals in research.

Additional expertise may be sought from the animal care staff, as these professional and technical staff are centrally involved in ensuring the welfare of animals used. Other participants, especially in relation to ethical review, may include statisticians, information scientists and ethicists and biosafety specialists, as appropriate to the studies conducted. It may be appropriate, in teaching institutions, to involve student representation.

Oversight responsibilities include three key elements:

1. Project proposal review

The purpose of the project proposal is to enable assessment of the quality of, and justification for, the study, work or activity.

Project proposals, or significant amendments to these, should be reviewed and approved prior to commencement of the work. The proposal should identify the person with primarily responsibility for the project and should include a description of the following elements, where relevant:

a) the scientific or educational aims, including consideration of the relevance of the experiment to human or animal health or welfare, the environment, or the advancement of biological knowledge;

b) an informative, non-technical (lay) summary may enhance understanding of the project and facilitate the ethical review of the proposal by allowing full and equitable participation of members of the oversight body or committees who may be dealing with matters outside their specific field. Subject to safeguarding confidential information, such summaries may be made publicly available;

c) the experimental design, including justification for choice of species, source and number of animals, including any proposed reuse;

d) the experimental procedures;
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e) methods of handling and restraint and consideration of refinements such as animal training and operant conditioning;
f) the methods to avoid or minimise pain, discomfort, distress, suffering or lasting impairment of physical or physiological function, including the use of anaesthesia and/or analgesia and other means to limit discomfort such as warmth, soft bedding and assisted feeding;
g) application of humane endpoints and the final disposition of animals, including methods of euthanasia;
h) consideration of the general health, husbandry and care of the species proposed to be used, including environmental enrichment and any special housing requirements;
i) ethical considerations such as the application of the Three Rs and a harm/benefit analysis; the benefits should be maximised and the harms, in terms of pain and distress, should be minimised;
j) an indication of any special health and safety risks;
k) resources/infrastructure necessary to support the proposed work, e.g. facilities, equipment, staff trained and found competent to perform the procedures described in the proposed project; and
l) the duration of approval of a project should normally be defined and progress achieved should be reviewed in considering renewal of a project approval.

The oversight body has a critical responsibility in determining the acceptability of project proposals, taking account of the animal welfare implications, the advancement of knowledge and scientific merit, as well as the societal benefits, in a risk-based assessment of each project using live animals.

Following approval of a project proposal, consideration should be given to implementing an independent (of those managing the projects) oversight method to ensure that animal activities conform with those described in the approved project proposal. This process is often referred to as post approval monitoring. Such monitoring may be achieved through animal observations made during the conduct of routine husbandry and experimental procedures; observations made by the veterinary staff during their rounds; or by inspections by the oversight body, which may be the local committee, animal welfare officer, compliance/quality assurance officer or government inspector.

2. Facility inspection
There should be regular inspections of the facilities, at least annually. These inspections should include the following elements:
a) the animals and their records, including cage labels and other methods of animal identification;
b) husbandry practices;
c) maintenance, cleanliness and security of the facility;
d) type and condition of caging and other equipment;
e) environmental conditions of the animals at the cage and room level;
f) procedure areas such as surgery, necropsy and animal research laboratories;
g) support areas such as washing equipment, animal feed, bedding and drug storage locations;
h) occupational health and safety concerns.
Principles of risk management should be followed when determining the frequency and nature of inspections.

3. Ethical evaluation
The ethical evaluation reflects the policies and practices of the institution in complying with regulations and relevant guidance. It should include consideration of the functioning of the local committee; training and competency of staff; veterinary care; husbandry and operational conditions, including emergency plans; sourcing and final disposition of animals; and occupational health and safety. The programme should be reviewed regularly. A requirement for the components of such a programme should be included in relevant regulations to empower the Competent Authority to take appropriate actions to ensure compliance.

Article 7.8.5.

Assurance of training and competency
An essential component of the animal care and use programme is the assurance that the personnel working with the animals are appropriately trained and competent to work with the species used and the procedures to be performed, including ethical considerations. A system (institutional, regional or national) to assure competency should be in place, which includes supervision during the training period until competence has been demonstrated. Continuing professional and paraprofessional educational opportunities should be made available to relevant staff. Senior management, given
their overarching responsibility for the animal care and use programme, should be knowledgeable about issues related to the competence of staff.

1. **Scientific staff**
   Researchers using animals have a direct ethical and legal responsibility for all matters relating to the welfare of the animals in their care. Due to the specialised nature of animal research, focused training should be undertaken to supplement educational and experiential backgrounds of scientists (including visiting scientists) before initiating a study. Focused training may include such topics as the national and/or local regulatory framework and institutional policies. The laboratory animal veterinarian is often a resource for this and other training. Scientific staff should have demonstrated competency in procedures related to their research, e.g. surgery, anaesthesia, sampling and administration, etc.

2. **Veterinarians**
   It is important that veterinarians working in an animal research environment have veterinary medical knowledge and experience in the species used. Furthermore, they should be educated and experienced in the normal behaviour, behavioural needs, stress responses and adaptability of the species, as well as research methodologies. Relevant approvals issued by the veterinary statutory body and appropriate national or regional schemes (where these exist) should be adopted as the reference for veterinary training.

3. **Animal care staff**
   Animal care staff should receive training that is consistent with the scope of their work responsibilities and have demonstrated competency in the performance of these tasks.

4. **Students**
   Students should learn scientific and ethical principles using non-animal methods (videos, computer models, etc.) when such methods can effectively reduce or replace the use of live animals and still meet learning objectives. Wherever it is necessary for students to participate in classroom or research activities involving live animals, they should receive appropriate supervision in the use of animals until such time that they have demonstrated competency in the related procedure(s).

5. **Members of the local oversight committee or others involved with oversight**
   Continuing education about the use of animals in research and education, including associated ethics, regulatory requirements and their institutional responsibility, should be provided.

Occupational health and safety training for research animal related risks should be provided as part of the assurance of training and competency for personnel. This might include consideration of human infectious diseases which may infect research animals and thus compromise research results, as well as possible zoonoses. Personnel should understand that there are two categories of hazards, those that are intrinsic to working in an animal facility and those associated with the research. Specific training may be required for particular species, for specific procedures, and for the use of appropriate protective measures for personnel who may be exposed to animal allergens. Research materials, such as chemicals of unknown toxicity, biological agents and radiation sources, may present special hazards

**Article 7.8.6.**

**Provision of veterinary care**

Adequate veterinary care includes responsibility for promoting an animal's health and welfare before, during and after research procedures and providing advice and guidance based on best practice. Veterinary care includes attention to the physical and behavioural status of the animal. The veterinarian should have authority and responsibility for making judgements concerning animal welfare. Veterinary advice and care should be available at all times. In exceptional circumstances, where species unfamiliar to the veterinarian are involved, a suitably qualified non-veterinary expert may provide advice.

1. **Clinical responsibilities**
   Preventive medicine programmes that include vaccinations, ectoparasite and endoparasite treatments and other disease control measures should be initiated according to currently acceptable veterinary medical practices appropriate to the particular animal species and source. Disease surveillance is a major responsibility of the veterinarian and should include routine monitoring of colony animals for the presence of parasitic, bacterial and viral agents that may cause overt or sub clinical diseases. The veterinarian should have the authority to use appropriate treatment or control measures, including euthanasia if indicated, and access to appropriate resources,
following diagnosis of an animal disease or injury. Where possible, the veterinarian should discuss the situation with the scientist to determine a course of action consistent with experimental goals. Controlled drugs prescribed by the veterinary staff should be managed in accordance with applicable regulations.

2. Post-mortem examinations
In the case of unexpected diseases or deaths, the veterinarian should provide advice based on post-mortem examination results. As part of health monitoring, a planned programme of post-mortem examinations may be considered.

3. Veterinary medical records
Veterinary medical records, including post-mortem records, are considered to be a key element of a programme of adequate veterinary care for animals used in research and education. Application of performance standards within the veterinary medical record programme allows the veterinarian to effectively employ professional judgment, ensuring that the animal receives the highest level of care available.

4. Advice on zoonotic risks and notifiable diseases
The use of some species of animals poses a significant risk of the transmission of zoonotic disease, e.g. some nonhuman primates. The veterinarian should be consulted to identify sources of animals that minimise these risks and to advise on measures that may be taken in the animal facility to minimize the risk of transmission, e.g. personal protective equipment, appropriate disinfection procedures, air pressure differentials in animal holding rooms, etc. Animals brought into the institution may carry diseases that require notification to government officials. It is important that the veterinarian be aware of, and comply with, these requirements.

