WORLD ORGANISATION FOR ANIMAL HEALTH

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

TERRESTRIAL ANIMAL HEALTH CODE

VOLUME I

General provisions

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VOLUME I

General provisions

FOREWORD

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 20th edition incorporates modifications to the* Terrestrial Code *agreed at the 79th OIE General Session in May 2011. The 2011 edition includes revised information on the following subjects: glossary; notification of diseases and epidemiological information; procedures for self declaration and for official recognition by the OIE; Veterinary Services; evaluation of Veterinary Services; design and implementation of identification systems to achieve animal traceability; zoning and compartmentalisation; application of compartmentalisation; general hygiene in semen collection and processing centres; collection and processing of bovine, small ruminant and porcine semen; collection and processing of* in vivo *derived embryos from livestock and horses; general recommendations on disinfection and disinsectisation; certification procedures; OIE procedures relevant to the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization; quarantine measures applicable to non-human primates; model veterinary certificates for international trade in live animals, hatching eggs and products of animal origin; control of hazards of animal health and public health importance in animal feed; biosecurity procedures in poultry production; prevention, detection and control of* Salmonella *in poultry; transport of animals by land; transport of animals by air; slaughter of animals; killing of animals for disease control purposes; control of stray dog populations and use of animals in research and education; anthrax; Aujeszky's disease; bluetongue; foot and mouth disease; vesicular stomatitis; avian influenza; Newcastle disease; contagious bovine pleuropneumonia; lumpy skin disease; equine influenza; equine viral arteritis;* Chlamydophila abortus *infection and scrapie.*

The chapters on avian tuberculosis, duck virus enteritis, fowl cholera, Marek's disease and teschovirus encephalomyelitis were deleted from this edition.

A new chapter on communication has been incorporated into this edition.

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 Members' veterinary authorities. The World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) formally recognises the role of the OIE to specify standards and recommendations as the international references for animal health and zoonotic diseases. The SPS Agreement provides a multilateral framework, incorporating WTO Members' rights and disciplines, to guide the development, adoption and enforcement of sanitary measures to facilitate safe international trade. According to the SPS Agreement, WTO Members should provide a scientific justification for their import health measures. It is preferable that these be based on OIE recommendations. Where there are no OIE recommendations or in cases where a government chooses to apply more*

restrictive conditions than those recommended by the OIE, the importing country should base its animal health measures on an import risk analysis as described in the Terrestrial Code. *The* Terrestrial Code *is thus a key part of the WTO legal framework for international trade.*

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

The User's Guide, which follows this foreword, is designed to help Veterinary Authorities and other interested parties to use the Terrestrial Code *and to promote fair access for all Members, 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 20th edition of the* Terrestrial Code.

Members of the OIE Code Commission (2011):
President: Dr A. Thiermann
Vice-President: Dr E. Bonbon
Secretary General: Dr J. Caetano
Members: Dr S.C. MacDiarmid, Dr A. Hassan and Dr S. Hargreaves

June 2011

USER'S GUIDE

A. General remarks

1. *The purpose of this guide is to assist the Veterinary Authorities of OIE Members 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 2 of the* Terrestrial Code *are designed to prevent the disease in question being introduced into the importing country, taking into account the nature of the commodity and the animal health status of the exporting country. 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. An OIE Member 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 Members.*

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. of the* Terrestrial Code.

7. *Section 5 of the* Terrestrial Code *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. *Members 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. of the* Terrestrial Code*, 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. of the* Terrestrial Code*) 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. of the* Terrestrial Code*, 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 OIE Member 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 humane *slaughter*/*killing*. *Animal welfare* refers to the state of the *animal*; the treatment that an *animal* receives is covered by other terms such as animal care, animal husbandry, and humane treatment.

Antimicrobial agent

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

Apiary

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

Appropriate level of protection

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

Approved

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

Artificial insemination centre

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

Beehive

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

Biosecurity plan

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

Border post

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

Captive wild animal

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

Case

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

Collection centre

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

Commodity

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

Compartment

means an animal *subpopulation* contained in one or more *establishments* under a common biosecurity management system with a distinct health status with respect to a specific *disease* or specific *diseases*

for which required *surveillance*, control and biosecurity measures have been applied for the purpose of *international trade*.

Competent Authority

means the *Veterinary Authority* or other Governmental Authority of a Member 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 arthropods which may cause *diseases* or are potential *vectors* of infectious agents of animal *diseases*, including *zoonoses*.

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* resulting from the evolution or change of an existing pathogenic agent, a known *infection* spreading to a new geographic area or *population*, or a previously unrecognized pathogenic

agent or *disease* diagnosed for the first time and which has a significant impact on animal or public health.

Epidemiological unit

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

Equivalence of sanitary measures

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

Eradication

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

Establishment

means the premises in which *animals* are kept.

Euthanasia

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

Exporting country

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

Feral animal

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

Flock

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

Free compartment

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

Free zone

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

Fresh meat

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

Greaves

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

Hatching eggs

means fertilised bird eggs, suitable for incubation and hatching.

Hazard

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

Hazard identification

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

Headquarters

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

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

Herd

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

Importing country

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

Incidence

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

Incubation period

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

Infected zone

means a *zone* in which a *disease* has been diagnosed.

Infection

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

Infective period

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

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. of the *Terrestrial Code*.

Loading/unloading

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

Market

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

Meat

means all edible parts of an *animal*.

Meat-and-bone meal

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

Meat products

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

Milk

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

Milk product

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

Modified stamping-out policy

see *stamping-out policy*.

Monitoring

means the 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. of the *Terrestrial Code*.

Official control programme

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

Official Veterinarian

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

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*.

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*s 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*.

Resting point

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

Restraint

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

Risk

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

Risk analysis

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

Risk assessment

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

Risk communication

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

Risk management

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

Sanitary measure

means a measure, such as those described in various chapters of the *Terrestrial Code*, destined to protect animal or human health or life within the territory of the OIE Member 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*.

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 to those who need to know 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 registered or licensed by the relevant *veterinary statutory body* of a country to practice veterinary medicine/science in that country.

Veterinary Authority

means the Governmental Authority of an OIE Member, 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 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 authority regulating *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 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, OIE Members 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. Members shall make available to other Members, through the OIE, whatever information is necessary to minimise the spread of important animal *diseases* and to assist in achieving better worldwide control of these *diseases*.

2. To achieve this, Members 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 disease agents and *diseases* is constantly developing and that the presence of an infectious agent does not necessarily imply the presence of a *disease*, Members shall ensure through their reports that they comply with the spirit and intention of point 1 above.

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

Article 1.1.3.

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 telegram, fax or e-mail, within 24 hours, of any of the following events:
   a) first occurrence of a *listed disease* and/or *infection* in a country, a *zone* or a *compartment*;
   b) re-occurrence of a *listed disease* and/or *infection* in a country, a *zone* or a *compartment* following a report declared the *outbreak* ended;
   c) first occurrence of a new strain of a pathogen of a *listed disease* in a country, a *zone* or a *compartment*;
   d) a sudden and unexpected increase in the distribution, incidence, morbidity or mortality of a *listed disease* prevalent within a country, a *zone* or a *compartment*;
   e) an *emerging disease* with significant morbidity or mortality, or zoonotic potential;
   f) evidence of change in the epidemiology of a *listed disease* (including host range, pathogenicity, strain) in particular if there is a zoonotic impact;
2. weekly reports by telegram, fax or e-mail subsequent to a *notification* under point 1 above, to provide further information on the evolution of an incident which justified urgent *notification*; these reports should continue until the situation has been resolved through either the *disease* being eradicated or it becoming endemic so that six-monthly reporting under point 3 will satisfy the obligation of the Member to the OIE; in any case, a final report on the incident should be submitted;
3. a six-monthly report on the absence or presence, and evolution of *listed disease* and information of epidemiological significance to other Members;
4. an annual report concerning any other information of significance to other Members.

Article 1.1.4.

1. The *Veterinary Authority* of a territory in which an *infected zone* was located shall inform the *Headquarters* when this zone is free from the *disease*.
2. An *infected zone* for a particular *disease* shall be considered as such until a period exceeding the *infective period* specified in the *Terrestrial Code* has elapsed after the last reported *case*, and when full prophylactic and appropriate animal health measures have been applied to prevent possible reappearance or spread of the *disease*. These measures will be found in detail in the various chapters of Volume II of the *Terrestrial Code*.
3. A Member may be considered to regain freedom from a specific *disease* when all conditions given in the relevant chapters of the *Terrestrial Code* have been fulfilled.
4. The *Veterinary Authority* of a Member which sets up one or several *free zones* shall inform the OIE giving necessary details, including the criteria on which the free status is based, the requirements for maintaining the status and indicating clearly the location of the *zones* on a map of the territory of the Member.

Article 1.1.5.

1. The *Headquarters* shall send by telegram, fax, e-mail or *Disease Information* to the *Veterinary Authorities* concerned, all *notifications* received as provided in Articles 1.1.2. to 1.1.4.
2. The *Headquarters* shall dispatch to the Delegates information on new *outbreaks* of *listed diseases*.

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

Article 1.1.6.

Telegrams or faxes sent by *Veterinary Authorities* in pursuance of Articles 1.1.3. and 1.1.5. shall receive priority in accordance with the circumstances. Communications by telephone, telegram or fax, sent in the case of exceptional urgency when there is danger of spread of a notifiable epizootic *disease*, shall be given the highest priority accorded to these communications by the International Arrangements of Telecommunications.

CHAPTER 1.2.

CRITERIA FOR LISTING DISEASES

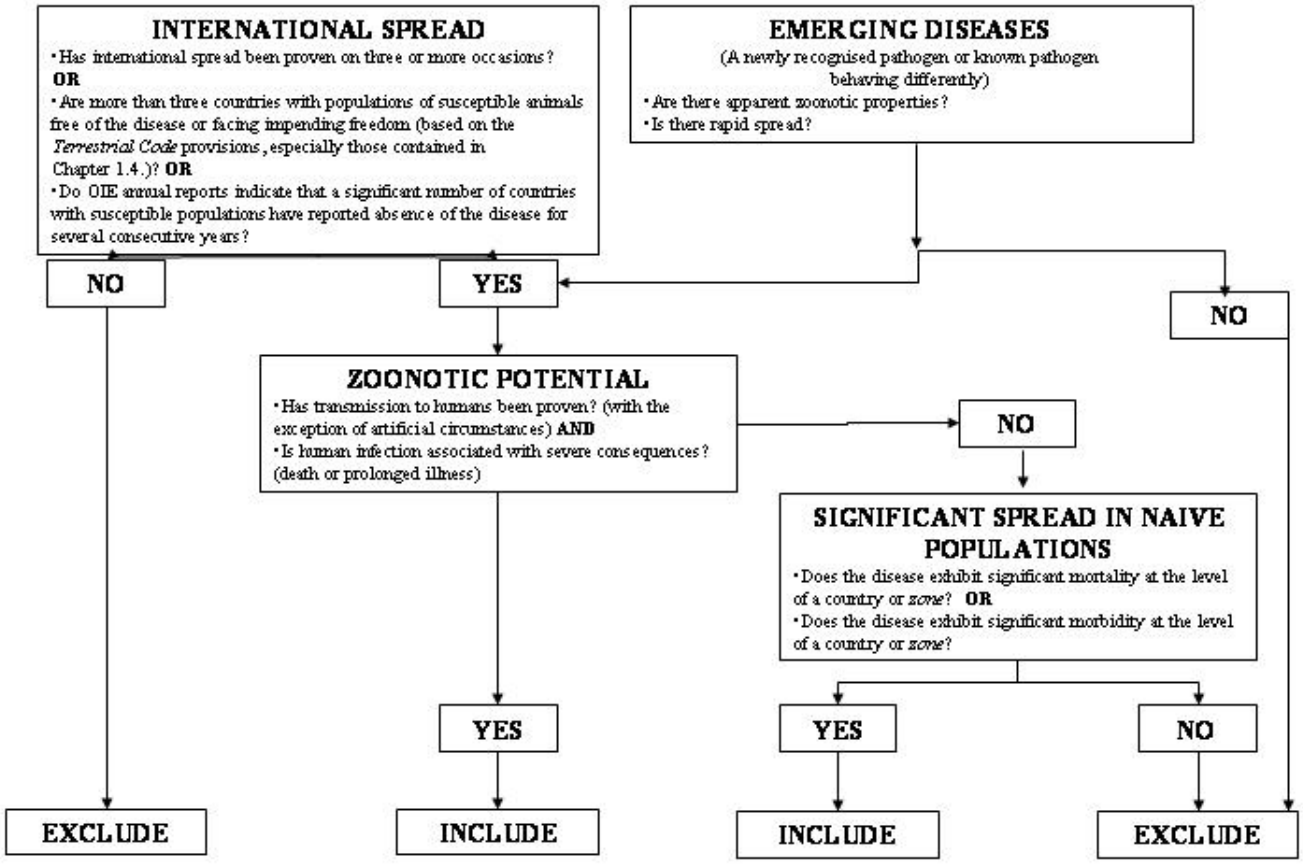
Article 1.2.1.

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

Basic criteria	**Parameters (at least one 'yes' answer means that the criterion has been met)**
International Spread	Has international spread been proven on three or more occasions? **OR** Are more than three countries with populations of susceptible animals free of the *disease* or facing impending freedom (based on the relevant provisions of the *Terrestrial Code*, and in particular those contained in Chapter 1.4.)? **OR** Do OIE annual reports indicate that a significant number of countries with susceptible populations have reported absence of the *disease* for several consecutive years?
Zoonotic Potential	Has transmission to humans been proven? (with the exception of artificial circumstances) **AND** Is human infection associated with severe consequences? (death or prolonged illness)
Significant Spread within Naïve Populations	Does the *disease* exhibit significant mortality at the level of a country or a *zone*? **OR** Does the *disease* exhibit significant morbidity at the level of a country or a *zone*?
Emerging Diseases	Are there apparent zoonotic properties or is there a rapid spread?

Article 1.2.2.

The criteria in Article 1.2.1. above are applied according to the decision-making model shown below:



Article 1.2.3.

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

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

1. The following *diseases* are included within the category of multiple species *diseases*:
   - Anthrax
   - Aujeszky's disease
   - Bluetongue
   - Brucellosis (*Brucella abortus*)
   - Brucellosis (*Brucella melitensis*)
   - Brucellosis (*Brucella suis*)
   - Crimean Congo haemorrhagic fever
   - Echinococcosis/hydatidosis
   - Epizootic haemorrhagic disease
   - Equine encephalomyelitis (Eastern)
   - Foot and mouth disease

- Heartwater
- Japanese encephalitis
- New World screwworm (*Cochliomyia hominivorax*)
- Old World screwworm (*Chrysomya bezziana*)
- Paratuberculosis
- Q fever
- Rabies
- Rift Valley fever
- Rinderpest
- Surra (*Trypanosoma evansi*)
- Trichinellosis
- Tularemia
- Vesicular stomatitis
- West Nile fever.

2. The following *diseases* are included within the category of cattle *diseases*:
   - Bovine anaplasmosis
   - Bovine babesiosis
   - Bovine genital campylobacteriosis
   - Bovine spongiform encephalopathy
   - Bovine tuberculosis
   - Bovine viral diarrhoea
   - Contagious bovine pleuropneumonia
   - Enzootic bovine leukosis
   - Haemorrhagic septicaemia
   - Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
   - Lumpy skin disease
   - Theileriosis
   - Trichomonosis
   - Trypanosomosis (tsetse-transmitted).
3. The following *diseases* are included within the category of sheep and goat *diseases*:
   - Caprine arthritis/encephalitis
   - Contagious agalactia
   - Contagious caprine pleuropneumonia
   - Enzootic abortion of ewes (ovine chlamydiosis)
   - Maedi–visna
   - Nairobi sheep disease
   - Ovine epididymitis (*Brucella ovis*)
   - Peste des petits ruminants

- Salmonellosis (*S.* abortusovis)
- Scrapie
- Sheep pox and goat pox.

4. The following *diseases* are included within the category of equine *diseases*:
   - African horse sickness
   - Contagious equine metritis
   - Dourine
   - Equine encephalomyelitis (Western)
   - Equine infectious anaemia
   - Equine influenza
   - Equine piroplasmosis
   - Equine rhinopneumonitis
   - Equine viral arteritis
   - Glanders
   - Venezuelan equine encephalomyelitis.
5. The following *diseases* are included within the category of swine *diseases*:
   - African swine fever
   - Classical swine fever
   - Nipah virus encephalitis
   - Porcine cysticercosis
   - Porcine reproductive and respiratory syndrome
   - Swine vesicular disease
   - Transmissible gastroenteritis.
6. The following *diseases* are included within the category of avian *diseases*:
   - Avian chlamydiosis
   - Avian infectious bronchitis
   - Avian infectious laryngotracheitis
   - Avian mycoplasmosis (*Mycoplasma gallisepticum*)
   - Avian mycoplasmosis (*Mycoplasma synoviae*)
   - Duck virus hepatitis
   - Fowl typhoid
   - Highly pathogenic avian influenza in birds and low pathogenicity notifiable avian influenza in *poultry* as defined in Chapter 10.4.
   - Infectious bursal disease (Gumboro disease)
   - Newcastle disease
   - Pullorum disease
   - Turkey rhinotracheitis.

7. The following *diseases* are included within the category of lagomorph *diseases*:
   - Myxomatosis
   - Rabbit haemorrhagic disease.
8. The following *diseases* are included within the category of bee *diseases*:
   - Acarapisosis of honey bees
   - American foulbrood of honey bees
   - European foulbrood of honey bees
   - Small hive beetle infestation (*Aethina tumida*)
   - *Tropilaelaps* infestation of honey bees
   - Varroosis of honey bees.
9. The following *diseases* are included within the category of other *diseases*:
   - Camelpox
   - Leishmaniosis.