5. Advice on surgery and postoperative care
A programme of adequate veterinary care includes input into the review and approval process of preoperative, surgical and postoperative procedures by an appropriately qualified veterinarian. A veterinarian's inherent responsibility includes providing advice concerning preoperative procedures, aseptic surgical techniques, the competence of staff to perform surgery and the provision of postoperative care. Veterinary oversight should include the detection and resolution of emerging patterns of surgical and post procedural complications.

6. Advice on analgesia, anaesthesia and euthanasia
Adequate veterinary care includes providing advice on the proper use of anaesthetics, analgesics, and methods of euthanasia.

7. Advice on humane endpoints
Humane endpoints should be established prior to commencement of a study in consultation with the veterinarian who also plays an important role in ensuring that approved humane endpoints are followed during the course of the study. It is essential that the veterinarian has the authority to ensure euthanasia or other measures are carried out as required to relieve pain and distress unless the project proposal approval specifically does not permit such an intervention on the basis of the scientific purpose and the ethical evaluation.

Ideal humane endpoints are those that can be used to end a study before the onset of pain and/or distress, without jeopardising the study’s objectives. In consultation with the veterinarian, humane endpoints should be described in the project proposal and, thus, established prior to commencement of the study. They should form part of the ethical review. Endpoint criteria should be easy to assess over the course of the study. Except in rare cases, death (other than euthanasia) as a planned endpoint is considered ethically unacceptable.

Article 7.8.7.

Source of animals
Animals to be used for research should be of high quality to ensure the validity of the data.

1. Animal procurement
Animals should be acquired legally. It is preferable that animals are purchased from recognised sources producing or securing high quality animals. The use of wild caught nonhuman primates is strongly discouraged.

Purpose bred animals should be used whenever these are available and animals that are not bred for the intended use should be avoided unless there is compelling scientific justification or are the only available and suitable source. In the case of farm animals, non-traditional breeds and species, and animals captured in the wild, non purpose bred animals are often used to achieve specific study goals.
2. **Documentation**

   Relevant documentation related to the source of the animals, such as health and other veterinary certification, breeding records, genetic status and animal identification, should accompany the animals.

3. **Animal health status**

   The health status of animals can have a significant impact on scientific outcomes. There also may be occupational health and safety concerns related to animal health status. Animals should have appropriate health profiles for their intended use. The health status of animals should be known before initiating research.

4. **Genetically defined animals**

   A known genetic profile of the animals used in a study can reduce variability in the experimental data resulting from genetic drift and increase the reproducibility of the results. Genetically defined animals are used to answer specific research questions and are the product of sophisticated and controlled breeding schemes which should be validated by periodic genetic monitoring. Detailed and accurate documentation of the colony breeding records should be maintained.

5. **Genetically altered (also genetically modified or genetically engineered) or cloned animals**

   A genetically altered animal is one that has had undergone genetic modification of its nuclear or mitochondrial genomes through a deliberate human intervention, or the progeny of such an animal(s), where they have inherited the modification. If genetically altered or cloned animals are used, such use should be conducted in accordance with relevant regulatory guidance. With such animals, as well as harmful mutant lines arising from spontaneous mutations and induced mutagenesis, consideration should be given to addressing and monitoring special husbandry and welfare needs associated with abnormal phenotypes. Records should be kept of biocontainment requirements, genetic and phenotypic information, and individual identification, and be communicated by the animal provider to the recipient. Archiving and sharing of genetically altered lines is recommended to facilitate the sourcing of these customised animals.

6. **Animals captured in the wild**

   If wild animals are to be used, the capture technique should be humane and give due regard to human and animal health, welfare and safety. Field studies have the potential to cause disturbance to the habitat thus adversely affecting both target and non-target species. The potential for such disturbance should be assessed and minimised. The effects of a series of stressors, such as trapping, handling, transportation, sedation, anaesthesia, marking and sampling, can be cumulative, and may produce severe, possibly fatal, consequences. An assessment of the potential sources of stress and management plans to eliminate or minimise distress should form part of the project proposal.

7. **Endangered species**

   Endangered species should only be used in exceptional circumstances where there is strong scientific justification that the desired outcomes cannot be achieved using any other species.

8. **Transport, importation and exportation**

   Animals should be transported under conditions that are appropriate to their physiological and behavioural needs and pathogen free status, with care to ensure appropriate physical containment of the animals as well as exclusion of contaminants. The amount of time animals spend on a journey should be kept to a minimum. It is important to ensure that there is a well-constructed journey plan, with key staff identified who have responsibility for the animals and that relevant documentation accompanies animals during transport to avoid unnecessary delays during the journey from the sender to the receiving institution.

9. **Risks to biosecurity**

   In order to minimise the risk of contamination of animals with unwanted infectious microorganisms or parasites that may compromise the health of animals or make them unsuitable for use in research, the microbiological status of the animals should be determined and regularly assessed. Appropriate biocontainment and bioexclusion measures should be practised to maintain their health status and, if appropriate, measures taken to prevent their exposure to certain human or environmental commensals.
Physical facility and environmental conditions

A well-planned, well-designed, well-constructed, and properly maintained facility should include animal holding rooms as well as areas for support services such as for procedures, surgery and necropsy, cage washing and appropriate storage. An animal facility should be designed and constructed in accordance with all applicable building standards. The design and size of an animal facility depend on the scope of institutional research activities, the animals to be housed, the physical relationship to the rest of the institution, and the geographic location. For indoor housing, non-porous, non-toxic and durable materials should be used which can be easily cleaned and sanitised. Animals should normally be housed in facilities designed for that purpose. Security measures, e.g. locks, fences, cameras, etc., should be in place to protect the animals and prevent their escape. For many species (e.g. rodents), environmental conditions should be controllable to minimise physiological changes which may be potentially confounding scientific variables and of welfare concern.

Important environmental parameters to consider include ventilation, temperature and humidity, lighting and noise:

1. Ventilation
The volume and physical characteristics of the air supplied to a room and its diffusion pattern influence the ventilation of an animal's primary enclosure and are thus important determinants of its microenvironment. Factors to consider when determining the air exchange rate include range of possible heat loads; the species, size, and number of animals involved; the type of bedding or frequency of cage changing; the room dimensions; and the efficiency of air distribution from the secondary to the primary enclosure. Control of air pressure differentials is an important tool for biocontainment and bioexclusion.

2. Temperature and humidity
Environmental temperature is a physical factor which has a profound effect on the welfare of animals. Typically, animal room temperature should be monitored and controlled. The range of daily fluctuations should be appropriately limited to avoid repeated demands on the animals' metabolic and behavioural processes to compensate for large changes in the thermal environment as well as to produce reproducible and valid scientific data. Relative humidity may also be controlled where appropriate for the species.

3. Lighting
Light can affect the physiology, morphology and behaviour of various animals. In general, lighting should be diffused throughout an animal holding area and provide appropriate illumination for the welfare of the animals while facilitating good husbandry practices, adequate inspection of animals and safe working conditions for personnel. It may also be necessary to control the light/dark cycle.

4. Noise
Separation of human and animal areas minimises disturbance to animal occupants of the facility. Noisy animals, such as dogs, pigs, goats and nonhuman primates, should be housed in a manner which ensures they do not adversely affect the welfare of quieter animals, such as rodents, rabbits and cats. Consideration should be given to insulating holding rooms and procedure rooms to mitigate the effects of noise sources. Many species are sensitive to high frequency sounds and thus the location of potential sources of ultrasound should be considered.

Husbandry

Good husbandry practices enhance the health and welfare of the animals used and contributes to the scientific validity of animal research. Animal care and accommodation should, as a minimum, demonstrably conform to relevant published animal care, accommodation and husbandry guidelines and regulations.

The housing environment and husbandry practices should take into consideration the normal behaviour of the species, including their social behaviour and age of the animal, and should minimise stress to the animal. During the conduct of husbandry procedures, personnel should be keenly aware of their potential impact on the animals' welfare.

1. Transportation
See Article 7.8.10.
2. Acclimatisation

Newly received animals should be given a period for physiological and behavioural stabilisation before their use. The length of time for stabilisation will depend on the type and duration of transportation, the age and species involved, place of origin, and the intended use of the animals. Facilities should be available to isolate animals showing signs of ill health.

3. Cages and pens

Cages and pens should be made out of material that can be readily cleaned and decontaminated. Their design should be such that the animals are unlikely to injure themselves. Space allocations should be reviewed and modified as necessary to address individual housing situations and animal needs (for example, for prenatal and postnatal care, obese animals, and group or individual housing). Both the quantity and quality of space provided is important. Whenever it is appropriate, social animals should be housed in pairs or groups, rather than individually, provided that such housing is not contraindicated by the protocol in question and does not pose an undue risk to the animals.

4. Enrichment

Animals should be housed with a goal of maximising species appropriate behaviours and avoiding or minimising stress induced behaviours. One way to achieve this is to enrich the structural and social environment of the animals and to provide opportunities for physical and cognitive activity. Such provision should not compromise the health and safety of the animals or people, nor interfere with the scientific goals.

5. Feeding

Provision should be made for each animal to have access to feed to satisfy its physiological needs. Precautions should be taken in packing, transporting, storing and preparing feed to avoid chemical, physical and microbiological contamination, deterioration or destruction. Utensils used for feeding should be regularly cleaned and, if necessary, sterilised.

6. Water

Uncontaminated potable drinking water should normally be available at all times. Watering devices, such as drinking tubes and automatic watering systems, should be checked daily to ensure their proper maintenance, cleanliness, and operation.

7. Bedding

Animals should have appropriate bedding provided, with additional nesting material if appropriate to the species. Animal bedding is a controllable environmental factor that can influence experimental data and animal welfare. Bedding should be dry, absorbent, non-dusty, non-toxic and free from infectious agents, vermin or chemical contamination. Soiled bedding should be removed and replaced with fresh material as often as is necessary to keep the animals clean and dry.

8. Hygiene

The successful operation of a facility depends very much on good hygiene. Special care should be taken to avoid spreading infection between animals through fomites, including through personnel traffic between animal rooms. Adequate routines and facilities for the cleaning, washing, decontamination and, when necessary, sterilisation of cages, cage accessories and other equipment should be established. A very high standard of cleanliness and organisation should also be maintained throughout the facility.

9. Identification

Animal identification is an important component of record keeping. Animals may be identified individually or by group. Where it is desirable to individually identify animals, this should be done by a reliable and the least painful method.

10. Handling

Staff dealing with animals should have a caring and respectful attitude towards the animals and be competent in handling and restraint. Familiarising animals to handling during routine husbandry and procedures reduces stress both to animals and personnel. For some species, for example dogs and non-human primates, a training programme to encourage cooperation during procedures can be beneficial to the animals, the animal care staff and the scientific programme. For certain species, social contact with humans should be a priority. However, in some cases handling should be avoided. This may be particularly the case with wild animals. Consideration should be given to setting up habituation and training programmes suitable for the animals, the procedures and length of projects.
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Article 7.8.10.

Transportation

Transportation is a typically stressful experience for animals. Therefore, every precaution should be taken to avoid unnecessary stress caused by inadequate ventilation, exposure to extreme temperatures, lack of feed and water, long delays, etc. General recommendations are made in Chapters 7.3. and 7.4. There may be a justifiable reason to transport animals whose welfare is compromised as a consequence of scientific procedures which the animals are undergoing or for which there are intended. In such cases, every precaution should be taken to avoid further stress. In addition, animals should be transported under conditions and in containers that are appropriate to their physiological and behavioural needs and pathogen free status, with care to ensure appropriate physical containment and safety of the animals. A contingency plan which addresses any possible delays should be in place and the name of an emergency contact person should be prominently displayed on the container.

1) The source of animals and therefore the mode and conditions of transport should be considered in the project proposal review described in point 1 c) of Article 7.8.4.
   a) The consigner and consignee should coordinate the means, route and duration of transport with emphasis on the potential impact on the health and welfare of the animal(s).
   b) The potential for delays in transportation should be anticipated and avoided

2) The documentation required for international transport should be based on the OIE Model Veterinary Certificate for International Trade in Laboratory Animals (Chapter 5.13.):
   a) There should be assurance that complete, relevant and legible documentation accompanies animals during transport to avoid unnecessary delays during the journey from the sender to the receiving institution.
   b) Electronic certificates should be implemented, wherever possible.

3) There should be a well-defined journey plan, commencing from the point when animals are placed in their containers until they are removed from the containers at their final destination:
   a) The journey plan should be designed so that the time in transit is the shortest possible and most comfortable for the animal. Where journeys of some distance are involved, this is often best achieved through air transport, preferably by direct routes.
   b) Key staff should be identified who have responsibility for the animals and have the authority for making decisions in unforeseen circumstances. Such staff should be contactable at all times.
   c) The journey plan should be under the general oversight of a veterinarian or other competent person, knowledgeable and experienced in the biology and needs of the particular species. The following should specifically be addressed:
      i) Some animals, such as genetically altered animals, may have special requirements.
      ii) Issues of biosecurity and bioexclusion, e.g. through container design and handling.

4) In accordance with Chapters 7.3. and 7.4. and IATA regulations, an appropriate environment, such as container design and construction, temperature, food and water, should be provided to the animal throughout the planned journey. Adequate supplies of food, water and bedding should be provided to accommodate a delay of at least 24 hours.

5) Personnel handling animals throughout the planned journey should be trained in the basic needs of animals and in good handling practices for the species to facilitate the loading and unloading of animals.

6) Delivery
   a) Consignments of animals should be accepted into the facility without avoidable delay and, after inspection, should be removed from their container under conditions compatible with their pathogen free status.
   b) They should then be transferred to clean cages or pens and be supplied with feed and water as appropriate.
   c) Social animals transported in established pairs or groups should be maintained in these on arrival.
CHAPTER 7.9.

ANIMAL WELFARE AND BEEF CATTLE PRODUCTIONS SYSTEMS

Article 7.9.1.

Definition

Beef cattle production systems are defined as all commercial cattle production systems where the purpose of the operation includes some or all of the breeding, rearing and finishing of cattle intended for beef consumption.

Article 7.9.2.

Scope

This chapter addresses the welfare aspects of beef cattle production systems, from birth through to finishing. This scope does not include veal production.

Article 7.9.3.

Commercial beef cattle production systems

Commercial beef cattle production systems include:

1. Intensive
   These are systems where cattle are in confinement and are fully dependent on humans to provide for basic animal needs such as food, shelter and water on a daily basis.

2. Extensive
   These are systems where cattle have the freedom to roam outdoors, and where the cattle have some autonomy over diet selection (through grazing), water consumption and access to shelter.

3. Semi Intensive
   These are systems where cattle are exposed to any combination of both intensive and extensive husbandry methods, either simultaneously, or varied according to changes in climatic conditions or physiological state of the cattle.

Article 7.9.4.

Criteria or measurables for the welfare of beef cattle

The following outcome-based measurables, specifically animal-based measurables, can be useful indicators of animal welfare. The use of these indicators and the appropriate thresholds should be adapted to the different situations where beef cattle are managed. Consideration should also be given to the design of the system.

1. Behaviour
   Certain behaviours could indicate an animal welfare problem. These include decreased feed intake, increased respiratory rate or panting (assessed by panting score), and the demonstration of stereotypic, aggressive, depressive or other abnormal behaviours.
2. **Morbidity rates**

Morbidity rates, including disease, lameness, post-procedural complication and injury rates, above recognised thresholds may be direct or indirect indicators of the *animal welfare* status of the whole herd. Understanding the aetiology of the disease or syndrome is important for detecting potential *animal welfare* problems. Scoring systems, such as lameness scoring, can provide additional information.

Post-mortem examination is useful to establish causes of death in cattle. Both clinical and post-mortem pathology could be utilised as an indicator of disease, injuries and other problems that may compromise *animal welfare*.

3. **Mortality rates**

Mortality rates, like morbidity rates, may be direct or indirect indicators of the *animal welfare* status. Depending on the production system, estimates of mortality rates can be obtained by analysing causes of death and the rate and temporo-spatial pattern of mortality. Mortality rates should be recorded regularly, i.e. daily, monthly, annually or with reference to key husbandry activities within the production cycle.

4. **Changes in weight and body condition**

In growing *Animal*, weight gain may be an indicator of animal health and *animal welfare*. Poor body condition and significant weight loss may be an indicator of compromised welfare.

5. **Reproductive efficiency**

Reproductive efficiency can be an indicator of animal health and *animal welfare* status. Poor reproductive performance can indicate *animal welfare* problems. Examples may include:
- anoestrus or extended post-partum interval,
- low conception rates,
- high abortion rates,
- high rates of dystocia.

6. **Physical appearance**

Physical appearance may be an indicator of animal health and *animal welfare*, as well as the conditions of management. Attributes of physical appearance that may indicate compromised welfare include:
- presence of ectoparasites,
- abnormal coat colour or texture or excessive soiling with faeces, mud or dirt,
- dehydration,
- emaciation.