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

Agent id.	Agent identification
Agg.	Agglutination test
AGID	Agar gel immunodiffusion
BBAT	Buffered *Brucella* antigen test
CF	Complement fixation (test)
DTH	Delayed-type hypersensitivity
ELISA	Enzyme-linked immunosorbent assay
FAVN	Fluorescent antibody virus neutralisation
FPA	Fluorescence polarisation assay
HI	Haemagglutination inhibition
IFA	Indirect fluorescent antibody (test)
MAT	Microscopic agglutination test
NPLA	Neutralising peroxidase-linked assay
PCR	Polymerase chain reaction
PRN	Plaque reduction neutralisation
VN	Virus neutralisation
_	No test designated yet

Terrestrial Code Chapter No.	*Terrestrial Manual* Chapter No.	Disease name	Prescribed tests	Alternative tests
OIE listed diseases				
Multiple species				
8.2.	2.1.2.	Aujeszky's disease	ELISA, VN	_
	2.1.9.	Leptospirosis	_	MAT
8.10.	2.1.13.	Rabies	VN, ELISA	_
8.9.	2.1.11.	Paratuberculosis	_	DTH, ELISA
8.6.	2.1.6.	Heartwater	_	ELISA, IFA
8.8.	2.1.10.	New world screwworm (*Cochliomyia hominivorax*) and old world screwworm (*Chrysomya bezziana*)	_	Agent id.
8.13.	2.1.16.	Trichinellosis	Agent id.	ELISA
8.5.	2.1.5.	Foot and mouth disease	ELISA[1], VN	CF
8.15.	2.1.19.	Vesicular stomatitis	CF, ELISA, VN	_
8.12.	2.1.15.	Rinderpest	ELISA	VN
8.3.	2.1.3.	Bluetongue	Agent id., ELISA, PCR	AGID, VN
8.11.	2.1.14.	Rift Valley fever	VN	HI, ELISA
8.14.	2.1.18.	Tularemia	_	Agent id.
Bovidae				
11.3.	2.4.3.	Bovine brucellosis	BBAT, CF, ELISA, FPA	–
11.4.	2.4.5.	Bovine genital campylobacteriosis	Agent id.	_
11.6.	2.4.7.	Bovine tuberculosis	Tuberculin test	Gamma interferon test
11.9.	2.4.11.	Enzootic bovine leukosis	AGID, ELISA	PCR
11.11.	2.4.13.	Infectious bovine rhinotracheitis/ infectious pustular vulvovaginitis	VN, ELISA, Agent id. (semen only), PCR	–
11.14.	2.4.17.	Trichomonosis	Agent id.	Mucus agg.
11.1.	2.4.1.	Bovine anaplasmosis	_	CF, Agg. card
11.2.	2.4.2	Bovine babesiosis	_	ELISA, IFA, CF
11.13.	2.4.16.	Theileriosis	Agent id., IFA	_
11.10.	2.4.12.	Haemorrhagic septicaemia	_	Agent id.
11.12.	2.4.14.	Lumpy skin disease	_	VN
11.8.	2.4.9.	Contagious bovine pleuropneumonia	CF, ELISA	_
Ovidae and capridae				
14.7.	2.7.9.	Ovine epididymitis (*Brucella ovis*)	CF	ELISA
14.1.	2.7.2.	Caprine and ovine brucellosis (excluding *Brucella ovis*)	BBAT, CF, ELISA, FPA	Brucellin test
14.2.	2.7.3.	Caprine arthritis/encephalitis	AGID, ELISA	_
14.6.	2.7.4.	Maedi-visna	AGID, ELISA	_

Terrestrial Code Chapter No.	*Terrestrial Manual* Chapter No.	Disease name	Prescribed tests	Alternative tests
OIE listed diseases (contd)				
Ovidae and capridae (contd)				
14.4.	2.7.6.	Contagious caprine pleuropneumonia	CF	–
14.5.	2.7.7.	Enzootic abortion of ewes	–	CF
14.8.	2.7.11.	Peste des petits ruminants	VN	ELISA
14.10	2.7.14.	Sheep pox and goat pox	–	VN
Equidae				
12.2.	2.5.2.	Contagious equine metritis	Agent id.	–
12.3.	2.5.3.	Dourine	CF	IFA, ELISA
12.4.	2.5.5.	Equine encephalomyelitis (Eastern and Western)	–	HI, CF, PRN
12.5.	2.5.6.	Equine infectious anaemia	AGID	ELISA
12.6.	2.5.7.	Equine influenza	–	HI
12.7.	2.5.8.	Equine piroplasmosis	IFA, ELISA	CF
12.8.	2.5.9.	Equine rhinopneumonitis	–	VN
12.10.	2.5.11.	Glanders	Mallein test, CF	–
12.9.	2.5.10.	Equine viral arteritis	VN, Agent id. (semen only)	–
12.11.	2.5.14.	Venezuelan equine encephalomyelitis	–	HI, CF, PRN
12.1.	2.5.1.	African horse sickness	CF, ELISA	VN, Agent id. (real time PCR)
Suidae				
15.3.	2.8.5.	Porcine brucellosis	BBAT, CF, ELISA, FPA	–
15.6.	2.8.11.	Transmissible gastroenteritis	–	VN, ELISA
15.4.	2.8.9.	Swine vesicular disease	VN	ELISA
15.1.	2.8.1.	African swine fever	ELISA	IFA
15.2.	2.8.3.	Classical swine fever	NPLA, FAVN, ELISA	–
Aves				
10.11.	2.3.12.	Infectious bursal disease	–	AGID, ELISA
10.12.	2.3.13.	Marek's disease	–	AGID
10.5.	2.3.5.	Avian mycoplasmosis (*Mycoplasma gallisepticum*)	–	Agg., HI
10.10.	2.3.11.	Fowl typhoid and Pullorum disease	–	Agg., Agent id.
10.2.	2.3.2.	Avian infectious bronchitis	–	VN, HI, ELISA
10.3.	2.3.3.	Avian infectious laryngotracheitis	–	AGID, VN, ELISA
10.4.	2.3.4.	Avian influenza	Virus isolation with pathogenicity testing	AGID, HI
10.13.	2.3.14.	Newcastle disease	Virus isolation	HI
Lagomorpha				
13.1.	2.6.1.	Myxomatosis	–	AGID, CF, IFA

Terrestrial Code Chapter No.	*Terrestrial Manual* Chapter No.	Disease name	Prescribed tests	Alternative tests
OIE listed diseases (contd)				
Aves (contd)				
13.2.	2.6.2.	Rabbit haemorrhagic disease	_	ELISA, HI

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

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 occurrence or distribution of *disease* or *infection*, while also detecting as early as possible exotic or *emerging diseases*. The type of *surveillance* applied depends on the desired outputs needed to support decision-making. The following recommendations may be applied to all *diseases*, their agents and all susceptible species (including *wildlife*) as listed in the *Terrestrial Code*, and are designed to assist with the development of *surveillance* methodologies. Except where a specific *surveillance* method for a certain *disease* or *infection* is already described in the *Terrestrial Code*, the recommendations in this chapter may be used to further refine the general approaches described for a specific *disease* or *infection*. Where detailed *disease/infection*-specific information is not available, suitable approaches should be based on the recommendations in this chapter.

2. Animal health *surveillance* is an essential tool to detect *disease* or *infection*, to monitor disease trends, to facilitate the control of *disease* or *infection*, to support claims for freedom from *disease* or *infection*, to provide data for use in *risk analysis*, for animal and/or public health purposes, and to substantiate the rationale for sanitary measures. Both domestic *animals* and *wild animals* are susceptible to certain *disease/infection*. However, *disease/infection* in *wild animals* does not mean that the same *disease/infection* is necessarily present in domestic *animals* in the same country or *zone* or vice versa. *Surveillance* data underpin the quality of disease status reports and should satisfy information requirements of *risk analysis* for *international trade* and for national decision-making. *Wildlife* may be included because they can serve as reservoirs and as indicators of human and domestic animal and *wildlife disease*. *Wildlife disease/infection surveillance* presents specific challenges that may differ significantly from *surveillance* in domestic *animals*.

3. Prerequisites to enable an OIE Member to provide information for the evaluation of its animal health status are:

   a) that the Member complies with the provisions of Chapter 3.1. of the *Terrestrial Code*;

   b) that, where possible, *surveillance* data be complemented by other sources of information (e.g. scientific publications, research data, documented field observations and other non-survey data);

   c) that transparency in the planning and execution of *surveillance* activities and the analysis and availability of data and information, be maintained at all times, in accordance with Chapter 1.1. of the *Terrestrial Code*.

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 *disease/infection 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: in the context of demonstrating freedom from *infection*, confidence is the probability that the type of *surveillance* applied would detect the presence of *infection* if the population were infected. The confidence depends on, among other parameters, the assumed prevalence of *infection*. The term refers to confidence in the ability of the *surveillance* applied to detect *disease/infection*, and is equivalent to the sensitivity of the *surveillance* system.

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 units: 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* (e.g. 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, disease or zoonosis status of animal populations.

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

Target population: 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/health schemes;
- targeted testing/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/infection*, including environmental, host population distribution, and climatic information;

ii) data on animal movements, including transhumance, as well as 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; and

vi) biosecurity measures in place;

vii) the likelihood and consequence of *disease/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

A case should be defined for each *disease/ infection* under *surveillance* using clear criteria, where they exist, the standards in the *Terrestrial Code*. For *wildlife disease/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 levels to facilitate effective decision making, whether it be planning interventions or demonstrating status.

Methodologies for the analysis of *surveillance* data should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. Different methodologies may be needed to accommodate the relevant host species, pathogens, varying production 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* by the use of appropriate case definitions based on the results of one or more tests for evidence of *infection* or immune status. In this context, a test may range from detailed laboratory examinations to field observations and the analysis of production records. The performance of a test at the population level (including field observations) may be described in terms of its sensitivity and specificity and predictive values. Imperfect sensitivity and/or specificity will have an impact on the conclusions from *surveillance*. Therefore, these parameters should be taken into account in the design of *surveillance* systems and analysis of *surveillance* data.

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

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

h) Quality assurance

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

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 government ministries, 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 for *surveillance* discussed above, the following recommendations should be used when planning, implementing and analysing surveys.

1. Types of surveys

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

a) non-probability based sampling methods, such as:

i) convenience;

ii) expert choice;

iii) quota;

b) probability based sampling methods, such as:

i) simple random selection;

ii) cluster sampling;

iii) stratified sampling;

iv) systematic sampling.

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

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

2. Survey design

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

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

Data on *wild animal* population size often do not exist and, to the extent possible, should be determined 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 from *wildlife* for *surveillance* 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 (e.g. simple random selection) should be used. When this is not possible, sampling should provide the best practical chance of generating a sample that is representative of the target population.

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

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 (e.g. disease reporting systems, sentinel sites, 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.

b) Control programmes / health schemes

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

c) Targeted testing / screening

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

d) Ante-mortem and post-mortem inspections

Inspections of *animals* at *slaughterhouses* may provide valuable *surveillance* data. The sensitivity and specificity of *slaughterhouse* inspection for detecting the presence of specified *diseases* under the inspection system in place should be pre-determined. 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 Authorities* 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/sites involve the identification and regular testing of one or more of *animals* of known health/immune status in a specified geographical location to detect the occurrence of *disease/infection* (usually serologically). They are particularly useful for *surveillance* for *diseases/infections* with a strong spatial component, such as *vector*-borne *diseases/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/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 an important component. Ideally, both the number of positive observations and the total number of observations should be recorded.

i) Farm production records

Systematic analysis of farm production records may be used as an indicator of the presence or absence of *disease/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 *wild animals* for *disease/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 such as coverage of the population, duplication of data, and sensitivity and specificity of tests that may give rise to difficulties in the interpretation of data. *Surveillance* data from non-random sources can, however, be a cost-effecient 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/infection

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

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

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

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

a) Historically free

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

i) there has never been occurrence of *disease*, or

ii) eradication has been achieved or the *disease/infection* has ceased to occur for at least 25 years,

provided that for at least the past 10 years:

iii) it has been a *notifiable disease*;

iv) an early detection system has been in place for all relevant species;

v) measures to prevent *disease/infection* introduction have been in place; no vaccination against the *disease* has been carried out unless otherwise provided in the *Terrestrial Code*;

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

b) Last occurrence within the previous 25 years

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

i) it has been a *notifiable disease*;

ii) an early detection system has been in place;

iii) measures to prevent *disease/infection* introduction have been in place;

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

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

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) it is a *notifiable disease*;

b) an early detection system is in place;

c) measures to prevent *disease/infection* introduction are in place;

d) vaccination against the *disease* is not applied;

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

3. Self declaration of disease/infection

Members may make a self declaration that a country, *zone* or *compartment* is free from a *listed disease*, based on the implementation of the provisions of the *Terrestrial Code* and the *Terrestrial Manual* - see relevant provisions in Chapter 1.6. The *Veterinary Authority* may wish to transmit this information to the OIE *Headquarters*, which may publish the information.

4. International recognition of disease/infection free status

For *diseases* for which procedures exist whereby the OIE can officially recognise the existence of a *disease/infection* free country or *zone*, a Member wishing to apply for recognition of this status shall, via its Permanent Delegate, send to the OIE all the relevant documentation relating to the country 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 for *surveillance* outlined in Article 1.4.3. of this chapter.

Freedom from *infection* implies the absence of the pathogenic agent in the country, *zone* or *compartment*. Scientific methods cannot provide absolute certainty of the absence of *infection*. Demonstrating freedom from *infection* involves providing sufficient evidence to demonstrate (to a level of confidence acceptable to Members) that *infection* with a specified pathogen is not present in a population. In practice, it is not possible to prove (i.e., be 100% confident) that a population is free

from *infection* (unless every member of the population is examined simultaneously with a perfect test with both sensitivity and specificity equal to 100%). Instead, the aim is to provide adequate evidence (to an acceptable level of confidence), that *infection*, if present, is present in less than a specified proportion of the population.

However, finding evidence of *infection* at any level in the target population automatically invalidates any freedom from *infection* claim unless otherwise stated in the relevant *disease* chapter. The implications of *disease/infection* in *wildlife* for the status of domestic *animals* 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 distribution and occurrence of *infection* or of other relevant health related events is widely used to assess progress in the control or eradication of selected *diseases* and pathogens and as an aid to decision making. It has, however, relevance for the international movement of *animals* and products when movement occurs among infected countries.

In contrast to *surveillance* to demonstrate freedom from *infection*, *surveillance* used to assess progress in control or eradication of selected *diseases* and pathogens is usually designed to collect data about a number of variables of animal health relevance, for example:

1. prevalence or incidence of *infection*;

2. morbidity and mortality rates;

3. frequency of *disease/infection risk* factors and their quantification;

4. frequency distribution of *herd* sizes or the sizes of other *epidemiological units*;

5. frequency distribution of antibody titres;

6. proportion of immunised *animals* after a vaccination campaign;

7. frequency distribution of the number of days elapsing between suspicion of *infection* and *laboratory* confirmation of the diagnosis and/or to the adoption of control measures;

8. farm production records;

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*;

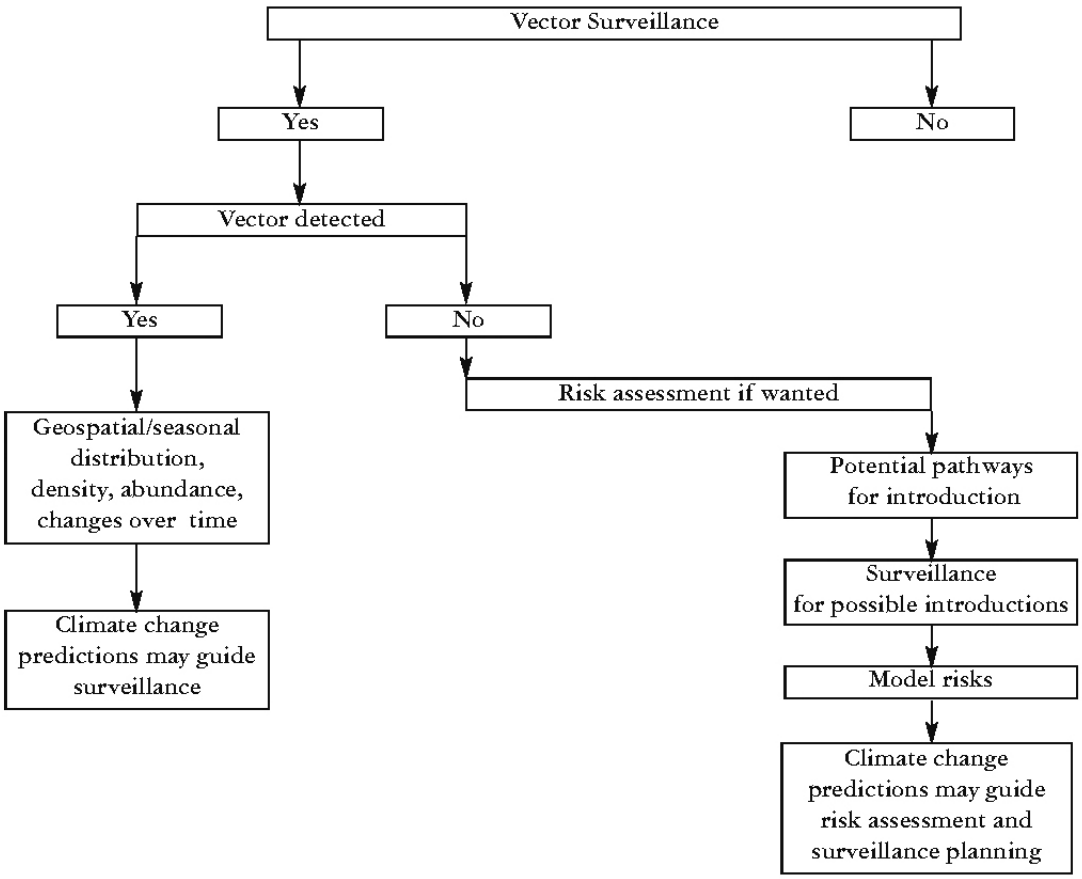
2. monitoring changes in the spatial and temporal distribution and abundance of these *vectors*;

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.

Figure 1 Decision Tree for Vector Surveillance



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),

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

Members may wish to make a self declaration as to the freedom of a country, *zone* or *compartment* from an OIE *listed disease*. The Member 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), rinderpest and contagious bovine pleuropneumonia (CBPP).

Members 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 from rinderpest;

4. the freedom of a country or *zone* from CBPP.