7. **Handling responses**

Improper handling can result in fear and distress in cattle. Indicators could include:
- chute or race exit speed,
- chute or race behaviour score,
- percentage of *animals* slipping or falling,
- percentage of *animals* moved with an electric goad,
- percentage of *animals* striking fences or gates,
- percentage of *animals* injured during handling, such as broken horns, broken legs, and lacerations,
- percentage of *animals* vocalizing during restraint.

8. **Complications due to routine procedure management**

Surgical and non-surgical procedures are commonly performed in beef cattle for improving animal performance, facilitating management, and improving human safety and *animal welfare*. However, if these procedures are not performed properly, *animal welfare* can be compromised. Indicators of such problems could include:
- post procedure infection and swelling,
- myiasis,
- mortality.
Chapter 7.9.- Animal welfare and beef cattle productions systems

Recommendations

Each recommendation includes a list of relevant outcome-based measurables derived from Article 7.9.4. This does not exclude other measures being used where appropriate.

1. Biosecurity and animal health
   a) Biosecurity and disease prevention
      Biosecurity means a set of measures designed to maintain a herd at a particular health status and to prevent the entry or spread of infectious agents.
      Biosecurity plans should be designed and implemented, commensurate with the desired herd health status and current disease risk and, for OIE listed diseases in accordance with relevant recommendations found in the Terrestrial Code.
      These biosecurity plans should address the control of the major sources and pathways for spread of pathogens:
      i) cattle,
      ii) other animals,
      iii) people,
      iv) equipment,
      v) vehicles,
      vi) air,
      vii) water supply,
      viii) feed.
      Outcome-based measurables: morbidity rate, mortality rate, reproductive efficiency, changes in weight and body condition.
   b) Animal health management
      Animal health management means a system designed to optimise the physical and behavioural health and welfare of the cattle herd. It includes the prevention, treatment and control of diseases and conditions affecting the herd, including the recording of illnesses, injuries, mortalities and medical treatments where appropriate.
      There should be an effective programme for the prevention and treatment of diseases and conditions consistent with the programmes established by a qualified veterinarian as appropriate.
      Those responsible for the care of cattle should be aware of the signs of ill-health or distress, such as reduced feed and water intake, changes in weight and body condition, changes in behaviour or abnormal physical appearance.
      Cattle at higher risk of disease or distress will require more frequent inspection by animal handlers. If animal handlers are not able to correct the causes of ill-health or distress or if they suspect the presence of a listed reportable disease they should seek advice from those having training and experience, such as veterinarians or other qualified advisers.
      Vaccinations and other treatments administered to cattle should be undertaken by people skilled in the procedures and on the basis of veterinary or other expert advice.
      Animal handlers should have experience in recognising and dealing with non-ambulatory cattle. They should also have experience in managing chronically ill or injured cattle.
      Non-ambulatory cattle should have access to water at all times and be provided with feed at least once daily. They should not be transported or moved unless absolutely necessary for treatment or diagnosis. Such movements should be done carefully using methods avoiding dragging or excessive lifting.
      When treatment is attempted, cattle that are unable to stand up unaided and refuse to eat or drink should be killed humanely according to Chapter 7.5. as soon as recovery is deemed unlikely.
      Outcome-based measurables: morbidity rate, mortality rate, reproductive efficiency, behaviour, physical appearance, and changes in weight and body condition.
2. Environment
   a) Thermal environment
      Although cattle can adapt to a wide range of thermal environments particularly if appropriate breeds are used
      for the anticipated conditions, sudden fluctuations in weather can cause heat or cold stress.
      i) Heat stress
         The risk of heat stress for cattle is influenced by environmental factors including air temperature, relative
         humidity and wind speed, and animal factors including breed, age, body condition, metabolic rate and
         coat colour and density.
         Animal handlers should be aware of the risk that heat stress poses to cattle. If conditions are expected
         to induce heat stress, routine daily activities that require moving cattle should cease. If the risk of heat
         stress reaches very high levels the animal handlers should institute an emergency action plan that could
         include reduction of stocking density, provision of shade, free access to drinking water, and cooling by
         the use of sprinkled water that penetrates the hair coat.
         Outcome-based measurables: behaviour, including panting score and respiratory rate, morbidity rate,
         mortality rate.
      ii) Cold stress
         Protection from extreme weather conditions should be provided when these conditions are likely to
         create a serious risk to the welfare of cattle, particularly in neonates and young cattle and others that
         are physiologically compromised. This could be provided by natural or man-made shelter structures.
         Animal handlers should also ensure that cattle have access to adequate feed and water during cold
         stress. During extreme cold weather conditions, animal handlers should institute an emergency action
         plan to provide cattle with shelter, appropriate feed and water.
         Outcome-based measurables: mortality rates, physical appearance, behaviour including abnormal
         postures, shivering and huddling.
   b) Lighting
      Confined cattle that do not have access to natural light should be provided with supplementary lighting which
      follow natural periodicity sufficient for their health and welfare, to facilitate natural behaviour patterns and to
      allow adequate inspection of the cattle.
      Outcome-based measurables: behaviour, morbidity, physical appearance.
   c) Air quality
      Good air quality is an important factor for the health and welfare of cattle. It is affected by air constituents such
      as gases, dust and micro-organisms, and is strongly influenced by management, particularly in intensive
      systems. The air composition is influenced by the stocking density, the size of the cattle, flooring, bedding,
      waste management, building design and ventilation system.
      Proper ventilation is important for effective heat dissipation in cattle and preventing the buildup of NH₃ and
      effluent gases in the confinement unit. Poor air quality and ventilation are risk factors for respiratory discomfort
      and diseases. The ammonia level in enclosed housing should not exceed 25 ppm.
      Outcome-based measurables: morbidity rate, behaviour, mortality rate, changes in weight and body
      condition.
   d) Noise
      Cattle are adaptable to different levels and types of noise. However, exposure of cattle to sudden or loud
      noises should be minimised where possible to prevent stress and fear reactions (e.g. stampede). Ventilation
      fans, feeding machinery or other indoor or outdoor equipment should be constructed, placed, operated and
      maintained in such a way that they cause the least possible amount of noise.
      Outcome-based measurables: behaviour.
   e) Nutrition
      The nutrient requirements of beef cattle have been well defined. Energy, protein, mineral and vitamin contents
      of the diet are major factors determining the growth, feed efficiency, reproductive efficiency, and body
      composition.
      Cattle should be provided with access to an appropriate quantity and quality of balanced nutrition that meets
      their physiological needs. Where cattle are maintained in extensive conditions, short term exposure to climatic
      extremes may prevent access to nutrition that meets their daily physiological needs. In such circumstances
the animal handler should ensure that the period of reduced nutrition is not prolonged and that mitigation strategies are implemented if welfare is at risk of being compromised.

Animal handlers should have adequate knowledge of appropriate body condition for their cattle and should not allow body condition to fall outside an acceptable range. If supplementary feed is not available, steps should be taken to avoid starvation, including slaughter, sale or relocation of the cattle, or humane killing.

Feedstuffs and feed ingredients should be of satisfactory quality to meet nutritional needs. Where appropriate, feed and feed ingredients should be tested for the presence of substances that would adversely impact on animal health.

Cattle in intensive production systems typically consume diets that contain a high proportion of grain(s) (corn, milo, barley, grain by-products) and a smaller proportion of roughages (hay, straw, silage, hulls, etc.). Diets with insufficient roughage can contribute to abnormal oral behaviour in finishing cattle, such as tongue rolling. As the proportion of grain increases in the diet, the relative risk of digestive upset in cattle increases. Animal handlers should understand the impact of cattle size and age, weather patterns, diet composition and sudden dietary changes in respect to digestive upsets and their negative consequences (acidosis, bloat, liver abscess, laminitis). Where appropriate beef producers should consult a cattle nutritionist for advice on ration formulation and feeding programmes.

Beef producers should become familiar with potential micronutrient deficiencies or excesses for intensive and extensive production systems in their respective geographical areas and use appropriately formulated supplements where necessary.

All cattle need an adequate supply and access to palatable water that meets their physiological requirements and is free from contaminants hazardous to cattle health.

Outcome-based measurables: mortality rates, morbidity rates, behaviour, changes in weight and body condition, reproductive efficiency.

f) Flooring, bedding, resting surfaces and outdoor areas

In all production systems cattle need a well-drained and comfortable place to rest. All cattle in a group should have sufficient space to lie down and rest at the same time.

Pen floor management in intensive production systems can have a significant impact on cattle welfare. Where there are areas that are not suitable for resting such as excessive water and faecal accumulation, these areas should not be of a depth that would compromise welfare and should not comprise the whole of usable area available to the cattle.

Slopes of pens should be maintained to allow water to drain away from feed troughs and not pool excessively in the pens.

Pens should be cleaned as conditions warrant and, at a minimum, after each production cycle. If cattle are kept on a slatted floor, the slat and gap widths should be appropriate to the hoof size of the cattle to prevent injuries. Wherever possible, cattle on slatted floor should have access to a bedded area.

In straw or other bedding systems, the bedding should be maintained to provide cattle with a dry and comfortable place in which to lie.

Surfaces of concrete alleys should be grooved or appropriately textured to provide adequate footing for cattle.

Outcome-based measurables: morbidity rates (e.g. lameness, pressure sores), behaviour, changes in weight and body condition, and physical appearance.

g) Social environment

Management of cattle should take into account the social environment as it relates to animal welfare, particularly in intensive systems. Problem areas include: agonistic and mounting activity, mixing of heifers and steers, feeding cattle of different size and age in the same pens, high stocking density, insufficient space at the feeder, insufficient water access and mixing of bulls.

Management of cattle in all systems should take into account the social interactions of cattle within groups. The animal handler should understand the dominance hierarchies that develop within different groups and focus on high risk animals, such as very young, very old, small or large size for cohort group, for evidence of bullying and excessive mounting behaviour. The animal handler should understand the risks of increased agonistic interactions between animals, particularly after mixing groups. Cattle that are suffering from excessive agonistic activity or mounting behaviour should be removed from the group.

Horned and non-horned cattle should not be mixed because of the risk of injury.

Adequate fencing should be provided to minimise any animal welfare problems that may be caused by mixing of inappropriate groups of cattle.

Outcome-based measurables: behaviour, physical appearance, changes in weight and body condition, morbidity and mortality rate.
h) Stocking density
High stocking densities may increase the occurrence of injuries and have an adverse effect on growth rate, feed efficiency and behaviour, such as locomotion, resting, feeding and drinking. Stocking density should be managed such that crowding does not adversely affect normal behaviour of cattle. This includes the ability to lie down freely without the risk of injuries, move freely around the pen and access feed and water. Stocking density should also be managed such that weight gain and duration of time spent lying is not adversely affected by crowding. If abnormal behaviour is seen, measures should be taken such as reducing stocking density.

In extensive systems, stocking density should be matched to the available feed supply.
Outcome-based measurables: behaviour, morbidity rate, mortality rate, changes in weight and body condition, physical appearance.

i) Protection from predators
Cattle should be protected as much as possible from predators.
Outcome-based measurables: mortality rate, morbidity rate (injury rate), behaviour, physical appearance.

3. Management
a) Genetic selection
Welfare and health considerations, in addition to productivity, should be taken into account when choosing a breed or subspecies for a particular location or production system. Examples of these include nutritional maintenance requirement, ectoparasite resistance and heat tolerance.

Individual animals within a breed can be genetically selected to propagate offspring that exhibit traits beneficial to animal health and welfare. These include maternal instincts, ease of calving, birth weight, milking ability, body conformation and temperament.
Outcome-based measurables: morbidity rate, mortality rate, behaviour, physical appearance, reproductive efficiency.

b) Reproductive management
Dystocia can be a welfare risk to beef cattle. Heifers should not be bred before they are physically mature enough to ensure the health and welfare of both dam and calf at birth. The sire has a highly heritable effect on final calf size and as such can have a significant impact on ease of calving. Sire selection should therefore account for the maturity and size of the female. Heifers and cows should not be implanted, inseminated or mated in such a way that the progeny results in increased risk to dam and calf welfare.
Pregnant cows and heifers should be managed during pregnancy so as not to become too fat or too thin. Excessive fatness increases the risk of dystocia, and both excessive condition gain and loss increase the risk of metabolic disorders during late pregnancy or after parturition.
Where possible, cows and heifers should be monitored when they are close to calving. Animals observed to be having difficulty in calving should be assisted by a competent handler as soon as possible after they are detected.
Outcome-based measurables: morbidity rate (rate of dystocia), mortality rate (cow and calf), reproductive efficiency.

c) Colostrum
Receiving adequate immunity from colostrum generally depends on the volume and quality of colostrum ingested, and how soon after birth the calf receives it.
Where possible, animal handlers should ensure that calves receive sufficient colostrum within 24 hours of birth.
Outcome-based measurables: mortality rate, morbidity rate, changes in weight.

d) Weaning
For the purposes of this chapter, weaning means the transfer of the calf from a milk-based diet to a fibrous diet. In beef cattle production systems, weaning can be a stressful time in the calf's life.
Calves should be weaned only when their ruminant digestive system has developed sufficiently to enable them to maintain growth and welfare.
There are different weaning strategies utilised in the beef cattle production systems. These include abrupt separation, fence line separation and the use of devices placed in the nose of the calf to discourage suckling.
Special care should be taken if abrupt weaning is immediately followed by additional stressors such as transportation, as calves are at risk of increased morbidity under these circumstances.
If necessary, beef cattle producers should seek expert advice on the most appropriate time and method of weaning for their type of cattle and production system.
Outcome-based measurables: morbidity rate, mortality rate, behaviour, physical appearance, changes in weight and body condition.
e) Painful husbandry procedures

Husbandry practices that have the potential to cause pain are routinely practiced on cattle for reasons of production efficiency, animal health and welfare and human safety. These procedures should be performed in such a way as to minimise any pain and stress to the animal. These procedures should be performed at as early an age as possible or using anaesthesia or analgesia under the recommendation or supervision of a veterinarian.

Future options for enhancing animal welfare in relation to these procedures include: ceasing the procedure and addressing the current need for the operation through management strategies; breeding cattle that do not require the procedure; or replacing the current procedure with a non-surgical alternative that has been shown to enhance animal welfare.

Example of such interventions include: castration, dehorning, ovariectomy (spaying), tail docking, identification.

i) Castration

Castration of beef cattle is performed in many production systems to reduce inter-animal aggression, improve human safety, avoid the risk of unwanted pregnancies in the herd, and enhance production efficiency.

Where it is necessary to castrate beef cattle, producers should seek guidance from veterinarians as to the optimum method and timing for their type of cattle and production system.

Methods of castration used in beef cattle include surgical removal of the testes, ischaemic methods, and crushing and disruption of the spermatic cord.

Where practical, cattle should be castrated before the age of three months, or at the first available handling opportunity beyond this age using the method available that causes least pain or suffering to the animal.

Producers should seek guidance from veterinarians on the availability and advisability of analgesia or anaesthesia for castration of beef cattle, particularly in older animals.

Operators performing castration of beef cattle should be trained and competent in the procedure used, and be able to recognise the signs of complications.

ii) Dehorning (including disbudding)

Beef cattle are commonly dehorned in order to reduce animal injuries and hide damage, improve human safety, reduce damage to facilities and facilitate transport and handling. Where practical and appropriate for the production system, the selection of polled cattle is preferable to dehorning.

Where it is necessary to dehorn beef cattle, producers should seek guidance from veterinary advisers as to the optimum method and timing for their type of cattle and production system.

Where practical, cattle should be dehorned while horn development is still at the horn bud stage, or at the first available handling opportunity beyond this age. This is because the procedure involves less tissue trauma when horn development is still at the horn bud stage, and there is no attachment of horn to the skull of the animal.

Methods of dehorning (disbudding) at the horn bud stage include removal of the horn buds with a knife, thermal cautery of the horn buds, or the application of chemical paste to cauterise the horn buds.

Methods of dehorning when horn development has commenced involve the removal of the horn by cutting or sawing through the base of the horn close to the skull.

Producers should seek guidance from veterinarians on the availability and advisability of analgesia or anaesthesia for dehorning of beef cattle, particularly in older animals, where horn development is more advanced.

Operators performing dehorning of beef cattle should be trained and competent in the procedure used, and be able to recognise the signs of complications.

iii) ovariectomy (spaying)

Ovariectomy of heifers is sometimes required to prevent unwanted pregnancies under extensive rangeland conditions. Surgical spaying should be performed by veterinarians or by highly trained operators. Producers should seek guidance from veterinarians on the availability and advisability of analgesia or anaesthesia for spaying of beef cattle. The use of analgesia or anaesthesia should be encouraged.

iv) Tail docking

Tail docking has been performed in beef cattle to prevent tail tip necrosis in confinement operations. Research shows that increasing space per animal and proper bedding are effective in preventing tail tip necrosis. Therefore it is not recommended for producers to dock the tails of beef cattle.
Chapter 7.9.- Animal welfare and beef cattle productions systems

v) Identification

Ear-tagging, ear-notching, tattooing, freeze branding and radio frequency identification devices (RFID) are preferred methods of permanently identifying beef cattle from an animal welfare standpoint. In some situations however hot iron branding may be required or be the only practical method of permanent identifying beef cattle. If cattle are branded, it should be accomplished quickly, expertly and with the proper equipment. Identification systems should be established also according to Chapter 4.1.