The OIE does not grant official recognition for other *diseases*.

In these cases, Members 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 should submit to the OIE Scientific and Technical Department a dossier providing the information requested (as appropriate) in Articles 1.6.3. (for BSE), 1.6.4. (for FMD), 1.6.5. (for rinderpest) or 1.6.6. (for CBPP).

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

Members 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 should submit to the OIE Scientific and Technical Department a dossier providing the information requested in Article 1.6.7.

Article 1.6.3.

Questionnaire on bovine spongiform encephalopathy

GENERAL INTRODUCTION

Acceptance of this submission is based on the compliance of the *Veterinary Service* of the applicant country, *zone* or *compartment* 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 a the cattle population of a country, *zone* or *compartment*. 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, *zone* or *compartment* (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, *zone* or *compartment* 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 release and exposure assessments in respect of:

Release assessment:

1. The potential for the release of the BSE agent through importation of *meat-and-bone meal* or *greaves*.
2. The potential for the release of the BSE agent through the importation of potentially infected live cattle.
3. The potential for the release 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 release and exposure assessment that follow, the contributor is guided in terms of the question, the rationale and the evidence required to support the country, *zone* or *compartment* status claim.

Release assessment

1. **The potential for the release 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 release of BSE agent. *Meat-and-bone meal* and *greaves* originating in countries of high BSE risk pose a higher release risk than that from low risk countries. *Meat-and-bone meal* and *greaves* originating in countries of unknown BSE risk pose an unknown release risk.

   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 release 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 release risks are dependent on:

   - country, *zone* or *compartment* 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, *zone* or *compartment* 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, *zone* or *compartment* of origin because feeding practices result in greater exposure of one category;
   - age at *slaughter*.

   Evidence required:

   a) Documentation including tables on the country, *zone* or *compartment* of origin of imports. This should identify the country, *zone* or *compartment* of origin of the cattle, the length of time they

lived in that country, *zone* or *compartment* 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, *zone* or *compartment* of origin.

3. **The potential for the release 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 release risks are dependent on:

- the origin of the cattle products and whether these products contain tissues known to contain BSE infectivity (Article 11.5.13.);
- country, *zone* or *compartment* 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, *zone* or *compartment* 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, *zone* or *compartment* of origin because feeding practices result in greater exposure of one category;
- age at *slaughter*.

Evidence required:

a) Documentation on the country, *zone* or *compartment* of origin of imports. This should identify the country, *zone* or *compartment* of origin of cattle from which the products were derived, the length of time they lived in that country, *zone* or *compartment* 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, *zone* or *compartment* 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, *zone* or *compartment* 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, *zone* or *compartment* 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*.

Year (information should be provided for each of the 8 years for effectiveness is claimed)	**Type of plant (renderer or feed mill)**	**Number of plants processing ruminant material**	**Number of plants in (A) inspected**	**Total number of visual inspections in (B)**	**Total number of plants in (B) with infractions**	**Total number of inspected plants in (B) with sampling**	**Total number of plants in (C) with positive test results**
		(A)	**(B)**			**(C)**	
Year 1	Renderer						
	Feed mill						
Year 2, etc.	Renderer						
	Feed mill						

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.

Year (information should be provided for each of the 8 years for effectiveness is claimed)	Type of plant (renderer or feed mill)	Number of plants processing non-ruminant material	Number of plants in (A) inspected	Total number of visual inspections in (B)	Total number of plants in (B) with infractions	Total number of inspected plants in (B) with sampling	Total number of plants in (C) with positive test results
		(A)	(B)			(C)	
Year 1	Renderer						
	Feed mill						
Year 2, etc.	Renderer						
	Feed mill						

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.

Year (information should be provided for each of the 8 years for effectiveness is claimed)	Type of plant (renderer or feed mill)	Plant ID	Nature of infraction	Method of resolution	Follow-up results
Year 1	Renderer	ID 1			
		ID 2			
		ID 3, etc.			
	Feed mill	ID 1			
		ID 2			
		ID 3, etc.			
Year 2, etc.	Renderer				
	Feed mill				

g) Documentation, in the form of the following table, on each plant above processing non-ruminant material with infractions, specifying the type of infraction and the method of resolution.

Year (information should be provided for each of the 8 years for effectiveness is claimed)	Type of plant (renderer or feed mill)	Plant ID	Nature of infraction	Method of resolution	Follow-up results
Year 1	Renderer	ID 1			
		ID 2			
		ID 3, etc.			
	Feed mill	ID 1			
		ID 2			
		ID 3, etc.			
Year 2, etc.	Renderer				
	Feed mill				

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:

a) Documentation as to the approved laboratories where samples of cattle tissues from the country, *zone* or *compartment* are examined for BSE. (If this is located outside the country, information should be provided on the cooperation agreement).

b) Documentation of the diagnostic procedures and methods used.

c) Documentation that the diagnostic procedures and methods have been applied through the entire *surveillance* period.

SECTION 3: BSE SURVEILLANCE AND MONITORING SYSTEM (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, *zone* or *compartment*.

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.

Laboratory identification number	Age	Clinical signs	Point of detection (farm, market channels, slaughterhouse)

6. Documentation according to the following table, that the number of target points applicable to the country, *zone* or *compartment* 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.

SUMMARY TABLE FOR BSE SURVEILLANCE								
Year: (complete a separate table for each year of surveillance)								
	Surveillance subpopulations							
	Routine slaughter		Fallen stock		Casualty slaughter		Clinical suspect	
	Samples	Points	Samples	Points	Samples	Points	Samples	Points
>1 and <2 years								
≥2 and <4 years								
≥4 and <7 years								
≥7 and <9 years								
≥9 years								
Subtotals								
Total points								

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

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

Questions to be answered:

- Has BSE occurred in the country, *zone* or *compartment*?
- How has it been dealt with?

Rationale:

The categorization of a country, *zone* or *compartment* 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, *zone* or *compartment*. This section provides the opportunity to describe the BSE history in the country, *zone* or *compartment*.

Evidence required:

1. Documentation of whether a *case* of BSE has ever been diagnosed in the country, *zone* or *compartment*.

   In the case of positive BSE findings:

2. Documentation on the origin of each BSE *case* in respect to the country, *zone* or *compartment*. 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, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.

Article 1.6.4.

Questionnaires on foot and mouth disease

FMD FREE COUNTRY WHERE VACCINATION IS NOT PRACTISED

Report of a Member which applies for recognition of status,
under Chapter 8.5. of the *Terrestrial Code* (2011),
as a 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 legislation 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, modified stamping-out, 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.

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 8.5.42. to 8.5.47. and Article 8.5.49. 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 centers? 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, 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 8.5.2. are properly implemented and supervised, the Delegate of the 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

   Countries applying for recovery of status should comply with the provisions of Article 8.5.9. 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 which applies for recognition of status,
under Chapter 8.5. of the *Terrestrial Code* (2011),
as a 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 legislation 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, modified stamping-out, 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 8.5.42. to 8.5.47. and Article 8.5.49. 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 8.5.46.? 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 centers? 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, 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 8.5.3. are properly implemented and supervised, the Delegate of the 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 8.5.42. to 8.5.47. and Article 8.5.49. 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

Countries applying for recovery of status should comply with the provisions of Article 8.5.9. 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 which applies for recognition of status,
under Chapter 8.5. of the *Terrestrial Code* (2011),
as a 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 legislation 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, modified stamping-out), 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 8.5.10. 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. 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 8.5.42. to 8.5.47. and Article 8.5.49. 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 centers? 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, 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 8.5.4. are properly implemented and supervised, the Delegate of the 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 8.5.10.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 8.5.9. 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 which applies for recognition of status,
under Chapter 8.5. of the *Terrestrial Code* (2011),
as a 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 legislation 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, modified stamping-out), 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 8.5.10. 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) 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 8.5.42. to 8.5.47. and Article 8.5.49. 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 8.5.46.? 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 centers? 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, 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 8.5.5. are properly implemented and supervised, the Delegate of the 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 8.5.42. to 8.5.47. and Article 8.5.49. is in operation.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 8.5.9. 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.

Article 1.6.5.

Questionnaire on rinderpest

RINDERPEST FREE COUNTRY

Report of a Member which applies for recognition of status,
under Chapter 8.12. of the *Terrestrial Code* (2011),
as a rinderpest 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 rinderpest 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 legislation in relation to rinderpest.

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 rinderpest related activities. Provide maps and tables wherever possible.

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

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

3. Rinderpest eradication

a) History. Provide a description of the rinderpest history in the country, date of first detection, origin of *infection*, date of eradication (date of last *case*), lineage(s) present.

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

c) Vaccines and vaccination. Was rinderpest vaccine ever used? If so, when was the last vaccination carried out? What species were vaccinated? Has heterologous vaccine been used in cattle, buffalo or yak?

d) Legislation, organisation and implementation of the rinderpest 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. Rinderpest 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 2.1.15. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

a) Is rinderpest 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 rinderpest 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. Rinderpest surveillance

Provide documentary evidence that *surveillance* for rinderpest in the country complies with the provisions of Articles 8.12.20. to 8.12.27. of the *Terrestrial Code* and Chapter 2.1.15. of the *Terrestrial Manual*. In particular, the following points should be addressed:

a) Clinical suspicion. What are the criteria for raising a suspicion of rinderpest? 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 rinderpest virus, species, type of sample, testing method(s) and

results (including differential diagnosis). In particular, provide evidence of compliance with the provisions of Articles 8.12.20. to 8.12.27. of the *Terrestrial Code*.

b) Serological surveillance. Are serological surveys conducted? If so, provide detailed information on the survey design in accordance with Articles 8.12.20. to 8.12.27. of the *Terrestrial Code* (see footnote [1]). 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 rinderpest 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) 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 centers? What are the patterns of livestock movement within the country? How are the *animals* transported and handled during these transactions?

6. Rinderpest 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* 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.

a) 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.

b) 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:

i) *animals*,

ii) genetic material (semen and embryos),

iii) animal products,

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

c) 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 rinderpest.

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 rinderpest *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 rinderpest;

iii) indicate the control and/or eradication procedures (e.g. vaccination, stamping-out, 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*

The Delegate of the country must submit documentary evidence that the provisions of Article 8.12.2. or point 1 of Article 1.4.6. (historical freedom) of the *Terrestrial Code* have been properly implemented and supervised.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 8.12.3. 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 1.6.6.

Questionnaires on contagious bovine pleuropneumonia

CONTAGIOUS BOVINE PLEUROPNEUMONIA FREE COUNTRY

Report of a Member which applies for recognition of status,
under Chapter 11.8. of the *Terrestrial Code* (2011),
as a bovine contagious pleuropneumonia 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 legislation 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, modified stamping-out, 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.

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, 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 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

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.

CONTAGIOUS BOVINE PLEUROPNEUMONIA FREE ZONE

Report of a Member which applies for recognition of status,
under Chapter 11.8. of the *Terrestrial Code* (2011),
as a bovine contagious pleuropneumonia infection 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 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 legislation 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, modified stamping-out, 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.

f) Slaughterhouses and markets. Where are the major livestock marketing or collection centers? 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 *Mmm*SC 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 occytes,
- 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, 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 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 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

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.

Questionnaire on foot and mouth disease

COUNTRY WITH AN OIE ENDORSED OFFICIAL CONTROL PROGRAMME FOR FMD

Report of a Member which applies for endorsement of status,
under Chapter 8.5. of the *Terrestrial Code* (2011),
as a Member with an endorsed official control programme for FMD

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 any *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 legislation in relation to the FMD control programme.

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 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*. Submit a detailed plan on the measures to control and eventually eradicate FMD in the country. Include the timelines of the control programme and the performance indicators to assess the efficacy of the control measures and plan.

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. Describe the funding for the control programme and annual budgets for the duration of the control programme.

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 (e.g. vaccination coverage, population immunity, etc.). Provide details on the studies carried out to determine the population immunity, including the study design. Provide details, if applicable, on a proposed timeline for the transition to the use of vaccines fully compliant with the standards and methods described in the *Terrestrial Manual* to enable demonstration of absence of virus circulation.

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 8.5.42. to 8.5.47. and Article 8.5.49. 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* (e.g. farms, markets, fairs, *slaughterhouse*, check points, etc.). Provide criteria for selection of populations for targeted *surveillance* and numbers of *animals*s 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 (e.g. *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) 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 (e.g. 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) 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 imported *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/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,
      - 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 official 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 a 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 and/or eradication procedures (e.g. vaccination, stamping-out, partial *slaughter*/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/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. Recovery of status

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 8.5.48. of the *Terrestrial Code*.

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1 Accounts of the ages for eruption of the incisor teeth vary markedly and are clearly dependent on species, breed, nutritional status and nature of the feed. Therefore, for the purposes of serosurveillance, it should be noted that a) cattle having only one pair of erupted permanent central incisor teeth are aged between 21 and 36 months (Asian buffalos 24-48 months) and b) cattle having only two pairs of erupted permanent central incisor teeth are aged between 30 and 48 months (Asian buffalos 48-60 months).

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*.

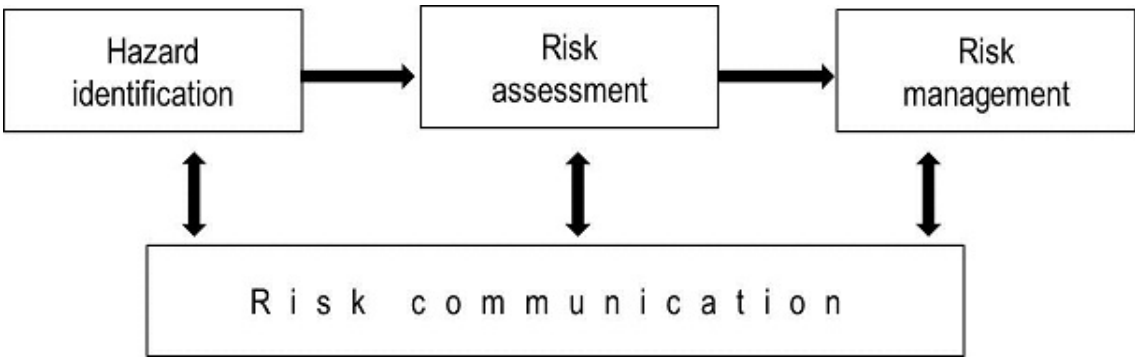
The principal aim of import *risk analysis* is to provide *importing countries* with an objective and defensible method of assessing the *disease risks* associated with the importation of *animals*, animal products, animal genetic material, feedstuffs, biological products and *pathological material*. 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.

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. Release assessment

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

   a) Biological factors

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

   b) Country factors

      - incidence/prevalence
      - evaluation of *Veterinary Services*, *surveillance* and control programmes and zoning 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 release assessment demonstrates no significant *risk*, the *risk assessment* does not need to continue.

2. Exposure assessment

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

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

   a) Biological factors

      - properties of the agent.

   b) Country factors

      - presence of potential vectors
      - human and animal demographics
      - customs and cultural practices
      - geographical and environmental characteristics.

c) Commodity factors

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

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

3. Consequence assessment

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

a) Direct consequences

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

b) Indirect consequences

- *surveillance* and control costs
- compensation costs
- potential trade losses
- adverse consequences to the environment.

4. Risk estimation

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

For a quantitative assessment, the final outputs may include:

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

Article 2.1.5.

Principles of risk management

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

consequences and its desire to import *commodities* and fulfil its obligations under *international trade* agreements.

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

Article 2.1.6.

Risk management components

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

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

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

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 is important to the establishment and maintenance of confidence in its *international veterinary certificates* by the *Veterinary Services* of other Members.

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 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 Members 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 should recognise the right of another Member to undertake, or request it to undertake, an evaluation of its *Veterinary Services* where the initiating Member 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 has the right to expect that the evaluation of its *Veterinary Services* will be conducted in an objective manner. A Member undertaking evaluation should be able to justify any measure taken as a consequence of its evaluation.

Article 3.1.4.

A Member which intends to conduct an evaluation of another Member'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, and following bilateral agreement of the evaluation process and criteria, a Member 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 should be provided in writing as soon as possible, and in any case within 4 months of receipt of the relevant information, to the Member which has undergone the evaluation. The evaluation report should detail any findings which affect trade prospects. The Member which conducts the evaluation should clarify in detail any points of the evaluation on request.

In the event of a dispute between two Members 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, upon request by the Member.

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 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.

The report is submitted to the Director General of the OIE and, with the consent of the Member, 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. In applying these recommendations on the evaluation, the OIE *Tool for the Evaluation of Performance of Veterinary Services* (OIE *PVS Tool*) should be used.

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

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

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

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

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

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

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

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

Article 3.2.2.

Scope

1. In the evaluation of *Veterinary Services*, the following items may be considered, depending on the purpose of the evaluation:
   - organisation, structure and authority of the *Veterinary Services*;
   - human resources;
   - material (including financial) resources;
   - *veterinary legislation*, regulatory frameworks and functional capabilities;
   - animal health, *animal welfare* and veterinary public health controls;
   - formal quality systems including quality policy;
   - performance assessment and audit programmes;
   - participation in OIE activities and compliance with OIE Members' obligations.
2. To complement the evaluation of *Veterinary Services*, the legislative and regulatory framework, the organisational structure and functioning of the *veterinary statutory body* should also be considered.
3. Article 3.2.14. outlines appropriate information requirements for:
   - self-evaluation by the *Veterinary Authority* which perceives a need to prepare information for national or international purposes;
   - evaluation by a prospective or actual *importing country* of the *Veterinary Services* of a prospective or actual *exporting country*;
   - verification or re-verification of an evaluation in the course of a visit to the *exporting country* by the *importing country*;
   - evaluation by third parties such as OIE PVS experts or regional organisations.

Article 3.2.3.

Evaluation criteria for the organisational structure of the Veterinary Services

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

the *Veterinary Services*. Formal relationships with statutory authorities and with industry organisations and associations should also be described. It is recognised that Services may be subject to changes in structure from time to time. Major changes should be notified to trading partners so that the effects of re-structuring may be assessed.

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

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

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

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

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

Article 3.2.4.

Evaluation criteria for quality systems

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

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

Article 3.2.5.