Outcome-based measurables: postprocedural complication rate, morbidity rate, behaviour, physical appearance, changes in weight and body condition.

f) Handling and inspection

Beef cattle should be inspected at intervals appropriate to the production systems and the risks to the health and welfare of the cattle. In intensive farming systems, cattle should be inspected at least once a day.

Some animals may benefit from more frequent inspection for example: neonatal calves, cows in late gestation, newly weaned calves, and cattle experiencing environmental stress and those that have undergone painful husbandry or veterinary surgical procedures.

Animal handlers need to be competent in recognising the clinical signs of health, disease and welfare of beef cattle. There should be a sufficient number of animal handlers to adequately ensure the health and welfare of the cattle.

Beef cattle identified as sick or injured should be given appropriate treatment at the first available opportunity by competent and trained animal handlers. If animal handlers are unable to provide appropriate treatment, the services of a veterinarian should be sought.

If the animal's condition suggests the prognosis is poor with little chance of recovery, the animal should be humanely killed as soon as possible. For a description of methods for the humane killing of beef cattle see Article 7.6.5.

Recommendations on the handling of cattle are also found in Chapter 7.5.

Where beef cattle are herded into a handling facility from extensive conditions, they should be moved quietly and calmly at the pace of the slowest animal. Weather conditions should be taken into account and cattle should not be herded in excessively hot or cold conditions. Cattle should not be driven to the point of distress. In situations where the gathering and handling of the cattle is likely to be stressful, consideration should be given to the avoidance of multiple handling events by combining necessary management procedures within the one handling event. Where handling itself is not stressful, management procedures should be staged over time to avoid additive stress of multiple procedures.

Properly trained dogs can be effective aids for cattle herding. Cattle are adaptable to different visual environments. However, exposure of cattle to sudden or persistent movement or visual contrasts should be minimised where possible to prevent stress and fear reactions.

Electroimmobilisation should not be used.

Outcome-based measurables: handling response, morbidity rate, mortality rate, behaviour, reproductive efficiency, changes in weight and body condition.

g) Personnel training

All people responsible for beef cattle should be competent according to their responsibilities and should understand cattle husbandry, behaviour, biosecurity, general signs of disease, and indicators of poor animal welfare such as stress, pain and discomfort, and their alleviation.

Competence may be gained through formal training or practical experience.

Outcome-based measurables: handling response, morbidity rate, mortality rate, behaviour, reproductive efficiency, changes in weight and body condition.

h) Emergency plans

Where the failure of power, water and feed supply systems could compromise animal welfare, beef producers should have contingency plans to cover the failure of these systems. These plans may include the provision of fail-safe alarms to detect malfunctions, backup generators, access to maintenance providers, ability to store water on farm, access to water cartage services, adequate on-farm storage of feed and alternative feed supply.

Plans should be in place to minimise and mitigate the effects of natural disasters or extreme climatic conditions, such as heat stress, drought, blizzard, fire and flooding. Humane killing procedures for sick or injured cattle should be part of the emergency action plan. In times of drought, animal management decisions should be made as early as possible and these should include a consideration of reducing cattle numbers.

Emergency plans should also cover the management of the farm in the face of an emergency disease outbreak, consistent with national programmes and recommendations of Veterinary Services as appropriate.
i) Location, construction and equipment

Farms for beef cattle should be situated in an appropriate geographical location for the health, welfare and productivity of the cattle.

All facilities for beef cattle should be constructed, maintained and operated to minimise the risk to the welfare of the cattle.

Equipment for handling and restraining beef cattle should only be used in a way that minimises the risk of injury, pain or distress.

Cattle in intensive or extensive production systems should be offered adequate space for comfort and socialisation.

Cattle that are kept tethered should, as a minimum, be able to lie down, and if tethered outdoors, turn around and walk.

In intensive production systems the feeder should be sufficiently large so that cattle have adequate access to feed and they should be clean and free of spoiled, mouldy, sour, packed or unpalatable feed. Also cattle should have access to water at all times.

Floors in housing facilities should be properly drained, and barns and races and chutes should provide traction to prevent injuries to cattle.

Races, chutes and pens should be free from sharp edges and protrusions to prevent injury to cattle.

Alleys and gates should be designed and operated to avoid impeding cattle movement. Slippery surfaces should be avoided. Grooved concrete, metal grating (not sharp), rubber mats or deep sand can be used to minimise slipping and falling. Quiet handling is essential to minimise slipping. When gates and catches are operated, excessive noise should be minimised, because it may cause distress to the cattle.

Hydraulic, pneumatic and manual restraining equipment should be adjusted, as appropriate, to the size of cattle to be handled. Hydraulic and pneumatic operated restraining equipment should have pressure limiting devices to prevent injuries. Regular cleaning and maintenance of working parts is imperative to ensure the system functions properly and is safe for the cattle.

Mechanical and electrical devices used in housing facilities should be safe for cattle.

Dipping baths are sometimes used in beef cattle production for ectoparasite control. Where these are used, they should be designed and operated to minimise the risk of crowding to prevent injury and drowning.

The loading of the cattle at the farms should be conducting accordingly to Chapters 7.2., 7.3. and 7.4.

Outcome-based measurables: handling response, morbidity rate, mortality rate, behaviour, changes in weight and body condition, physical appearance, lameness.

j) Humane killing

For sick and injured cattle a prompt diagnosis should be made to determine whether the animal should be humanely killed or receive additional care.

The decision to humanely kill an animal and the procedure itself should be undertaken by a competent person.

Reasons for humane **killing** may include:

i) severe emaciation, weak cattle that are non-ambulatory or at risk of becoming downers;

ii) non-ambulatory cattle that will not stand up, refuse to eat or drink, have not responded to therapy;

iii) rapid deterioration of a medical condition for which therapies have been unsuccessful;

iv) severe, debilitating pain;

v) compound (open) fracture;

vi) spinal injury;

vii) central nervous system **disease**; and

viii) multiple joint **infections** with chronic weight loss.

For a description of methods for the humane **killing** of beef cattle see Article 7.6.5.
CHAPTER 7.10.

ANIMAL WELFARE AND BROILER CHICKEN PRODUCTION SYSTEMS

Article 7.10.1.

Definitions

For the purpose of this chapter:

Broiler: means a bird of the species Gallus galus kept for commercial meat production. Poultry kept in village or backyard flocks are not included.

Harvesting: means the catching and loading of birds on farm for transportation to the slaughterhouse/abattoir.

Article 7.10.2.

Scope

These recommendations cover the production period from arrival of day-old birds on the farm to harvesting the broilers in commercial production systems. Such systems involve confinement of the birds, the application of biosecurity measures, and trade in the products of those birds, regardless of scale of production. These recommendations cover broilers kept in cages, on slatted floors, litter or dirt and indoors or outdoors.

Broiler production systems include:

1. Completely housed system
   Broilers are completely confined in a poultry house, with or without environmental control.

2. Partially housed system
   Broilers are kept in a poultry house with access to a restricted outdoor area.

3. Completely outdoors system
   Broilers are not confined inside a poultry house at any time during the production period but are confined in a designated outdoor area.

This chapter should be read in conjunction with Chapters 7.2., 7.3. and 7.4. on the welfare of the broiler during transport to the slaughterhouse/abattoir.

Article 7.10.3.

Criteria or measurables for the welfare of broilers

The following outcome-based measurable, specifically animal-based measurable, can be useful indicators of animal welfare. The use of these indicators and the appropriate thresholds should be adapted to the different situations where broilers are managed, also taking into account the strain of bird concerned. Consideration should also be given to the resources provided and the design of the system.

Some criteria can be measured in the farm setting, such as gait, mortality and morbidity rates, while others are best measured at the slaughterhouse/abattoir. For example, at slaughter flocks can be assessed for presence of bruising, broken limbs and injuries. The age of these lesions can help to determine the source. Back scratching, contact dermatitis and breast blisters are also easily observed at the slaughterhouse/abattoir. Other conditions such as ascites, leg deformities, dehydration and disease conditions can also be assessed at slaughter. It is recommended that values for welfare measurables be determined with reference to appropriate national, sectoral or perhaps regional norms for commercial broiler production.
Chapter 7.10.- Animal welfare and broiler chicken production systems

The following outcome-based criteria and measurables are useful indicators of broiler welfare:

1. **Mortality, culling and morbidity**
   Daily, weekly and cumulative mortality, culling and morbidity rates should be within expected ranges. Any unforeseen increase in these rates could reflect an *animal welfare* problem.