Evaluation criteria for human resources

1. The *Veterinary Services* should demonstrate that their human resource component includes an integral core of full-time civil service employees. This core should always include *veterinarians*. It should also include administrative officials and *veterinary para-professionals*. The human resources may also include part-time and private sector *veterinarians* and *veterinary para-professionals*. It is essential that all the

above categories of personnel be subject to legal disciplinary provisions. Data relating to the resource base of the *Veterinary Services* undergoing evaluation should be available.

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

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

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

Article 3.2.6.

Evaluation criteria for material resources

1. Financial

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

2. Administrative

   a) Accommodation

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

   b) Communications

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

      Examples of types of communications which should be routinely available on an adequate country-wide basis are national postal, freight and telephone networks. Rapid courier services, facsimile and electronic data interchange systems (e.g. e-mail and Internet services) are examples

of useful communication services which, if available, can supplement or replace the others. A means for rapid international communication should be available to the *Veterinary Authority*, to permit reporting of changes in national disease status consistent with OIE recommendations and to allow bilateral contact on urgent matters with counterpart *Veterinary Authorities* in trading-partner countries.

c) Transport systems

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

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

3. Technical

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

a) Cold chain for laboratory samples and veterinary medicines

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

b) Diagnostic laboratories

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

This emphasis is valid whether one relates it to the actual testing performed on individual export consignments or to the more broad and ongoing testing regimes which are used to determine the animal health and veterinary public health profiles of the country and to support its disease control programmes. For the purposes of evaluation, veterinary diagnostic laboratories include those which are concerned with either animal health or veterinary public health activities. The *Veterinary Services* should approve and designate these laboratories for such purposes and have them audited regularly.

c) Research

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

Article 3.2.7.

Legislation and functional capabilities

1. Animal health, animal welfare and veterinary public health

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

2. Export/import inspection

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

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

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

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

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

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

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

Article 3.2.8.

Animal health controls

1. Animal health status

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

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

2. Animal health control

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

3. National animal disease reporting systems

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

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

Article 3.2.9.

Veterinary public health controls

1. Food hygiene

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

2. Zoonoses

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

3. Chemical residue testing programmes

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

4. Veterinary medicines

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

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

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

5. Integration between animal health controls and veterinary public health

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

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

Article 3.2.10.

Performance assessment and audit programmes

1. Strategic plans

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

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

2. Performance assessment

   If a strategic plan is used, it is desirable to have a process which allows the organisation to assess its own performance against its objectives. Performance indicators and the outcomes of any review to measure achievements against pre-determined performance indicators should be available for evaluation. The results should be considered in the evaluation process.

3. Compliance

   Matters which can compromise compliance and adversely affect a favourable evaluation include instances of inaccurate or misleading official certification, evidence of fraud, corruption, or interference by higher political levels in international veterinary certification, and lack of resources and poor infrastructure.

   It is desirable that the *Veterinary Services* contain (or have a formal linkage with) an independent internal unit/section/commission the function of which is to critically scrutinise their operations. The aim of this unit should be to ensure consistent and high integrity in the work of the individual officials in the *Veterinary Services* and of the corporate body itself. The existence of such a body can be important to the establishment of international confidence in the *Veterinary Services*.

   An important feature when demonstrating the integrity of the *Veterinary Services* is their ability to take corrective action when miscertification, fraud or corruption has occurred.

   A supplementary or an alternative process for setting performance standards and application of monitoring and audit is the implementation of formal quality systems to some or all activities for which the *Veterinary Services* are responsible. Formal accreditation to international quality system standards should be utilised if recognition in the evaluation process is to be sought.

4. Veterinary Services administration

   a) Annual reports

      Official government annual reports should be published, which provide information on the organisation and structure, budget, activities and contemporary performance of the *Veterinary Services*. Current and retrospective copies of such reports should be available to counterpart Services in other countries, especially trade partners.

   b) Reports of government review bodies

      The reports of any periodic or ad hoc government reviews of *Veterinary Services* or of particular functions or roles of the *Veterinary Services* should be considered in the evaluation process. Details of action taken as a consequence of the review should also be accessible.

c) Reports of special committees of enquiry or independent review bodies

Recent reports on the *Veterinary Services* or elements of their role or function, and details of any subsequent implementation of recommendations contained in these reports should be available. The *Veterinary Services* concerned should recognise that the provision of such information need not be detrimental to the evaluation outcome; in fact, it may demonstrate evidence of an effective audit and response programme. The supplying of such information can reinforce a commitment to transparency.

d) In-service training and development programme for staff

In order to maintain a progressive approach to meeting the needs and challenges of the changing domestic and international role of *Veterinary Services*, the national administration should have in place an organised programme which provides appropriate training across a range of subjects for relevant staff. This programme should include participation in scientific meetings of animal health organisations. Such a programme should be used in assessing the effectiveness of the Services.

e) Publications

Veterinary Services can augment their reputation by demonstrating that their staff publish scientific articles in refereed veterinary journals or other publications.

f) Formal linkages with sources of independent scientific expertise

Details of formal consultation or advisory mechanisms in place and operating between the *Veterinary Services* and local and international universities, scientific institutions or recognised veterinary organisations should be taken into consideration. These could serve to enhance the international recognition of the *Veterinary Services*.

g) Trade performance history

In the evaluation of the *Veterinary Services* of a country, it is pertinent to examine the recent history of their performance and integrity in trade dealings with other countries. Sources of such historical data may include Customs Services.

Article 3.2.11.

Participation in OIE activities

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

Article 3.2.12.

Evaluation of veterinary statutory body

1. Scope

In the evaluation of the *veterinary statutory body*, the following items may be considered, depending on the purpose of the evaluation:

a) objectives and functions;

b) legislative basis, autonomy and functional capacity;

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

d) accountability and transparency of decision-making;

e) sources and management of funding;

f) administration of training programmes and continuing professional development for *veterinarians* and *veterinary para-professionals*.

2. Evaluation of objectives and functions

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

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

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

c) to determine the standards of professional conduct of *veterinarians* and *veterinary para-professionals* and to ensure these standards are met.

3. Evaluation of legislative basis, autonomy and functional capacity

The *veterinary statutory body* should be able to demonstrate that it has the capacity, supported by appropriate legislation, to exercise and enforce control over all *veterinarians* and *veterinary para-professionals*. These controls should include, where appropriate, compulsory licensing and registration, minimum standards of education (initial and continuing) for the recognition of degrees, diplomas and certificates, setting standards of professional conduct and exercising control and the application of disciplinary procedures.

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

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

4. Evaluation of membership representation

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

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

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

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

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

e) representative(s) of veterinary academia;

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

g) election procedures and duration of appointment;

h) qualification requirements for members.

5. Evaluation of accountability and transparency of decision-making

Detailed information should be available on disciplinary procedures regarding the conducting of enquiries into professional misconduct, transparency of decision-making, publication of findings, sentences and mechanisms for appeal.

Additional information regarding the publication at regular intervals of activity reports, lists of registered or licensed persons including deletions and additions should also be taken into consideration.

6. Evaluation of financial sources and financial management

   Information regarding income and expenditure, including fee structure(s) for the licensing/registration of persons should be available.

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

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

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/licensed by the *Veterinary statutory body* of the country.

ii) Numbers of:

- full time government *veterinarians*: national and sub-national;
- part time government *veterinarians*: national and sub-national;
- private *veterinarians* authorised by the *Veterinary Services* to perform official veterinary functions *[Describe accreditation standards, responsibilities and/or limitations applying to these private veterinarians.]*;
- other *veterinarians*.

iii) Animal health:

Numbers associated with farm livestock sector on a majority time basis in a veterinary capacity, by geographical area *[Show categories and numbers to differentiate staff involved in field service, laboratory, administration, import/export and other functions, as applicable.]*:

- full time government *veterinarians*: national and sub-national;
- part time government *veterinarians*: national and sub-national;
- other *veterinarians*.

iv) Veterinary public health:

Numbers employed in food inspection on a majority time basis, by commodity *[Show categories and numbers to differentiate staff involved in inspection, laboratory and other functions, as applicable.]*:

- full time government *veterinarians*: national and sub-national;
- part time government *veterinarians*: national and sub-national;
- other *veterinarians*.

v) Numbers of veterinarians relative to certain national indices:

- per total human population;
- per farm livestock population, by geographical area;
- per livestock farming unit, by geographical area.

vi) Veterinary education:

- number of veterinary schools;
- length of veterinary course (years);
- curriculum addressing the minimum competencies of day 1 veterinary graduates to assure the delivery of quality veterinary services, as described in the relevant chapter(s) of the *Terrestrial Code*;
- international recognition of veterinary degree.

vii) Veterinary professional associations.

b) Graduate personnel (non-veterinary)

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

c) Veterinary para-professionals employed by the Veterinary Services

i) Animal health:

- Categories and numbers involved with farm livestock on a majority time basis:
  - by geographical area;

- proportional to numbers of field Veterinary Officers in the *Veterinary Services*, by geographical area.

- Education/training details.

ii) Veterinary public health:

- Categories and numbers involved in food inspection on a majority time basis:
  - *meat* inspection: export *meat* establishments with an export function and domestic *meat* establishments (no export function);
  - dairy inspection;
  - other foods.
- Numbers in import/export inspection.
- Education/training details.

d) Support personnel

Numbers directly available to *Veterinary Services* per sector (administration, communication, transport).

e) Descriptive summary of the functions of the various categories of staff mentioned above

f) Veterinary, *veterinary para-professionals*, livestock owner, farmer and other relevant associations

g) Additional information and/or comments.

3. Financial management information

a) Total budgetary allocations to the *Veterinary Authority* for the current and past two fiscal years:

i) for the national *Veterinary Authority*;

ii) for each of any sub-national components of the *Veterinary Authority*;

iii) for other relevant government-funded institutions.

b) Sources of the budgetary allocations and amount:

i) government budget;

ii) sub-national authorities;

iii) taxes and fines;

iv) grants;

v) private services.

c) Proportional allocations of the amounts in a) above for operational activities and for the programme components of *Veterinary Services*.

d) Total allocation proportionate of national public sector budget. *[This data may be necessary for comparative assessment with other countries which should take into account the contexts of the importance of the livestock sector to the national economy and of the animal health status of the country.]*

e) Actual and proportional contribution of animal production to gross domestic product.

4. Administration details

a) Accommodation

Summary of the numbers and distribution of official administrative centres of the *Veterinary Services* (national and sub-national) in the country.

b) Communications

Summary of the forms of communication systems available to the *Veterinary Services* on a nation-wide and local area bases.

c) Transport

i) Itemised numbers of types of functional transport available on a full-time basis for the *Veterinary Services*. In addition provide details of transport means available part-time.

ii) Details of annual funds available for maintenance and replacement of motor vehicles.

5. Laboratory services

a) Diagnostic laboratories (laboratories engaged primarily in diagnosis)

i) Descriptive summary of the organisational structure and role of the government veterinary laboratory service in particular its relevance to the field *Veterinary Services*.

ii) Numbers of veterinary diagnostic laboratories operating in the country:

- government operated laboratories;
- private laboratories accredited by government for the purposes of supporting official or officially-endorsed animal health control or public health testing and monitoring programmes and import/export testing.

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

iv) Human and financial resources allocated to the government veterinary *laboratories*, including staff numbers, graduate and post-graduate qualifications and opportunities for further training.

v) List of diagnostic methodologies available against major *diseases* of farm livestock (including *poultry*).

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

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

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

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

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

xi) Strategic and operational plans for the official veterinary laboratory service (if available).

b) Research laboratories (laboratories engaged primarily in research)

i) Numbers of veterinary research *laboratories* operating in the country:

- government operated *laboratories*;
- private *laboratories* involved in full time research directly related to animal health and veterinary public health matters involving production animal species.

ii) Summary of human and financial resources allocated by government to veterinary research.

iii) Published programmes of future government sponsored veterinary research.

iv) Annual reports of the government research *laboratories*.

6. Veterinary legislation, regulations and functional capabilities

a) Animal health and veterinary public health

i) Assessment of the adequacy and implementation of relevant legislation (national or sub-national) concerning the following:

- animal and veterinary public health controls at national frontiers;

- control of endemic animal diseases, including *zoonoses*;
- emergency powers for control of exotic disease outbreaks, including *zoonoses*;
- inspection and registration of facilities;
- animal feeding;
- veterinary public health controls of the production, processing, storage and marketing of *meat* for domestic consumption;
- veterinary public health controls of the production, processing, storage and marketing of fish, dairy products and other foods of animal origin for domestic consumption;
- registration and use of veterinary pharmaceutical products including vaccines;
- *animal welfare*.

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

b) Export/import inspection

i) Assessment of the adequacy and implementation of relevant national legislation concerning:

- veterinary public health controls of the production, processing, storage and transportation of *meat* for export;
- veterinary public health controls of production, processing, storage and marketing of fish, dairy products and other foods of animal origin for export;
- animal health and veterinary public health controls of the export and import of *animals*, animal genetic material, animal products, animal feedstuffs and other products subject to veterinary inspection;
- animal health controls of the importation, use and bio-containment of organisms which are aetiological agents of animal diseases, and of pathological material;
- animal health controls of importation of veterinary biological products including vaccines;
- administrative powers available to *Veterinary Services* for inspection and registration of facilities for veterinary control purposes (if not included under other legislation mentioned above);
- documentation and compliance.

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

7. Animal health and veterinary public health controls

a) Animal health

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

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

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

- epidemiological surveillance or monitoring programmes;
- officially approved industry administered control or eradication programmes for specific *diseases*.

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

v) Recent history of animal disease status:

- animal *diseases* eradicated nationally or from defined sub-national zones in the last ten years;
- animal *diseases* of which the prevalence has been controlled to a low level in the last ten years;
- animal *diseases* introduced to the country or to previously free sub national regions in the last ten years;
- *emerging diseases* in the last ten years;
- animal *diseases* of which the prevalence has increased in the last ten years.

b) Veterinary public health

i) Food hygiene

- Annual national *slaughter* statistics for the past three years according to official data by species of *animals* (bovine, ovine, porcine, caprine, *poultry*, farmed game, wild game, equine, other).
- Estimate of total annual slaughterings which occur but are not recorded under official statistics.
- Proportion of total national *slaughter* which occurs in registered export establishments, by category of *animal*.
- Proportion of total national *slaughter* which occurs under veterinary control, by category of *animal*.
- Numbers of commercial *fresh meat* establishments in the country which are registered for export by the *Veterinary Authority*:
  - *slaughterhouses* (indicate species of *animals*);
  - cutting/packing plants (indicate *meat* type);
  - *meat* processing establishments (indicate *meat* type);
  - cold stores.
- Numbers of commercial *fresh meat* establishments in the country approved by other *importing countries* which operate international assessment inspection programmes associated with approval procedures.
- Numbers of commercial *fresh meat* establishments under direct public health control of the *Veterinary Services* (including details of category and numbers of inspection staff associated with these premises).
- Description of the veterinary public health programme related to production and processing of animal products for human consumption (including *fresh meat*, *poultry meat*, *meat products*, game *meat*, dairy products, fish, fishery products, molluscs and crustaceans and other foods of animal origin) especially including details applying to exports of these *commodities*.
- Descriptive summary of the roles and relationships of other official organisations in public health programmes for the products listed above if the *Veterinary Authority* does not have responsibility for those programmes which apply to national production destined to domestic consumption and/or exports of the *commodities* concerned.

ii) Zoonoses

- Descriptive summary of the numbers and functions of staff of the *Veterinary Authority* involved primarily with monitoring and control of zoonotic diseases.

- Descriptive summary of the role and relationships of other official organisations involved in monitoring and control of *zoonoses* to be provided if the *Veterinary Authority* does not have these responsibilities.

iii) Chemical residue testing programmes

- Descriptive summary of national surveillance and monitoring programmes for environmental and chemical residues and contaminants applied to animal-derived foodstuffs, *animals* and animal feedstuffs.
- Role and function in these programmes of the *Veterinary Authority* and other *Veterinary Services* to be described in summary form.
- Descriptive summary of the analytical methodologies used and their consistency with internationally recognised standards.

iv) Veterinary medicines

- Descriptive summary of the administrative and technical controls involving registration, supply and use of veterinary pharmaceutical products especially including biological products. This summary should include a focus on veterinary public health considerations relating to the use of these products in food-producing *animals*.
- Role and function in these programmes of the *Veterinary Authority* and other *Veterinary Services* to be described in summary form.

8. Quality systems

a) Accreditation

Details and evidence of any current, formal accreditation by external agencies of the *Veterinary Services* of any components thereof.

b) Quality manuals

Documented details of the quality manuals and standards which describe the accredited quality systems of the *Veterinary Services*.

c) Audit

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

9. Performance assessment and audit programmes

a) Strategic plans and review

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

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

b) Compliance

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

c) Annual reports of the Veterinary Authority

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

d) Other reports

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

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

e) Training

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

ii) Summary descriptions of training courses and duration.

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

f) Publications

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

g) Sources of independent scientific expertise

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

10. Membership of the OIE

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

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 expertises is essential for effective communication.

Communication should be an integral part of all the activities of the *Veterinary Services* including animal health (*surveillance*, early detection and rapid response, prevention and control), *animal welfare* and veterinary public health (food safety, *zoonoses*) and veterinary medicine.

Objectives of this chapter on communication for the *Veterinary Services* are to provide guidance for the development of a communication system, strategic and operational communication plans and elements to assess their quality.

Article 3.3.2.

Principles of communication

1. *Veterinary Services* should have the authority and capability to communicate on matters within their mandate.
2. Veterinary and communication 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 be responsible for planning, implementing, monitoring, evaluating and revising their strategic and operational communication plans.

Article 3.3.3.

Definitions

Communication: means the discipline of informing, guiding and motivating individual, institutional and public groups, ideally on the basis of interactive exchanges, about any issue under the competence of the *Veterinary Services*.

Crisis: means a situation of great threat, difficulty or uncertainty when issues under the competence of the *Veterinary Services* require immediate action.

Crisis communication: means the process of communicating information of potentially incomplete nature within time constraints in the event of a crisis.

Outbreak communication: means the process of communicating in the event of an *outbreak*. Outbreak communication includes notification.

Article 3.3.4.

Communication system

In addition to the Principles for Communication the following elements should be used in conjunction with Chapter 3.1., when planning, implementing and assessing a communication system:

1. Organisational chart indicating a direct link between the communication personnel and the Veterinary Authority, through the chain of command (e.g. dedicated communication unit, communication officer)

2. Human resources

    a) Identified and accessible official communication focal point

    b) Job descriptions of communication personnel identifying roles and responsibilities

    c) Sufficient number of qualified personnel with knowledge, skills, attitude and abilities relevant to communication

    d) Continuous training and education on communication provided to communication personnel.

3. Financial and physical resources

    a) Clearly identified budget for communication that provides adequate funding

    b) Provision and/or access to appropriate material resources in order to carry out roles and responsibilities: suitable premise/accommodation that is adequately equipped with sufficient office and technical equipment, including information technology and access to the Internet.

4. Management of the communication system

    a) Roles and responsibilities of the communication personnel

        i) Report to the *Veterinary Authority*

        ii) Engage in decision-making process

        iii) Be responsible for the planning, implementation and evaluation of the strategic and operational plans for communication and relevant standard operating procedures

        iv) Function as contact point on communication issues for the *Veterinary Services*

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

        vi) Provide and coordinate continuous education on communication for the *Veterinary Services*.

    b) Strategic plan for communication

        A well-designed strategic plan for communication should support the *Veterinary Services* strategic plan and have management support and commitment. The strategic plan for communication should address all high level organization-wide communication objectives. The plan should be a long-term plan.

        A strategic plan for communication should be monitored, periodically reviewed and should identify measurable performance objectives and techniques to assess.

The strategic plan for communication should consider the different types of communication: routine communication, risk communication, outbreak communication and crisis communication, to allow individuals, affected and/or interested parties, an entire community or the general public to make best possible decisions and be informed of and/or accept policy decisions and their rationale.

The key outcomes in effectively implementing a strategic plan for communication are increased knowledge and awareness of issues by the public and stakeholders, higher understanding of the role of the *Veterinary Services*, higher visibility of and improved trust and credibility in the *Veterinary Services*. These will enhance understanding and/or acceptance of policy decisions and subsequent change of perception, attitude and/or behaviour.

c) Operational plans for communication

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

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

SECTION 4.

GENERAL RECOMMENDATIONS: DISEASE PREVENTION AND CONTROL

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.

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 Members 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* where the event took place, and the code for the event itself.

i) 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.

ii) 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,
- 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:

i) desired outcomes and scope;

ii) obligations of the *Veterinary Authority* and other parties;

iii) organisational arrangements, including the choice of technologies and methods used for the *animal identification system* and *animal traceability*;

iv) management of animal movement;

v) confidentiality of data;

vi) data access / accessibility;

vii) checking, verification, inspection and penalties;

viii) where relevant, funding mechanisms;

ix) 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 OIE Members. 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 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 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 OIE Members 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'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 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*, Members 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 Members 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 OIE Members. 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*, OIE Members 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 the Members 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. of the *Terrestrial Code*.

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 in the event of a change in the level of exposure;

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*. 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.

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. on the Evaluation of *Veterinary Services* of the *Terrestrial Code*, 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.

Article 4.5.4.

Conditions applicable to semen laboratories

1. The semen laboratory should be physically separated from the semen collection facilities, and include separate areas for artificial vagina cleaning and preparation, semen evaluation and processing, semen pre-storage and storage. Entry to the laboratory should be prohibited to unauthorised personnel.
2. The laboratory personnel should be technically competent and observe high standards of personal hygiene to preclude the introduction of pathogenic organisms during semen evaluation, processing and storage.
3. Visitors to the laboratory should be kept to a minimum, and visits should be subject to formal authorisation and control.
4. The laboratory should be constructed with materials that permit effective cleaning and *disinfection*.
5. The laboratory should be regularly cleaned. Work surfaces for semen evaluation and processing should be cleaned and disinfected at the end of each workday.
6. The laboratory should be treated against rodents and insects on a regular basis as needed to control these pests.
7. The storage rooms and individual semen containers should be easy to clean and disinfect.

8. Only semen collected from donors having a health status equivalent to or better than the donors at the semen collection facilities should be processed in the laboratory.

Article 4.5.5.

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-mucosal disease (BVD-MD)

      The *animals* should be subjected to:

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

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

   d) Infectious bovine rhinotracheitis-infectious pustular vulvovaginitis

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

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

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

   e) Bluetongue

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

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

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

a) Bovine brucellosis

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

b) BVD-MD

i) All *animals* should be tested for viraemia as described in point 1c) above.

Only when all the *animals* in pre-entry isolation test negative for viraemia, may the *animals* enter the semen collection facilities upon completion of the 28–day pre-entry isolation period.

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

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

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

c) *Campylobacter fetus* subsp. *venerealis*

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

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

d) *Tritrichomonas foetus*

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

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

e) IBR-IPV

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

f) Bluetongue

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

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

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

a) Bovine brucellosis

b) Bovine tuberculosis

c) BVD-MD

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

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

d) *Campylobacter fetus* subsp. *venerealis*

i) A preputial specimen should be tested.

ii) Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a 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-MD prior to the initial dispatch of semen from each serologically positive bull

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

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

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

Article 4.6.3.

Conditions applicable to testing of rams/bucks and teaser animals

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

1. Prior to entering pre-entry isolation facility

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

   a) Caprine and ovine brucellosis – Article 14.1.6.

   b) Ovine epididymitis – Article 14.7.3.

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

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

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

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

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

   h) Maedi-visna – Article 14.6.2.

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

   j) Bluetongue

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

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

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

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

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

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

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

   d) Bluetongue

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

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

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

   a) caprine and ovine brucellosis;

   b) ovine epididymitis;

   c) Maedi-visna and caprine arthritis/encephalitis;

d) tuberculosis (for goats only);

e) bluetongue.

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

Article 4.6.4.

Conditions applicable to testing of boars

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

1. Prior to entering pre-entry isolation facility

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

a) Porcine brucellosis – Article 15.3.3.

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

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

d) Transmissible gastroenteritis – Article 15.5.2.

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

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

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

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

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

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

a) Porcine brucellosis – Article 15.3.5.

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

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

d) Transmissible gastroenteritis – Article 15.5.4.

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

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

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

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

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

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

a) Porcine brucellosis – Article 15.3.5.

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

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

d) Transmissible gastroenteritis – Article 15.5.4.

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

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

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

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

Article 4.6.5.

General considerations for hygienic collection and handling of semen

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

Article 4.6.6.

Conditions applicable to the collection of semen

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

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

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

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

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

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

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

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

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

Article 4.6.7.

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

1. Diluents

   a) All receptacles used should have been sterilised.

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

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

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

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

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

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

2. Procedure for dilution and packing

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

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

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

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

3. Conditions applicable to the storage of semen

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

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

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

4. Sperm sorting

Equipment used for sex-sorting sperm should be clean and disinfected between *animals* according to the recommendations of the licencer of the system.

Where seminal plasma, or components thereof, is added to sorted semen prior to cryopreservation and storage, it should be derived from *animals* of same or better health status.

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

CHAPTER 4.7.

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

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*.

2. While embryos for export are being handled prior to their storage in ampoules, vials or straws, no embryos of a lesser health status should be processed.

3. The processing laboratory should be protected against rodents and insects.

4. The processing laboratory should be constructed with materials which permit its effective cleansing and *disinfection*. This should be done frequently, and always before and after each occasion on which embryos for export are processed.

Article 4.7.4.

Conditions applicable to the introduction of donor animals

1. Donor animals

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

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

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

2. Semen donors

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

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

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

Article 4.7.5.

Risk management

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Article 4.7.6.

Conditions applicable to the collection and storage of embryos

1. Media

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

2. Equipment

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

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

Article 4.7.7.

Optional tests and treatments

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

   a) Non-viable embryos/oocytes

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

   b) Embryo collection (flushing) fluids

      The collection fluid should be placed in a sterile, closed container and, if there is a large amount, it should be allowed to stand undisturbed for one hour. The supernatant fluid should then be removed and the bottom 10–20 ml, along with accumulated debris, decanted into a sterile bottle. If a filter is used in the collection of embryos/oocytes then any debris that is retained on the filter should be rinsed off into the retained fluid.

   c) Washing fluids

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

   d) Samples

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

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

Article 4.7.8.

Conditions applicable to the storage and transport of embryos

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

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

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

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

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

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

Article 4.7.9.

Procedure for micromanipulation

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

Article 4.7.10.

Specific conditions applicable to porcine embryos

The *herd* of origin should be free of clinical signs of swine vesicular disease and brucellosis.

The development of effective cryopreservation methods for the storage of zona pellucida-intact porcine embryos is still at a very early stage.

Article 4.7.11.

Specific conditions/comments applicable to equine embryos

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

Article 4.7.12.

Specific conditions/comments applicable to camelid embryos

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

Article 4.7.13.

Specific conditions/comments applicable to cervid embryos

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

Article 4.7.14.

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

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

1. Category 1

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

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

      - Aujeszky's disease (pseudorabies) (swine): trypsin treatment required
      - Bluetongue (cattle)
      - Bovine spongiform encephalopathy (cattle)
      - *Brucella abortus* (cattle)
      - Enzootic bovine leukosis
      - Foot and mouth disease (cattle)
      - Infectious bovine rhinotracheitis: trypsin treatment required
      - Scrapie (sheep).

2. Category 2

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

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

      - Bluetongue (sheep)
      - Caprine arthritis/encephalitis
      - Classical swine fever (hog cholera).

3. Category 3

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

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

      - Bovine immunodeficiency virus
      - Bovine spongiform encephalopathy (goats)
      - Bovine viral diarrhea virus (cattle)
      - *Campylobacter fetus* (sheep)

- Foot and mouth disease (swine, sheep and goats)
- *Haemophilus somnus* (cattle)
- Maedi-visna (sheep)
- *Mycobacterium paratuberculosis* (cattle)
- *Neospora caninum* (cattle)
- Ovine pulmonary adenomatosis
- Porcine reproductive and respiratory disease syndrome (PRRS)
- 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[2] between collection and transfer.

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

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

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

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

2 Manual of the International Embryo Transfer Society.

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.

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.

Article 4.8.5.

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:

a) non-viable oocytes/embryos from any stage of the *in vitro* production line from batches intended for export;

b) samples of *in vitro* maturation medium taken prior to mixing the oocytes with semen for the fertilisation process;

c) 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 -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[1] and handled in such a manner as to ensure that sterility is maintained. Antibiotics should be added to all fluids and media as recommended in the IETS Manual[1].

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[1].

Article 4.8.6.

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 4.7.4., 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 Manual1[1]. 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[1];

    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;

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 Manual[1].
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.

1 Manual of the International Embryo Transfer Society.

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 Manual [1] 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[1] and handled in such a manner as to ensure that sterility is maintained. Antibiotics should be added to all fluids and media as recommended in the IETS Manual[1].

2. Equipment

   Equipment (e.g. microsurgical instruments which have direct contact with embryos) should either be of the single-use type (disposed of after each embryo/oocytes batch) or should be effectively sterilised between embryos/oocytes batch in accordance with recommendations in the IETS Manual[1].

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.

Article 4.9.4.

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 that from zona pellucida-intact embryos (e.g. somatic or sperm cells) are used as donors of nuclei for transplantation, then samples or cultures of those donor cells may also be tested.

2. Treatments

Treatments of embryos with the enzyme trypsin or other substances proven to inactivate or remove pathogenic organisms 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[1].

Article 4.9.5.

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.

1 Manual of the International Embryo Transfer Society.

CHAPTER 4.10.

COLLECTION AND PROCESSING OF LABORATORY RODENT AND RABBIT EMBRYOS/OVA

Article 4.10.1.

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[1].

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.

Article 4.10.2.

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[2] 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[2]. 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.
    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 Manual[2].
    d) The zona pellucida of each embryo, after washing, should be examined over its entire surface area at not less than 50X magnification to ensure that it is intact and (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 elsewhere[1].

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 Manual[2].

   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 Manual[2]. 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 Manual[2] 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 Manual[2]. 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.

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1 **Recommendations for the health monitoring of mouse, rat, hamster, guineapig and rabbit breeding colonies**.- Report of the Federation of European Laboratory Animal Science Associations (FELASA), Working Group on Animal Health accepted by the FELASA Board of Management, November 1992.

2 Manual of the International Embryo Transfer Society (1998).

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 for established animal reproductive biotechnologies (see Chapter 4.8.). An analysis of SCNT methodology allows the procedural details to be categorised into:

a) 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.

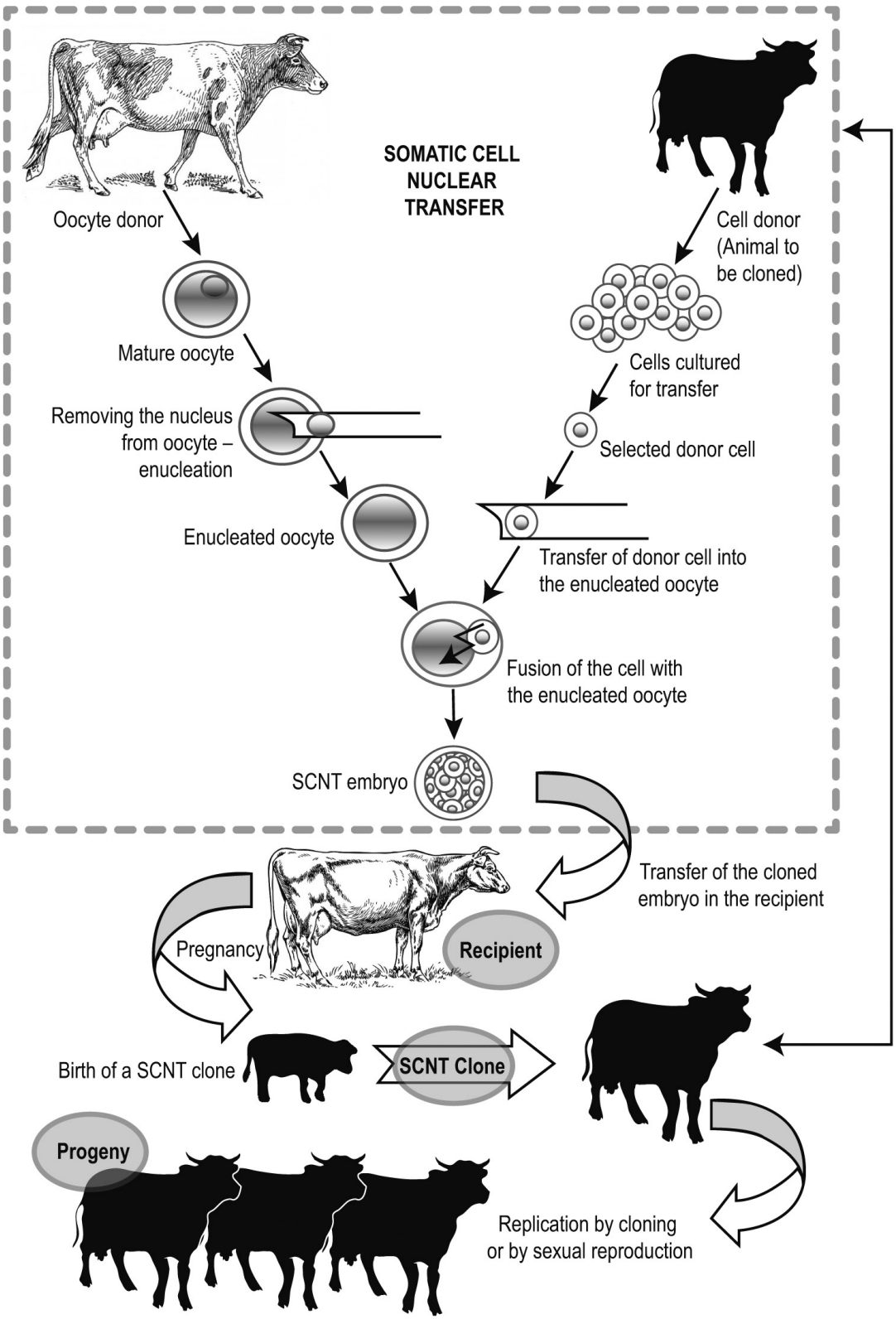
b) Donor cells (cells obtained from animals chosen to be cloned – by biopsy, harvesting at slaughter or after death)

   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.

c) *In vitro* culture of reconstructed embryos (procedure used to fuse the donor and recipient material and to culture the reconstructed embryo)

d) *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 anii, umblical 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.

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 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:

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.

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 alkali conditions of the process destroy the protein coats of viruses and the peptide bonds of prions. Both lipids and nucleic acids are degraded. The process is carried out in an insulated steam-jacketed, stainless steel pressure vessel.

10. Bio-refining

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 180ºC 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 1. ***Decision Making Process***

Method		Rendering		Fixed Incineration		Pyre Burning		Composting		Mass Burial		On-Farm Burial		Commercial Landfill	
	Weight	Utility	Value	Utility	Value	Utility	Value	Utility	Value	Utility	Value	Utility	Value	Utility	Value
Factors															
Operator Safety	20	7	140	4	80	8	160	3	60	7	140	8			
Speed of Resolution	20	8	160	8	160	2	40	5	100	5	100	6			
Pathogen Inactivation	15	10	150	10	150	8	120	5	75	4	60	4			
Impact on Environment	10	10	100	8	80	3	30	10	100	3	30	3			
Reaction of the Public	10	10	100	7	70	1	10	9	90	3	30	4			
Transport Availability	5	1	5	1	5	8	40	5	25	3	15	8			
Acceptable to Industry	5	7	35	7	35	7	35	7	35	6	30	7			
Cost	5	4	20	1	5	6	30	9	45	8	40	9			
Risk to Wildlife	5	10	50	10	50	5	25	4	20	5	25	5			
Capacity to Meet Requirements	5	5	25	3	15	9	45	9	45	9	45	9			
Total Weight to Equal 100 Units	100	sum	785	sum	650	sum	535	sum	595	sum	515	sum		sum	

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 0.1percent histidine and incubated overnight at 37°C. If fumigation has been effective, there will be no bacterial growth.]*

CHAPTER 4.14.