2. **Gait**
   Broilers are susceptible to developing a variety of infectious and non-infectious musculoskeletal disorders. These disorders may lead to lameness and to gait abnormalities. Broilers that are lame or have gait abnormalities may have difficulty reaching the food and water, may be trampled by other broilers, and may experience pain. Musculoskeletal problems have many causes, including genetics, nutrition, sanitation, lighting, litter quality, and other environmental and management factors. Broilers in commercial *flocks* should be assessed for gait abnormalities. There are several gait scoring systems available.

3. **Contact dermatitis**
   Contact dermatitis affects skin surfaces that have prolonged contact with wet litter or other wet flooring surfaces. The condition is manifested as blackened skin progressing to erosions and fibrosis on the lower surface of the foot pad, at the back of the hocks, and sometimes in the breast area. If severe, the foot and hock lesions may contribute to lameness and lead to secondary *infections*. Validated scoring systems for contact dermatitis have been developed for use in *slaughterhouse/abattoir*.

4. **Feather condition**
   Evaluation of the feather condition of broilers provides useful information about aspects of welfare. Plumage dirtiness is correlated with contact dermatitis and lameness for individual birds or may be associated with the environment and production system. Plumage dirtiness can be assessed as part of on-farm inspections, at the time of harvesting or prior to plucking. A scoring system has been developed for this purpose.

5. **Incidence of diseases, metabolic disorders and parasitic infestations**
   Ill-health, regardless of the cause, is a welfare concern, and may be exacerbated by poor environmental or husbandry management.

6. **Behaviour**
   a) **Fear behaviour**
      Fearful broilers show avoidance of humans, and this behaviour is seen in flocks where *animal handlers* walk through the poultry house quickly when performing their tasks rather than moving more slowly while interacting with the broilers. Fearfulness (e.g., of sudden loud noises) can also lead to the broilers piling on top of, and even suffocating, one another. Fearful broilers may be less productive. Validated methods have been developed for evaluating fearfulness.
   b) **Spatial distribution**
      Changes in the spatial distribution (e.g., huddling) of the birds may indicate thermal discomfort or the existence of areas of wet litter or uneven provision of light, food or water.
   c) **Panting and wing spreading**
      Excessive panting and wing spreading indicates heat stress or high levels of ammonia.
   d) **Dust bathing**
      Dust bathing is an intricate body maintenance behaviour performed by many birds, including broilers. During dust bathing, broilers work loose material, such as litter, through their feathers. Dust bathing helps to keep the feathers in good condition, which in turns helps to maintain body temperature and protect against skin injury. Reduced dust bathing behaviour in the *flock* may indicate problems with litter or range quality, such as litter or ground being wet or not friable.
   e) **Feeding, drinking and foraging**
      Reduced feeding or drinking behaviour can indicate management problems, including inadequate feeder or drinker space or placement, dietary imbalance, poor water quality, or feed contamination. Feeding and drinking behaviour are often depressed when broilers are ill, and intake may be also reduced during periods of heat stress and increased during cold stress. Foraging is the act of searching for food, typically by walking and pecking or scratching the litter substrate; reduced foraging activity could suggest problems with litter quality or presence of conditions that decrease bird movement.
f) Feather pecking and cannibalism
Feather pecking can result in significant feather loss and may lead to cannibalism. Cannibalism is the tearing of the flesh of another bird, and can result in severe injury. These abnormal behaviours have multi-factorial causes.

7. Water and feed consumption
Monitoring daily water consumption is a useful tool to indicate disease and other welfare conditions, taking into consideration ambient temperature, relative humidity, feed consumption and other related factors. Problems with the water supply can result in wet litter, diarrhoea, dermatitis or dehydration.
Changes in feed consumption can indicate unsuitability of feed, the presence of disease or other welfare problems.

8. Performance
a) Growth rate - an index that indicates the average daily gain (gr) of weight per average broiler of a flock.
b) Feed conversion - an index that measures the quantity of feed consumed by a flock relative to the total live weight harvested, expressed as the weight of feed required to produce one kg of broiler body weight. Higher values than expected may indicate welfare problems.
c) Liveability - an index that indicates the percentage of broilers present at the end of the production period. More commonly this indicator is measured as its opposite, mortality.

9. Injury rate
The rate of these injuries can indicate welfare problems in the flock during production or harvesting. Injuries include those due to other broilers (scratches, feather loss or wounding due to feather pecking and cannibalism) and those due to environmental conditions, such as skin lesions, and those due to human intervention, such as catching. The most prevalent injuries seen during catching are bruises, broken limbs, dislocated hips, and damaged wings.

10. Eye conditions
Conjunctivitis can indicate the presence of irritants such as dust and ammonia. High ammonia levels can also cause corneal burns and eventual blindness. Abnormal eye development can be associated with low light intensity.

11. Vocalisation
Vocalisation can indicate emotional states, both positive and negative. Interpretation of flock vocalisations is possible by experienced animal handlers.

Article 7.10.4.

Recommendations

1. Biosecurity and animal health
a) Biosecurity and disease prevention
Biosecurity means a set of measures designed to maintain a flock at a particular health status and to prevent the entry (or exit) of specific infectious agents.
Biosecurity programmes should be designed and implemented, commensurate with the best possible flock health status and current disease risk (endemic and exotic or transboundary) that is specific to each epidemiological group of broilers and in accordance with relevant recommendations found in the Terrestrial Code.
These programmes should address the control of the major routes for disease and pathogen transmission:
i) direct transmission from other poultry, domesticated and wild animals and humans,
ii) fomites, such as equipment, facilities and vehicles,
iii) vectors (e.g. arthropods and rodents),
iv) aerosols,
v) water supply,
vi) feed.
b) Animal health management, preventive medicine and veterinary treatment

Animal health management means a system designed to optimise the health and welfare of the broilers. It includes prevention, treatment and control of diseases and adverse conditions.

Those responsible for the care of broilers should be aware of the signs of ill-health or distress, such as a change in feed and water intake, reduced growth, changes in behaviour, abnormal appearance of feathers, faeces, or other physical features.

If persons in charge are not able to identify the causes of diseases, ill-health or distress, or to correct these, or if they suspect the presence of a reportable disease, they should seek advice from veterinarians or other qualified advisers. Veterinary treatments should be prescribed by a veterinarian.

There should be an effective programme for the prevention and treatment of diseases consistent with the programmes established by Veterinary Services as appropriate.

Vaccinations and treatments should be administered, on the basis of veterinary or other expert advice, by personnel skilled in the procedures and with consideration for the welfare of the broilers.

Sick or injured broilers should be humanely killed as soon as possible. Similarly, killing broilers for diagnostic purposes should be done in a humane manner according to Chapter 7.6.

Outcome-based measurables: incidence of diseases, metabolic disorders and parasitic infestations, mortality, performance, gait.

2. Environment and management

a) Thermal environment

Thermal conditions for broilers should be appropriate for their stage of development, and extremes of heat, humidity and cold should be avoided. For the growing stage, a heat index can assist in identifying the comfort zones for the broilers at varying temperature and relative humidity levels.

When environmental conditions move outside these zones, strategies should be used to mitigate the adverse effects on the broilers. These may include higher air speeds, evaporative cooling and reducing stocking density.

Management of the thermal environment should be checked frequently enough so that failure of the system would be noticed before it caused a welfare problem.

Outcome-based measurables: behaviour, mortality, contact dermatitis, water and feed consumption, performance, feather condition.

b) Lighting

There should be an adequate period of continuous darkness during each 24-hour period to allow the broilers to rest. There should also be an adequate period of continuous light.

The light intensity during the light period should be sufficient and homogeneously distributed to allow the broilers to find feed and water after they are placed in the poultry house, to stimulate activity, and allow adequate inspection.

There should be a period for gradual adjustment to lighting changes.

Outcome-based measurables: gait, metabolic disorders, performance, behaviour, eye condition, injury rate.

c) Air quality

Adequate ventilation is required at all times to provide fresh air, to remove waste gases such as carbon dioxide and ammonia, dust and excess moisture content from the environment.

Ammonia concentration should not routinely exceed 25 ppm at broiler level.

Dust levels should be kept to a minimum. Where the health and welfare of broilers depend on an artificial ventilation system, provision should be made for an appropriate back-up power and alarm system.