HYGIENE AND DISEASE SECURITY PROCEDURES IN APIARIES

Article 4.14.1.

In each country, official health control of bee *diseases* should include:

a) an organisation for permanent health *surveillance*;

b) approval of breeding apiaries for export trade;

c) measures for cleaning, *disinfection* and *disinfestation* of apicultural equipment;

d) rules precisely stating the requirements for issuing an *international veterinary certificate*.

Article 4.14.2.

Organisation for permanent official sanitary surveillance of apiaries

Permanent official sanitary *surveillance* of apiaries should be under the authority of the *Veterinary Authority* and should be performed either by representatives of this Authority or by representatives of an approved organisation, with the possible assistance of bee-keepers specially trained to qualify as 'health inspectors and advisers'.

The official *surveillance* service thus established should be entrusted with the following tasks:

1. visit apiaries:
    a) annual visits during the most appropriate periods for the detection of *diseases*;
    b) unexpected visits to apiaries where breeding or transport operations are carried out for trade or transfer to other regions, or any other purpose whereby *diseases* could be spread, as well as to apiaries located in the vicinity;
    c) special visits for sanitary *surveillance* to sectors where breeding apiaries have been approved for export purposes;
2. collect the samples required for the diagnosis of contagious *diseases* and despatch them to an official laboratory; the results of laboratory examinations must be communicated within the shortest delay to the *Veterinary Authority*;
3. apply hygiene measures, comprising, in particular, treatment of colonies of bees, as well as *disinfection* of the equipment and possibly the destruction of affected or suspect colonies and of the contaminated equipment so as to ensure rapid eradication of any *outbreak* of a contagious *disease*.

Article 4.14.3.

Conditions for approval of breeding apiaries for export trade

The apiaries must:

1. be situated in the centre of an area defined as follows and in which:
    a) no *case* of varroosis has been reported for at least the past two years within a radius of 50 kilometres;

b) no *case* of any other contagious *disease* of bees included in this *Terrestrial Code* has been reported for at least the past eight months within a radius of five kilometres;

2. have received, for at least the past two years, visits by a health inspector and adviser, carried out at least three times a year (in spring, during the breeding period and in autumn), for the systematic examination of the hives containing bees and of all the apicultural equipment, and for the collection of samples to be sent to an official laboratory.

Bee-keepers must:

3. immediately notify the *Veterinary Authority* of any suspicion of a contagious *disease* of bees in the breeding apiary and in other apiaries in the vicinity;

4. not introduce into the apiary any bee (including larval stages) or apicultural material or product originating from another apiary unless health control has been previously performed by the *Veterinary Authority*;

5. apply special breeding and despatch techniques to ensure protection against any outside contamination, especially for the breeding and sending of queen-bees and accompanying bees and to enable retesting in the *importing country*;

6. collect at least every ten days, during the breeding and despatch period, samples from breeding material, brood-combs, queen-bees and bees (including possibly separately raised accompanying bees), to be sent to an official laboratory.

Article 4.14.4.

Conditions for sanitation and disinfection of apicultural equipment

Veterinary Authorities of *exporting countries* are requested to regulate the use of products and means for sanitation and *disinfection* of apicultural equipment in their own country, taking into account the following recommendations.

1. Any apicultural equipment kept in an *establishment* which has been recognised as being affected with a contagious *disease* of bees shall be subjected to sanitary measures ensuring the elimination of pathogens.

2. In all cases, these measures comprise the initial cleaning and scraping of the equipment, followed by sanitation or *disinfection* depending on the *disease* concerned.

3. The kind of equipment (hives, small hives, combs, extractor, small equipment, appliances for handling or storage) shall also be taken into account in the choice of procedures to be applied.

4. Infected or contaminated equipment which cannot be subjected to the above-mentioned measures must be destroyed, preferably by burning. Any equipment in bad condition, especially hives, as well as larvae in combs affected with varroosis, American foulbrood or European foulbrood, must be destroyed by burning.

5. The products and means used for sanitation and *disinfection* shall be recognised as being effective by the *Veterinary Authority*. They shall be used in such a manner as to exclude any risk of contaminating the equipment which could eventually affect the health of bees or adulterate the products of the hive.

6. When these procedures are not performed, the products shall be kept away from the bees and any contact with apicultural equipment and products must be prevented.

7. Waste water from the cleaning, sanitation and *disinfection* of apicultural equipment shall be kept away from the bees at all times and disposed of in a sewer or in an unused well.

Article 4.14.5.

Preparation of the international veterinary certificate for export

This Certificate covers hives containing bees, swarms, consignments of bees (worker bees or drones), queen bees (with accompanying bees), brood-combs, royal cells, etc.

This document shall be prepared in accordance with the model contained in Chapter 5.10.

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 OIE Members should base their import requirements on the OIE standards.

These requirements should be included in the model certificates approved by the OIE which are included from Chapters 5.10. to 5.12. of the *Terrestrial Code*.

Certification requirements should be exact and concise, and should clearly convey the wishes of the *importing country*. For this purpose, prior consultation between *Veterinary Authorities* of *importing* and *exporting countries* 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 OIE standards. *Importing countries* should restrict their requirements to those necessary to achieve the national appropriate level of protection. If these are stricter than the OIE standards, 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*.

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 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 OIE Members. 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 OIE Members 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, Members should base their *sanitary measures* on OIE standards, guidelines and recommendations.

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

Article 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.

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, OIE Members 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 OIE Members 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:

a) semen,

b) embryos/ova,

c) *hatching eggs*,

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

Article 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. of the *Terrestrial Code*) and worded in the languages agreed upon between the *exporting country* and the *importing country*, and, where necessary, with the *transit countries*.

Article 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. of the *Terrestrial Code*). These must be worded in the languages agreed upon between the *exporting country* and the *importing country*, and, where necessary, with the *transit countries*.

2. Products of animal origin intended for use in animal feeding, or for pharmaceutical or surgical or agricultural or industrial use, should be accompanied by an *international veterinary certificate* conforming with the models approved by the OIE (as shown in Chapters 5.10. to 5.12. of the *Terrestrial Code*).

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*:

a) semen,

b) embryos/ova,

c) *hatching eggs*,

d) brood-combs of bees,

e) animal products,

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

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

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

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

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

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

Article 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:

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

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

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

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

The presence of *disease* or *infection* in imported *animals* in a *quarantine station* does not affect the *animal health status*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:

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

b) the period of time required for notice to be given for the application of the arrangements contained in point 2 of Articles 5.7.1. to 5.7.4.;

c) 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.

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

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

Article 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.

Article 5.8.5.

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. Therefore, quarantine practices should:

1. encompass measures which effectively isolate animals or groups of animals thereby preventing the spread of communicable diseases;
2. protect the health of personnel working in the quarantine;
3. encompass measures to promote the health and welfare of quarantined animals including social and behavioural needs of non-human primates.

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.

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.
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

Country:	Name of the country that issues the certificate.
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). For products of animal origin: the premises from which the products are to be dispatched.

Box I.10.	Name of the place from which the animals or products are being shipped (this will be a land, sea or airport).
Box I.11.	Date of departure. For animals include the expected time of departure.
Box I.12.	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.
Box I.13.	Name of expected border post and, if available, its UN/LOCODE (refer to the United Nations Code for Trade and Transport Locations).
Box I.14.	CITES permit number(s) if the commodity concerns species listed in the Convention on International Trade in Endangered Species of Wild Fauna and Flora.
Box I.15.	Describe the commodity or use the titles as they appear in the Harmonised System of the World Customs Organization.
Box I.16.	Heading or HS Code of the Harmonized System set up by the World Customs Organization.
Box I.17.	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.
Box I.18.	Temperature of products for transport and storage.
Box I.19.	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.
Box I.20.	Identify the containers/seal numbers where required.
Box I.21.	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).
Box I.22.	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.

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

COUNTRY :

Part I: Details of dispatched consignment

I.1. Consignor: Name: Address:	I.2. Certificate reference number: I.3. Veterinary Authority:
I.4. Consignee: Name: Address:	
I.5. Country of origin: ISO code*	I.6. Zone or compartment of origin**:
I.7. Country of destination: ISO code*	I.8. Zone or compartment of destination**:
I.9. Place of origin: Name: Address:	
I.10. Place of shipment:	I.11. Date of departure:
I.12. Means of transport: Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification:	I.13. Expected border post: I.14. CITES permit No(s).**:
I.15. Description of commodity:	I.16. Commodity code (HS code): 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 and ** If referenced in Part II.

COUNTRY :

Part II. Zoosanitary information		II.a. Certificate reference number:
	II. The undersigned Official Veterinarian certifies that the animal(s)/hatching eggs described above satisfy(ies) the following requirements: 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

COUNTRY :

<table>
<tr><td rowspan="10">Part I: Details of dispatched consignment</td><td colspan="2">I.1. Consignor:
Name :

Address:</td><td>I.2. Certificate reference number:

I.3. Veterinary Authority:</td></tr>
<tr><td colspan="3">I.4. Consignee:
Name:

Address:</td></tr>
<tr><td colspan="2">I.5. Country of origin: ISO code*</td><td>I.6. Zone or compartment of origin**:</td></tr>
<tr><td colspan="2">I.7. Country of destination: ISO code*</td><td>I.8. Zone or compartment of destination**:</td></tr>
<tr><td colspan="3">I.9. Place of origin:
Name:

Address:</td></tr>
<tr><td colspan="2">I.10. Place of shipment:</td><td>I.11. Date of departure:</td></tr>
<tr><td colspan="2">I.12. Means of transport:

Aeroplane ☐ Ship ☐ Railway wagon ☐

Road vehicle ☐ Other ☐
Identification :</td><td>I.13. Expected border post:

I.14. CITES permit No(s).**:</td></tr>
<tr><td colspan="2">I.15. Description of commodity:</td><td>I.16. Commodity code (HS code):

I.17. Total quantity:</td></tr>
<tr><td colspan="2">I.18.</td><td>I.19. Total number of packages:</td></tr>
<tr><td colspan="2">I.20. Identification of container/seal number:</td><td>I.21.</td></tr>
<tr><td colspan="3">I.22. Commodities intended for use as:

Artificial reproduction ☐ Other ☐</td></tr>
<tr><td colspan="3">I.23.</td></tr>
<tr><td colspan="3">I.24. Identification of commodities:

Species (Scientific name) Breed* Donor identity

Date of collection Approval number of the centre/team Identification mark

Quantity</td></tr>
</table>

* Optional and ** If referenced in Part II.

COUNTRY :

Part II. Zoosanitary information

II.a. Certificate reference number

II. The undersigned Official Veterinarian certifies that the embryos, ova and semen described above satisfy(ies) the following requirements:

Official Veterinarian:

Name and address (in capital letters):

Official position:

Date:

Signature:

Stamp:

Article 5.10.4.

Model veterinary certificate for international trade in products of animal origin

COUNTRY :

<table>
<tr><td rowspan="9">Part I: Details of dispatched consignment</td><td>I.1. Consignor:
Name:

Address:</td><td>I.2. Certificate reference number:

I.3. Veterinary Authority:</td></tr>
<tr><td colspan="2">I.4. Consignee:
Name:

Address:</td></tr>
<tr><td>I.5. Country of origin: ISO code*</td><td>I.6. Zone or compartment of origin**:</td></tr>
<tr><td>I.7. Country of destination: ISO code*</td><td>I.8. Zone or compartment of destination**:</td></tr>
<tr><td colspan="2">I.9. Place of origin:
Name:

Address:</td></tr>
<tr><td>I.10. Place of shipment:</td><td>I.11. Date of departure:</td></tr>
<tr><td rowspan="4">I.12. Means of transport:

Aeroplane ☐ Ship ☐ Railway wagon ☐

Road vehicle ☐ Other ☐

Identification:</td><td>I.13. Expected border post:

I.14. CITES permit No(s).**:</td></tr>
<tr><td>I.15. Description of commodity:</td><td>I.16. Commodity code (HS code):</td></tr>
<tr><td></td><td>I.17. Total quantity:</td></tr>
<tr><td>I.18. Temperature of product:

Ambient ☐ Chilled ☐ Frozen ☐</td><td>I.19. Total number of packages:</td></tr>
<tr><td colspan="2">I.20. Identification of container/seal number:

I.21. Type of packaging:</td></tr>
<tr><td colspan="3">I.22. Commodities intended for use as:

Human consumption ☐ Animal feed ☐

Further processing ☐ Technical use ☐

Other ☐</td></tr>
<tr><td colspan="3">I.23.</td></tr>
<tr><td colspan="3">I.24. Identification of commodities:

Species (Scientific name) Nature of commodity Treatment type

Approval number of establishments

Number of packages Net weight Lot ID/date code</td></tr>
</table>

* Optional and ** If referenced in Part II.

COUNTRY :

Part II. Zoosanitary information

II.a. Certificate reference number

II. The undersigned Official Veterinarian certifies that the products of animal origin described above satisfy(ies) the following requirements:

Official Veterinarian:

Name and address (in capital letters):

Official position:

Date:

Signature:

Stamp:

Article 5.10.5.

Model veterinary certificate for international trade in bees and brood combs

COUNTRY :

<table>
<tr><td rowspan="10">Part I: Details of dispatched consignment</td><td colspan="2">I.1. Consignor:
Name:

Address:</td><td>I.2. Certificate reference number:

I.3. Veterinary Authority:</td></tr>
<tr><td colspan="3">I.4. Consignee:
Name:

Address:</td></tr>
<tr><td colspan="2">I.5. Country of origin: ISO code*</td><td>I.6. Zone or compartment of origin**:</td></tr>
<tr><td colspan="2">I.7. Country of destination: ISO code*</td><td>I.8. Zone or compartment of destination**:</td></tr>
<tr><td colspan="3">I.9. Place of origin:
Name:

Address:</td></tr>
<tr><td colspan="2">I.10. Place of shipment:</td><td>I.11. Date of departure:</td></tr>
<tr><td colspan="2">I.12. Means of transport:

Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:</td><td>I.13. Expected border post:

I.14. CITES permit No(s).**:</td></tr>
<tr><td colspan="2">I.15. Description of commodity:</td><td>I.16. Commodity code (HS code):

I.17. Total quantity:</td></tr>
<tr><td colspan="2">I.18.</td><td>I.19. Total number of packages:</td></tr>
<tr><td colspan="2">I.20. Identification of container/seal number:</td><td>I.21.</td></tr>
<tr><td colspan="3">I.22. Commodities intended for use as:

Breeding/rearing ☐ Other ☐</td></tr>
<tr><td colspan="3">I.23.</td></tr>
<tr><td colspan="3">I.24. Identification of commodities:

Category Breed* / Variety*

Quantity Identification details</td></tr>
</table>

* Optional and ** If referenced in Part II.

COUNTRY :

Part II. Zoosanitary informationh

II.a. Certificate reference number

II. The undersigned Official Veterinarian certifies that the bees/brood comb(s) described above satisfy(ies) the following requirements:

Official Veterinarian:

Name and address (in capital letters):

Official position:

Date:

Signature:

Stamp:

CHAPTER 5.11.

MODEL INTERNATIONAL VETERINARY CERTIFICATE FOR DOGS AND CATS ORIGINATING FROM RABIES INFECTED COUNTRIES

I. OWNER

Name and address: .....
.....
.....
.....

II. DESCRIPTION

Species of animal: .....

Age or date of birth: .....

Sex: .....

Breed: .....

Colour: .....

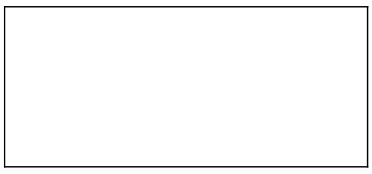
Coat type and marking/Distinguishing marks: .....

.....

.....

.....

Identification number (tattoo or other permanent method of identification) (see note 1)



III. ADDITIONAL INFORMATION

Country of origin: .....
.....

Countries visited .....
over the past 2 years .....
as declared by the owner .....
(give dates) .....
.....
.....

IV. VACCINATION (Rabies)

I the undersigned declare herewith that I have vaccinated the animal described in Part II against rabies as shown below. The animal was found to be healthy on the day of vaccination.

Date of vaccination (dd/mm/yy)	Name of inactivated virus vaccine (see note 2)	1. Manufacturing laboratory 2. Batch number 3. Expiry date	Name (in capital letters) and signature of the veterinarian (see note 6)
		1. ..... 2. ..... 3.	

PERIOD OF VALIDITY OF VACCINATION FOR INTERNATIONAL MOVEMENT (see note 3)		Name (in capital letters) and signature of the Official Veterinarian
from (dd/mm/yy)	to (dd/mm/yy)	

V. SEROLOGICAL TESTING (Rabies)

I the undersigned declare herewith that I have taken a blood sample from the animal described in Part II and have received the following result from the official diagnostic laboratory which has carried out the neutralising antibody titration test (see note 4).

Date of sampling (dd/mm/yy)	Name and address of the official diagnostic laboratory	Result of the antibody titration test (in International Units [IU]/ml)	Name (in capital letters) and signature of the veterinarian (see note 6)

PERIOD OF VALIDITY OF SEROLOGICAL TESTING FOR INTERNATIONAL MOVEMENT (see note 3)		Name (in capital letters) and signature of the Official Veterinarian
from (dd/mm/yy)	to (dd/mm/yy)	

VI. CLINICAL EXAMINATION (Rabies)

I the undersigned declare herewith that I have examined on the date indicated below the animal described in Part II and have found it to be clinically healthy (see note 5).

Date (dd/mm/yy)	Name (in capital letters) and signature of the veterinarian (see note 6)	Name (in capital letters) and signature of the Official Veterinarian

NOTE

1. The identification number stated in the certificate should be identical to that which can be found on the animal. When electronic identification is used, the type of microchip and the name of the manufacturer should be specified.

2. Only inactivated virus vaccines are authorised for international movements of dogs and cats.

3. In the case of a primary vaccination, the animal should have been vaccinated not less than 6 months and not more than 1 year prior to its introduction into the importing country; the vaccination should have been carried out when the animal was at least 3 months old.

   In the case of a booster vaccination, the animal should have been vaccinated not more than 1 year prior to its introduction into the importing country.

4. The animal should have been subjected not less than 3 months and not more than 24 months prior to its introduction into the importing country, to a neutralising antibody titration test. It should be carried out by an official diagnostic laboratory approved by the Competent Authority of the exporting country. The animal's serum should contain at least 0.5 International Units (IU)/ml.

5. The clinical examination referred to in Part VI of the certificate must be carried out within 48 hours of shipment.

The Competent Authority of the importing country may require the placing of the animals which do not comply with any of the above-mentioned conditions in a quarantine station located on its territory; the conditions of stay in quarantine are laid down by the legislation of the importing country.

6. If the veterinarian whose name and signature appear on the certificate is not an official veterinarian, his signature must be authenticated in the relevant column by the signature and stamp of an official veterinarian. The expression 'Official Veterinarian' means a civil service veterinarian or a specially appointed veterinarian, as authorised by the Veterinary Authority of the country.

7. If so required, the certificate should be written in the language of the importing country. In such circumstances, it should also be written in a language understood by the certifying veterinarian.

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

Propriétaires successifs

1. La nationalité du cheval est celle de son propriétaire.
2. Lors de tout changement de propriétaire, le passeport doit être immédiatement retourné, en mentionnant le nom et l'adresse du nouveau propriétaire, à la Fédération équestre nationale, qui le remettra au nouveau propriétaire après enregistrement.
3. S'il y a plus d'un seul propriétaire, ou si le cheval appartient à une société, on indiquera dans le passeport le nom de la personne responsable du cheval et sa nationalité. Si les propriétaires sont de nationalités différentes, ils doivent préciser la nationalité du cheval.
4. Lorsqu'il y a location du cheval, dûment enregistrée par une Fédération équestre nationale avec accord de la Fédération équestre internationale, celle-ci doit être mentionnée sur cette page par cette Fédération nationale.

Details of ownership

1. The nationality of the horse is that of its owner.
2. On change of ownership the passport must immediately be lodged with the National Equestrian Federation, giving the name and address of the new owner, for re-registration and forwarding to the new owner.
3. If there is more than one owner or the horse is owned by a company, then the name of the individual responsible for the horse shall be entered in the passport together with his nationality. If the owners are of different nationalities, they have to determine the nationality of the horse.
4. When the Federation Equestre Internationale approves the leasing of a horse by a National Equestrian Federation, the details of these transactions must be recorded on this page by the National Equestrian Federation concerned.

Detalles del propietario

1. La nacionalidad del caballo es la nacionalidad de su propietario.
2. En caso de cambio de propietario, el pasaporte debe ser entregado inmediatamente, indicando el nombre y la dirección del nuevo propietario, a la Federación Ecuestre Nacional, que lo remitirá al nuevo propietario después de haberlo registrado.
3. Si el caballo tiene más de un propietario, o si pertenece a una sociedad, el nombre y la nacionalidad de la persona responsable del caballo deben inscribirse en el pasaporte. Si los propietarios son de diferente nacionalidad, deben precisar la nacionalidad del caballo.
4. Cuando la Federación Ecuestre Internacional aprueba el alquiler de un caballo por una Federación Ecuestre Nacional, la Federación Ecuestre Nacional debe registrar los detalles de la transacción en esta página.

Date d'enregistrement par la Fédération équestre nationale Date of registration by the National Equestrian Federation Fecha de registro por la Federación Ecuestre Nacional	Nom du propriétaire Name of owner Nombre del propietario	Adresse du propriétaire Address of owner Dirección del propietario	Nationalité du propriétaire Nationality of owner Nacionalidad del propietario	Signature du propriétaire Signature of owner Firma del propietario	Cachet de la Fédération équestre nationale et signature officielle National Equestrian Federation stamp and signature of the secretary Sello de la Federación Ecuestre Nacional y firma oficial

Appendix B

(1) N° d'identification :

Identification No.:

N° de identificación:

(2) Nom :

Name:

Nombre:

(3) Sexe :

Sex:

Sexo:

(4) Robe :

Colour:

Color:

(5) Race :

Breed:

Raza:

(6) par :

by:

por:

(7) et :

out of:

y:

(8) par :

by:

por:

(9) Date de naissance :

Date of foaling:

Fecha de nacimiento:

(10) Lieu d'élevage :

Place where bred:

Lugar de cría:

(11) Naisseur(s) :

Breeder(s):

Criador(es):

(12) Certificat d'origine validé le :

par :

Origin certificate validated on:

by:

Certificado de origen visado el:

por:

- Nom de l'autorité compétente :

  Name of the competent authority:

  Nombre de la autoridad competente:

- Adresse :

  Address:

  Dirección:

- N° de téléphone : - N° de télécopie :

  Telephone No.: - Telecopy No.:

  N° de teléfono: - N° de fax:

- Signature :

  (nom en lettres capitales et qualité du signataire)

- Signature:

  (Name in capital letters and capacity of signatory)

  Firma:

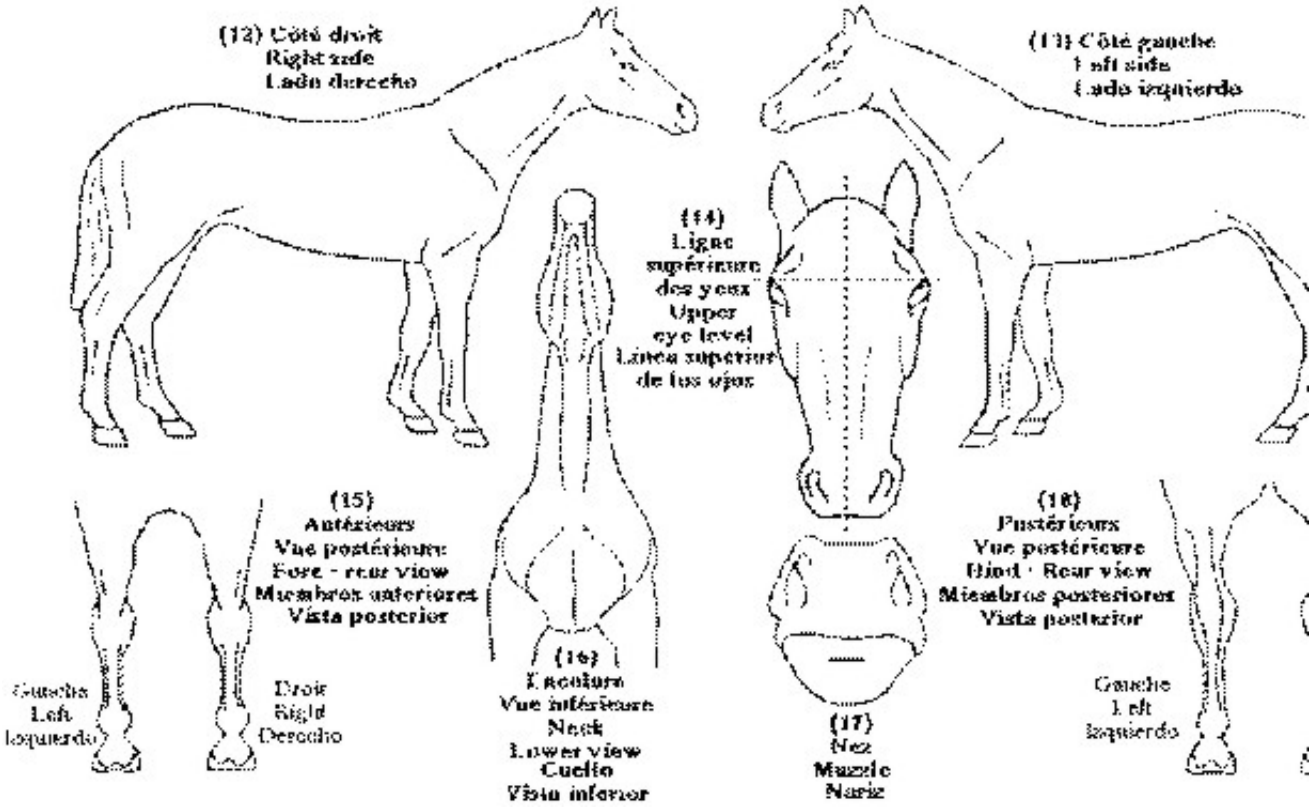
  (Nombre en letras mayúsculas y calidad del firmante)

- Cachet

  Stamp

  Sello

Appendix C


(12) Côté droit
Right side
Lado derecho
(11) Côté gauche
Left side
Lado izquierdo
(14)
Ligne supérieure des yeux
Upper eye level
Línea superior de los ojos
(15)
Antérieurs
Vue postérieure
Fore - rear view
Miembros anteriores
Vista posterior
Gauche
Left
Izquierdo
Droit
Right
Derecho
(16)
Encolure
Vue inférieure
Neck
Lower view
Cuello
Vista inferior
(17)
Nez
Muzzle
Nariz
(18)
Postérieurs
Vue postérieure
Hind - Rear view
Miembros posteriores
Vista posterior
Gauche
Left
Izquierdo

(2) Nom :
Name:
Nombre:

(5) Race :
Breed:
Raza:

(3) Sexe :
Sex:
Sexo:

(4) Robe :
Colour:
Color:

(19) Signalement relevé sous la mère par :
Description taken with dam by:
Descripción registrada con la madre por:

Tête :
Head:
Cabeza:

Ant. G. :
Foreleg L.:
Ant. I.:

Ant. D. :
Foreleg R.:
Ant. D.:

Post. G. :
Hindleg L.:
Post. I.:

Post. D. :
Hindleg R.:
Post. D.:

Corps :
Body:
Cuerpo:

(21) Signature et cachet du vétérinaire agréé
(ou de l'autorité compétente)
Signature and stamp of qualified veterinary surgeon
(or competent authority)

Marques :
Markings:
Marcas:

Firma y sello del veterinario autorizado
(o de la autoridad competente)
(en lettres capitales)
(in capital letters)
(en letras mayúsculas)

Fait le (date) :
Made on (date):
A (fecha):

Date :
Date:
Fecha:

Appendix D

Contrôles d'identité du cheval décrit dans ce passeport

L'identité du cheval doit être contrôlée chaque fois que les lois et règlements l'exigent : signer cette page signifie que le signalement du cheval présenté est conforme à celui de la page du signalement.

Identification of the horse described in this passport

The identity of the horse must be checked each time it is required by the rules and regulations and certified that it conforms with the description given on the diagram page of this passport.

Controles de identidad del caballo descrito en este pasaporte

Se controlará la identidad del caballo cada vez que lo exijan las leyes y reglamentos, y se certificará, firmando esta página, que el caballo presentado corresponde al caballo descrito en este pasaporte.

Date	Ville et pays	Motif du contrôle (concours, certificat sanitaire, etc.)	Signature, nom en lettres capitales et position de la personne ayant vérifié l'identité
Date	Town and country	Purpose of control (event, veterinary certificate, etc.)	Signature, name (in capital letters) and status of official verifying the identification
Fecha	Ciudad y país	Motivo del control (concurso, certificado sanitario, etc)	Firma, nombre (en letras mayúsculas) y calidad de la persona que controla la identidad

Appendix E

GRIPPE ÉQUINE SEULEMENT
Enregistrement des vaccinations

Toute vaccination subie par le cheval doit être portée dans le cadre ci-dessous de façon lisible et précise avec le nom et la signature du vétérinaire.

EQUINE INFLUENZA ONLY
Vaccination record

Details of every vaccination which the horse undergoes must be entered clearly and in detail, and certified with the name and signature of the veterinarian.

GRIPE EQUINA SOLAMENTE
Registro de vacunas

Todas las vacunas administradas al caballo, así como el nombre y la firma del veterinario, deben figurar de manera clara y detallada en el cuadro siguiente.

Date Date Fecha	Lieu Place Lugar	Pays Country País	Vaccin/Vaccine/Vacuna		Nom en lettres capitales et signature du vétérinaire Name (in capital letters) and signature of the veterinarian Nombre (en letras mayúsculas) y firma del veterinario
			Nom Name Nombre	Numéro de lot Batch number Número de lote	

Appendix F

MALADIES AUTRES QUE LA GRIPPE ÉQUINE
Enregistrement des vaccinations

Toute vaccination subie par le cheval doit être portée dans le cadre ci-dessous de façon lisible et précise avec le nom et la signature du vétérinaire.

DISEASES OTHER THAN EQUINE INFLUENZA
Vaccination record

Details of every vaccination which the horse undergoes must be entered clearly and in detail, and certified with the name and signature of the veterinarian.

ENFERMEDADES DISTINTAS DE LA GRIPE EQUINA
Registro de vacunas

Todas las vacunas administradas al caballo, así como el nombre y la firma del veterinario, deben figurar de manera clara y detallada en el cuadro siguiente.

Date Date Fecha	Lieu Place Lugar	Pays Country País	Vaccin/Vaccine/Vacuna			Nom en lettres capitales et signature du vétérinaire Name (in capital letters) and signature of the veterinarian Nombre (en letras mayúsculas) y firma del veterinario
			Nom Name Nombre	Numéro de lot Batch number Número de lote	Maladie(s) Disease(s) Enfermedad(es)	

Appendix G

Contrôles sanitaires effectués par des laboratoires

Le résultat de tout contrôle effectué par un vétérinaire pour une maladie transmissible ou par un laboratoire agréé par le Service vétérinaire gouvernemental du pays doit être noté clairement et en détail par le vétérinaire qui représente l'autorité demandant le contrôle.

Laboratory health test

The result of every test undertaken for a transmissible disease by a veterinarian or a laboratory authorised by the Government Veterinary Service of the country must be entered clearly and in detail by the veterinarian acting on behalf of the authority requesting the test.

Controles sanitarios efectuados por laboratorios

El veterinario que representa a la autoridad que solicita el control sanitario debe inscribir en el cuadro siguiente, de manera clara y detallada, el resultado de cada control relativo a una enfermedad transmisible efectuado por un veterinario o por un Servicio Veterinario gubernamental.

Date	Maladies transmissibles concernées	Nature de l'examen	Résultat de l'examen	Laboratoire officiel ayant analysé le prélèvement	Nom en lettres capitales et signature du vétérinaire
Date	Transmissible diseases tested for	Type of test	Result of test	Official laboratory to which sample transmitted	Name (in capital letters) and signature of Veterinarian
Fecha	Enfermedades transmisibles examinadas	Tipo de examen	Resultado del examen	Laboratorio oficial que ha analizado la muestra	Nombre (en letras mayúsculas) y firma del veterinario

Appendix H

EXIGENCES SANITAIRES DE BASE - BASIC HEALTH REQUIREMENTS - REQUISITOS SANITARIOS BÁSICOS

Je soussigné certifie[1] que le cheval décrit dans le passeport n° ..... délivré par ..... satisfait aux conditions suivantes :

I, the undersigned, certify[1] that the horse described in the Passport No. ..... issued by ..... meets the following requirements:

El que suscribe certifica[1] que el caballo descrito en el pasaporte n° ..... extendido por ..... cumple con los siguientes requisitos:

(a) il a été examiné ce jour, ne présente aucun signe clinique de maladie et est apte au transport ;

(a) it has been examined today, shows no clinical sign of disease and is fit for transport;

(a) ha sido examinado hoy, no presenta ningún signo clínico de enfermedad y se encuentra en condiciones de ser transportado;

(b) il n'est pas destiné à l'abattage dans le cadre d'un programme national d'éradication d'une maladie transmissible ;

(b) it is not intended for slaughter under a national programme of transmissible disease eradication;

(b) no ha sido destinado al sacrificio sanitario en el marco de un programa nacional de erradicación de una enfermedad transmisible;

(c) il ne provient pas d'une écurie mise en interdit pour des raisons zoosanitaires et n'a pas été en contact avec des équidés d'une écurie de ce type ;

(c) it does not come from a holding which was subject to prohibition for animal health reasons nor had contact with equidae from a holding which was subject to such prohibition;

(c) no procede de una cuadra sujeta a interdicción por razones zoosanitarias ni ha estado en contacto con équidos procedentes de una cuadra sujeta a interdicción;

(d) à ma connaissance, après avoir dûment enquêté, il n'a pas été en contact avec des équidés atteints d'une maladie transmissible au cours des 15 jours précédant l'embarquement.

(d) to the best of my knowledge and after due inquiry, it has not been in contact with equidae suffering from transmissible disease during 15 days prior to embarkation.

(d) según me consta, tras haber efectuado las indagaciones pertinentes, no ha estado en contacto con équidos afectados de enfermedades transmisibles durante los 15 días anteriores a su embarque.

LE PRÉSENT CERTIFICAT EST VALABLE 10 JOURS À COMPTER DE LA DATE DE SA SIGNATURE.

THIS CERTIFICATE IS VALID FOR 10 DAYS FROM THE DATE OF SIGNATURE.

EL PRESENTE CERTIFICADO ES VÁLIDO 10 DÍAS A PARTIR DE LA FECHA DE SU FIRMA.

Date Date Fecha	Lieu Place Lugar	Pour des raisons épidémiologiques particulières, un certificat sanitaire séparé accompagne le présent passeport. For special epizootic reasons a separate veterinary certificate accompanies this passport. Por razones epidemiológicas particulares se adjunta al presente pasaporte un certificado sanitario.	Nom en lettres capitales et signature du vétérinaire officiel Name (in capital letters) and signature of official veterinarian Nombre en letras mayúsculas y firma del veterinario oficial
		Oui/non (barrer la mention inutile) Yes/No (Delete One) Si/no (tachar lo que no procede)	
		Oui/non (barrer la mention inutile) Yes/No (Delete One) Si/no (tachar lo que no procede)	

(1) Ce document doit être signé dans les 48 heures précédant le déplacement international du cheval.

(1) The document should be signed within the 48 hours prior to international movement of the horse.

(1) Este documento debe ser firmado 48 horas antes del desplazamiento internacional del caballo.