Outcome-based measurables: incidence of respiratory diseases, metabolic disorders, eye conditions, performance, contact dermatitis.

d) Noise

Broilers are adaptable to different levels and types of noise. However, exposure of broilers to sudden or loud noises should be minimised where possible to prevent stress and fear reactions, such as piling. Ventilation fans, feeding machinery or other indoor or outdoor equipment should be constructed, placed, operated and maintained in such a way that they cause the least possible amount of noise.

Location of farms should, where possible, take into account existing local sources of noise.

Outcome-based measurables: daily mortality rate, morbidity, performance, injury rate, fear behaviour.
Chapter 7.10.- Animal welfare and broiler chicken production systems

e) Nutrition

Broilers should always be fed a diet appropriate to their age and genetics, which contains adequate nutrients to meet their requirements for good health and welfare.

Feed and water should be acceptable to the broilers and free from contaminants at a concentration hazardous to broiler health.

The water system should be cleaned regularly to prevent growth of hazardous microorganisms.

Broilers should be provided with adequate access to feed on a daily basis. Water should be available continuously. Special provision should be made to enable young chicks access to appropriate feed and water.

Broilers that are physically unable to access feed or water should be humanely killed as soon as possible.

Outcome-based measurables: feed and water consumption, performance, behaviour, gait, incidence of diseases, metabolic disorders and parasitic infestations, mortality, injury rate.

f) Flooring, bedding, resting surfaces and litter quality

The floor of a poultry house should preferably be easy to clean and disinfect.

The provision of loose and dry bedding material is desirable in order to encourage dust bathing and foraging.

Litter should be managed to minimise any detrimental effects on welfare and health. Poor litter quality can lead to contact dermatitis and breast blisters. Litter should be replaced or adequately treated when required to prevent diseases in the next flock.

Litter quality is partly related to the type of substrate used and partly to different management practices. The type of substrate should be chosen carefully. Litter should be maintained so that it is dry and friable and not dusty, caked or wet. Poor litter quality can result from a range of factors including water spillage, inappropriate feed composition, enteric infections, poor ventilation and overcrowding.

If broilers are kept on slatted floors, where a very humid climate precludes the use of other flooring substrates, the floors should be designed, constructed and maintained to adequately support the broilers, prevent injuries and ensure that manure can fall through or be adequately removed.

To prevent injury and keep them warm, day-old birds should be placed on an appropriate type of flooring suitable for their size.

If day-old birds are housed on litter, before they enter the poultry house, a layer of uncontaminated substrate, such as wood shavings, straw, rice husk, shredded paper, treated used litter should be added to a sufficient depth to allow normal behaviour and to separate them from the floor.

Outcome-based measurables: contact dermatitis, feather condition, gait, behaviour (dust bathing and foraging), eye conditions, incidence of diseases, metabolic disorders and parasitic infestations, performance.

g) Prevention of feather pecking and cannibalism

Feather pecking and cannibalism are rarely seen in broilers because of their young age. However, management methods, such as reducing light intensity, providing foraging materials, nutritional modifications, reducing stocking density, selecting the appropriate genetic stock should be implemented where feather pecking and cannibalism are a potential problem.

If these management strategies fail, therapeutic beak trimming is the last resort.

Outcome-based measurables: injury rate, behaviour, feather condition, mortality.

h) Stocking density

Broilers should be housed at a stocking density that allows them to access feed and water and to move and adjust their posture normally. The following factors should be taken into account: management capabilities, ambient conditions, housing system, production system, litter quality, ventilation, biosecurity strategy, genetic stock, and market age and weight.

Outcome-based measurables: injury rate, contact dermatitis, mortality, behaviour, gait, incidence of diseases, metabolic disorders and parasitic infestations, performance, feather condition.

i) Outdoor areas

Broilers can be given access to outdoor areas as soon as they have sufficient feather cover and are old enough to range safely. There should be sufficient exit areas to allow them to leave and re-enter the poultry house freely.

Management of outdoor areas is important in partially housed and completely outdoors production systems. Land and pasture management measures should be taken to reduce the risk of broilers being infected by
pathogens or infested by parasites. This might include limiting the stocking density or using several pieces of land consecutively in rotation.

Outdoor areas should be placed on well drained ground and managed to minimise swampy conditions and mud.

Outdoor areas should provide shelter for broilers and be free from poisonous plants and contaminants.

Protection from adverse climatic conditions should be provided in completely outdoors systems.

Outcome-based measurables: behaviour, incidence of parasitic infestations, performance, contact dermatitis, feather condition, injury rate, mortality, morbidity.

j) Protection from predators
Broilers should be protected from predators.
Outcome-based measurables: fear behaviour, mortality, injury rate.

k) Choice of broiler strain
Welfare and health considerations, in addition to productivity, should be taken into account when choosing a strain for a particular location or production system. For example, broilers selected with faster growth rates may have greater risks of metabolic disorders and contact dermatitis which should be mitigated by relevant management procedures. [Under study]

Outcome-based measurables: gait, metabolic disorders, contact dermatitis, mortality, behaviour, performance.

l) Painful interventions

Painful interventions, such as beak trimming, toe trimming and dubbing, should not be routinely practised on broilers.

If therapeutic beak trimming is required, it should be carried out by trained and skilled personnel at as early an age as possible and care should be taken to remove the minimum amount of beak necessary using a method which minimises pain and controls bleeding.

Surgical caponisation should not be performed without adequate pain and infection control methods and should only be performed by veterinarians or trained and skilled personnel under veterinary supervision.

Outcome-based measurables: mortality, culling and morbidity, behaviour.

m) Handling and inspection

Broilers should be inspected at least daily. Inspection should have three main objectives: to identify sick or injured broilers to treat or cull them to detect and correct any welfare or health problem in the flock, and to pick up dead broilers.

Inspection should be done in such a way that broilers are not unnecessarily disturbed, for example animal handlers should move quietly and slowly through the flock.

When broilers are handled, they should not be injured or unnecessarily frightened or stressed.

Broilers which have an incurable illness, significant deformity or injury should be removed from the flock and killed humanely as soon as possible as described in Chapter 7.6.

Cervical dislocation is an accepted method for killing small numbers of broilers if carried out competently as described in Article 7.6.17.

Outcome-based measurables: behaviour, performance, injury rate, mortality, vocalisation, morbidity.

n) Personnel training

All people responsible for the broilers should have received appropriate training or be able to demonstrate that they are competent to carry out their responsibilities and should have sufficient knowledge of broiler behaviour, handling techniques, emergency killing procedures, biosecurity, general signs of diseases, and indicators of poor animal welfare and procedures for their alleviation.

Outcome-based measurables: all measurables could apply.

o) Emergency plans

Broiler producers should have emergency plans to minimise and mitigate the consequences of natural disasters, disease outbreaks and the failure of mechanical equipment. Planning may include the provision of fail-safe alarm devices to detect malfunctions, backup generators, access to maintenance providers, alternative heating or cooling arrangements, ability to store water on farm, access to water cartage services, adequate on farm storage of feed and alternative feed supply and a plan for managing ventilation emergencies.

The emergency plans should be consistent with national programmes established or recommended by Veterinary Services.
p) Location, construction and equipment of farms
The location of broiler farms should be chosen to be safe from the effects of fires and floods and other natural disasters to the extent practical. In addition farms should be sited to avoid or minimise biosecurity risks, exposure of broilers to chemical and physical contaminants, noise and adverse climatic conditions. Broiler houses, outdoor areas and equipment to which broilers have access should be designed and maintained to avoid injury or pain to the broilers. Broiler houses should be constructed and electrical and fuel installations should be fitted to minimise the risk of fire and other hazards. Broiler producers should have a maintenance programme in place for all equipment the failure of which can jeopardise broiler welfare.

q) On farm harvesting
Broilers should not be subject to an excessive period of feed withdrawal prior to the expected slaughter time. Water should be available up to the time of harvesting. Broilers that are not fit for loading or transport because they are sick or injured should be killed humanely. Catching should be carried out by skilled animal handlers and every attempt should be made to minimise stress and fear reactions, and injury. If a broiler is injured during catching, it should be killed humanely. Broilers should not be picked up by their neck or wings. Broilers should be carefully placed in the transport container. Mechanical catchers, where used, should be designed, operated and maintained to minimise injury, stress and fear to the broilers. A contingency plan is advisable in case of mechanical failure. Catching should preferably be carried out under dim or blue light to calm the broilers. Catching should be scheduled to minimise the time to slaughter as well as climatic stress during catching, transport and holding. Stocking density in transport containers should suit climatic conditions and maintain comfort. Containers should be designed and maintained to avoid injury, and they should be cleaned and, if necessary, disinfected regularly. Outcome-based measurables: injury rate, mortality rate at harvesting and on arrival at the slaughterhouse/abattoir.
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