LIST OF DISEASES WHICH SHOULD BE CONSIDERED FOR INCLUSION IN THE VETERINARY CERTIFICATE WHICH ACCOMPANIES THE PASSPORT

1. African horse sickness
2. Vesicular stomatitis
3. Dourine
4. Glanders
5. Equine encephalomyelitis (all types)
6. Equine infectious anaemia
7. Rabies
8. Anthrax

---

1 *For the movement of competition horses between countries or zones of countries with a different health status, Veterinary Services may require additional veterinary certification.*

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 OIE Members 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. of the *Terrestrial Code* 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. of the *Terrestrial Code* 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. of the *Terrestrial Code*. Recommendations for the evaluation of *Veterinary Services* are provided in Chapter 3.2. of the *Terrestrial Code* 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. of the *Terrestrial Code*.

   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. of the *Terrestrial Code*.

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. of the *Terrestrial Code*.

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. of the *Terrestrial Code*).

CHAPTER 6.4.

BIOSECURITY PROCEDURES IN POULTRY PRODUCTION

Article 6.4.1.

Introduction

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

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

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

Article 6.4.2.

Purpose and scope

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

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

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

Article 6.4.3.

Definitions

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

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

Article 6.4.4.

Recommendations on the location and construction of poultry establishments

1. All establishments (poultry farms and hatcheries)

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

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

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

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

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

2. Additional measures for poultry farms

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

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

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

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

3. Additional measures for hatcheries

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

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

      i) personnel changing, showering and sanitary facilities;

      ii) receipt, storage and transfer of eggs;

      iii) incubation;

      iv) hatching;

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

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

      vii) equipment washing;

      viii) waste disposal;

      ix) dining facilities for personnel;

      x) office space.

Article 6.4.5.

Recommendations applicable to the operation of poultry establishments

1. All establishments (poultry farms and hatcheries)

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

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

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

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

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

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

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

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

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

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

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

2. Additional measures for all poultry farms

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3. Additional measures for layers

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

4. Additional measures for breeders

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

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

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

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

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

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

5. Additional measures for hatcheries

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

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

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

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, in addition to the general biosecurity measures described previously, management procedures should be adjusted to effectively isolate it from other *flocks* on the *establishment* and other epidemiologically related *establishments*. The following measures are recommended:

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

2. A *veterinarian* should be consulted immediately.

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

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

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

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

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

6. Depending on the epidemiology of the *disease*, *risk assessment*, vaccine availability and public and animal health policies, vaccination is an option to minimise the dissemination of the infectious agent. When used, vaccines should be administered in accordance with the directions of the *Veterinary Services* and the manufacturer's instructions. Recommendations in the *Terrestrial Manual* should be followed as appropriate.

Article 6.4.7.

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

1. Personnel should be educated on the significance of infectious agents and the need to apply biosecurity practices to prevent dissemination of these agents. Education should be targeted to personnel at all levels of operations in these markets (e.g. drivers, owners, handlers, processors). Programmes should be implemented to raise consumer awareness about the risks associated with activities of live bird markets.

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

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

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

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

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

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

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

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).
- 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*. Enteriditis.
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 *hatching 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 OIE Members 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 Members 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 surveillance and monitoring programmes,

in *animals* and in products of animal origin intended for human consumption.

Article 6.7.2.

Purpose of surveillance and monitoring

1. Surveillance and monitoring of antimicrobial resistance is necessary to:
   a) follow trends in antimicrobial resistance in bacteria;
   b) detect the emergence of new antimicrobial resistance mechanisms;
   c) provide the data necessary for conducting *risk analyses* with relevance for human and animal health;
   d) provide a basis for policy recommendations for animal and public health;
   e) provide information for prescribing practices and prudent use recommendations.
2. National antimicrobial resistance monitoring and surveillance programmes may include the following components:
   a) scientifically based surveys (including statistically based programmes);
   b) routine sampling and testing of *animals* on the farm, at *market* or at *slaughter*;
   c) an organised sentinel programme, sampling *animals*, *herds*, *flocks*, and vectors;
   d) analysis of veterinary practice and diagnostic *laboratory* records.
3. Countries should conduct active surveillance and monitoring. Passive surveillance and monitoring may offer additional information.
4. Targeted surveillance is conducted through an active sampling scheme designed to meet programme objectives. Passive surveillance is conducted when samples are submitted to a *laboratory* for testing from sources outside the programme.

Article 6.7.3.

The development of antimicrobial resistance surveillance and monitoring programmes

1. General aspects

Surveillance of antimicrobial resistance at regular intervals or ongoing monitoring of prevalence changes of resistant bacteria of animal, food, environmental and human origin, constitutes a critical part of a strategy aimed at limiting the spread of antimicrobial resistance and optimising the choice of antimicrobials used in therapy.

Monitoring of bacteria from products of animal origin intended for human consumption collected at different steps of the food chain, including processing, packing and retailing, should also be considered.

2. Sampling strategies

a) General

i) Sampling should be conducted on a statistical basis. The sampling strategy should assure:

- the sample representativeness of the population of interest;
- the robustness of the sampling method.

ii) The following criteria are to be considered:

- sample size;
- sample source (*animal*, food, animal feed);
- animal species;
- category of *animal* within species (age group, production type);
- stratification within category;
- health status of the *animals* (healthy, diseased);
- random sample (targeted, systematic);
- sample specimens (faecal, carcass, processed food).

b) Sample size

The sample size should be:

i) large enough to allow detection of existing resistance,

ii) not excessively large to avoid waste of resources.

Details are provided in Table 1. Sampling fall follow standard operating procedures.

3. Sample sources

a) Animals

Each OIE Member should examine its livestock production systems and decide, after *risk analysis*, the relative importance of antimicrobial resistance and its impact on animal and human health.

Categories of livestock that should be considered for sampling include cattle and calves, slaughter pigs, broiler chickens, layer hens and/or other poultry and farmed fish.

b) Food and animal feed

Contaminated food is commonly considered to be the principal route for the transfer of antimicrobial resistance from *animals* to humans. Plants and vegetables of different types may be exposed to manure or sewage from livestock and may thereby become contaminated with resistant bacteria of animal origin. Animal feed, including imported feed, may also be considered in surveillance and monitoring programmes.

Table 1. ***Sample size estimates for prevalence of antimicrobial resistance in a large population***

	Level of confidence					
Expected prevalence	**90% Desired precision**			**95% Desired precision**		
	10%	**5%**	**1%**	**10%**	**5%**	**1%**
10%	24	97	2.429	35	138	3.445
20%	43	173	4.310	61	246	6.109
30%	57	227	5.650	81	323	8.003
40%	65	260	6.451	92	369	9.135
50%	68	270	6.718	96	384	9.512
60%	65	260	6.451	92	369	9.135
70%	57	227	5.650	81	323	8.003
¨80%	43	173	4.310	61	246	6.109
90%	24	97	2.429	35	138	3.445

Calculations based on Epi Info v6.04b to c Upgrade, October 1997, Centers for Disease Control (public domain software available at hpp://www.cdc.gov/epo/epi/epiinfo.htm)

4. Sample specimens to be collected

Faecal samples should be collected from livestock, and whole caeca should be collected from poultry. In cattle and pigs, a faecal sample size at least of 5 g provides a sufficient sample for isolation of the bacteria of concern.

Sampling of the carcasses at the *abattoir* provides information on *slaughter* practices, *slaughter* hygiene and the level of faecal contamination of *meat* during the *slaughter* process. Further sampling from the retail chain provides information on prevalence changes before the food reaches the consumer.

Existing food processing microbiological monitoring and 'hazard analysis and critical control points' (HACCP) programmes may provide useful samples for surveillance and monitoring of resistance in the food chain after *slaughter*.

5. Bacterial isolates

The following categories of bacteria could be monitored:

a) Animal bacterial pathogens

Monitoring of antimicrobial resistance in animal pathogens is important, both to:

i) detect emerging resistance that may pose a concern for human and animal health;

ii) guide *veterinarians* in their prescribing decisions.

Information on the occurrence of antimicrobial resistance in animal pathogens is in general derived from routine clinical material sent to veterinary diagnostic *laboratories*. These samples, often derived from severe or recurrent clinical cases including therapy failure, may provide biased information.

b) Zoonotic bacteria

i) *Salmonella*

Salmonella should be sampled from cattle, pigs, broilers and other poultry. For the purpose of facilitating sampling and reducing the concurrent costs, samples should preferably be taken at the *abattoir*. Surveillance and monitoring programmes may also use bacterial isolates from designated national *laboratories* originating from other sources.

Isolation and identification of bacteria and bacterial strains should follow internationally accepted procedures.

Serovars of epidemiological importance such as *S*. Typhimurium and *S*. Enteritidis should be included. The selection of other relevant serovars will depend on the epidemiological situation in each country.

All *Salmonella* isolates should be serotyped and, where appropriate, phage-typed according to standard methods used at the nationally designated *laboratories*.

Validated methods should be used.

ii) *Campylobacter*

Campylobacter jejuni and *C. coli* can be isolated from the same samples as commensal bacteria. Isolation and identification of these bacteria should follow internationally accepted procedures. *Campylobacter* isolates should be identified to the species level.

Agar or broth micro-dilution methods are recommended for *Campylobacter* susceptibility testing. Internal and external quality control programmes should be strictly adhered to.

Validated methods with appropriate reference strains are expected to become available in the near future.

iii) Enterohaemorrhagic *Escherichia coli*

Enterohaemorrhagic *Escherichia coli* (EHEC), such as the serotype O157, which is pathogenic to humans but not to *animals*, may be included in resistance surveillance and monitoring programmes.

c) Commensal bacteria

Escherichia coli and *enterococci* are common commensal bacteria. These bacteria are considered to constitute a reservoir of antimicrobial resistance genes, which may be transferred to pathogenic bacteria causing *disease* in *animals* or humans. It is considered that these bacteria should be isolated from healthy *animals*, preferably at the *abattoir*, and be monitored for antimicrobial resistance.

Validated methods should be used.

Table 2. ***Examples of sampling sources, sample types and outcome of monitoring***

Source	Sample type	Outcome	Additional information required/additional stratification
Herd of origin		Prevalence of resistance in bacteria originating from animal populations (of different production types) Relationship resistance - antibiotic use	Per age categories, production types, etc. Antibiotic use over time
Abattoir	Faecal	Prevalence of resistance in bacterial populations originating from animals at slaughter age	
	Intestine	As above	
	Carcass	Hygiene, contamination during slaughter	
Processing, packing	Meat products	Hygiene, contamination during processing and handling	
Retail	Meat products	Prevalence of resistance in bacteria originating from food, exposure data for consumers	
	Vegetables	Prevalence of resistance in bacteria originating from vegetables, exposure data for consumers	
Various origin	Animal feed	Prevalence of resistance in bacteria originating from animal feed, exposure data for animals	

6. Storage of bacterial strains

   If possible, isolates should be preserved at least until reporting is completed. Preferably, isolates should be permanently stored. Bacterial strain collections, established by storage of all isolates from certain years, will provide the possibility of conducting retrospective studies.

7. Antimicrobials to be used in susceptibility testing

   Clinically important antimicrobial classes used in human and veterinary medicine should be monitored. However, the number of tested antimicrobials may have to be limited according to the financial resources of the country.

8. Type of data to be recorded and stored

   Data on antimicrobial susceptibility should be reported quantitatively.

   Appropriate validated methods should be used in accordance with Chapter 1.1.6. of the *Terrestrial Manual* concerning laboratory methodologies for bacterial antimicrobial susceptibility testing.

9. Recording, storage and interpretation of results

a) Because of the volume and complexity of the information to be stored and the need to keep these data available for an undetermined period of time, careful consideration should be given to database design.

b) The storage of raw (primary, non-interpreted) data is essential to allow the evaluation of the data in response to various kinds of questions, including those arising in the future.

c) Consideration should be given to the technical requirements of computer systems when an exchange of data between different systems (comparability of automatic recording of laboratory data and transfer of these data to resistance monitoring programmes) is envisaged. Results should be collected in a suitable national database. They shall be recorded quantitatively:

i) as distribution of minimum inhibitory concentrations (MICs) in milligrams per litre;

ii) or inhibition zone diameters in millimetres.

d) The information to be recorded should include at least the following aspects:

i) sampling programme;

ii) sampling date;

iii) animal species/livestock category;

iv) type of sample;

v) purpose of sampling;

vi) geographical origin of *herd*, *flock* or *animal*;

vii) age of *animal*.

e) The reporting of laboratory data should include the following information:

i) identity of *laboratory*,

ii) isolation date,

iii) reporting date,

iv) bacterial species,

and, where relevant, other typing characteristics, such as:

v) serovar,

vi) phage-type,

vii) antimicrobial susceptibility result/resistance phenotype.

f) The proportion of isolates regarded as resistant should be reported, including the defined breakpoints.

g) In the clinical setting, breakpoints are used to categorise bacterial strains as susceptible, intermediate susceptible or resistant. These breakpoints, often referred to as clinical or pharmacological breakpoints, are elaborated on a national basis and vary between countries.

h) The system of reference used should be recorded.

i) For surveillance purposes, the microbiological breakpoint, which is based on the distribution of MICs or inhibition zone diameters of the specific bacterial species tested, is preferred. When using microbiological breakpoints, only the bacterial population with acquired resistance that clearly deviates from the distribution of the normal susceptible population will be designated as resistant.

j) If available, the phenotype of the isolates (resistance pattern) should be recorded.

10. Reference laboratory and annual reports

a) Countries should designate a national reference centre that assumes the responsibility to:

i) coordinate the activities related to the resistance surveillance and monitoring programmes;

ii) collect information at a central location within the country;

iii) produce an annual report on the resistance situation of the country.

b) The national reference centre should have access to the:

i) raw data;

ii) complete results of quality assurance and inter-laboratory calibration activities;

iii) proficiency testing results;

iv) information on the structure of the monitoring system;

v) information on the chosen laboratory methods.

Table 3. ***Examples of animal bacterial pathogens that may be included in resistance surveillance and monitoring***

Target animals	Respiratory pathogens	Enteric pathogens	Udder pathogens	Other pathogens
Cattle	*Pasteurella* spp.	*Escherichia coli*	*Staphylococcus aureus*	
	Haemophilus somnus	*Salmonella* spp.	*Streptococcus* spp.	
Pigs	*Actinobacillus pleuropneumoniae*	*Escherichia coli*		*Streptococcus suis*
		Brachyspira spp.		
		Salmonella spp.		
Poultry				*Escherichia coli*
Fish				*Vibrio* spp.
				Aeromonas spp.

CHAPTER 6.8.

MONITORING OF THE QUANTITIES OF ANTIMICROBIALS USED IN ANIMAL HUSBANDRY

Article 6.8.1.

Purpose

The purpose of these recommendations is to describe an approach to the monitoring of quantities of antimicrobials used in animal husbandry.

These recommendations are intended for use by OIE Members to collect objective and quantitative information to evaluate usage patterns by animal species, antimicrobial class, potency and type of use in order to evaluate antimicrobial exposure.

Article 6.8.2.

Objectives

The information provided in these recommendations is essential for *risk analyses* and planning, can be helpful in interpreting resistance surveillance data and can assist in the ability to respond to problems of antimicrobial resistance in a precise and targeted way. This information may also assist in evaluating the effectiveness of efforts to ensure prudent use and mitigation strategies (for example, by identifying changes in prescribing practices for *veterinarians*) and to indicate where alteration of antimicrobial prescribing practices might be appropriate, or if changes in prescription practice have altered the pattern of antimicrobial use.

The continued collection of this basic information will also help give an indication of trends in the use of animal antimicrobials over time and the role of these trends in the development of antimicrobial resistance in *animals*.

For all OIE Members, the minimum basic information collected should be the annual weight in kilograms of the active ingredient of the antimicrobial(s) used in food animal production. In addition, the type of use (therapeutic or growth promotion) and route of administration (parenteral or oral administration) should be recorded.

Members may wish to consider, for reasons of cost and administrative efficiency, collecting medical, food *animal*, agricultural and other antimicrobial use data in a single programme. A consolidated programme would also facilitate comparisons of animal use with human use data for relative *risk analysis* and help to promote optimal usage of antimicrobials.

Article 6.8.3.

Development and standardisation of monitoring systems

Systems to monitor antimicrobial usage consist of the following elements:

1. Sources of antimicrobial data

   a) Basic sources

      Sources of data will vary from country to country. Such sources may include customs, import and export data, manufacturing and manufacturing sales data.

   b) Direct sources

      Data from animal drug registration, wholesalers, retailers, pharmacists, veterinarians, feed stores, feed mills and organised industry associations in these countries might be efficient and practical sources. A possible mechanism for the collection of this information is to make the provision of appropriate information by manufacturers to the regulatory authority one of the requirements of antimicrobial registration.

   c) End-use sources (veterinarians and food animal producers)

      This may be appropriate when basic or direct sources cannot be used for the routine collection of this information and when more accurate and locally specific information is required.

      Periodic collection of this type of information may be sufficient.

      It may be important when writing recommendations on antimicrobial resistance to take into account factors such as seasonality and disease conditions, species affected, agricultural systems (e.g. extensive range conditions and feedlots), dose rate, duration and length of treatment with antimicrobials.

      Collection, storage and processing of data from end-use sources are likely to be inefficient and expensive processes unless carefully designed and well managed, but should have the advantage of producing accurate and targeted information.

2. Categories of data

   a) Requirements for data on antimicrobial use

      The minimal data collected should be the annual weight in kilograms of the active ingredient of the antimicrobial(s) used in food animal production. This should be related to the scale of production (see point 3 below).

      For active ingredients present in the form of compounds or derivatives, the mass of active entity of the molecule should be recorded. For antibiotics expressed in International Units, the calculation required to convert these units to mass of active entity should be stated.

      If a Member has the infrastructure for capturing basic animal antimicrobial use data for a specific antimicrobial, then additional information can be considered to cascade from this in a series of subdivisions or levels of detail. Such a cascade of levels should include the following:

      i) The absolute amount in kilograms of active antimicrobial used per antimicrobial family per year, or for a specific antimicrobial chemical entity when this information is required.

      ii) Therapeutic and growth promotion use in kilograms of the specific active antimicrobial.

      iii) Subdivision of antimicrobial use into therapeutic and growth promotion use by animal species.

      iv) Subdivision of the data into the route of administration, specifically in-feed, in-water, injectable, oral, intramammary, intra-uterine and topical.

v) Further subdivision of these figures by season and region by a Member may be useful. *(Note: This may be especially management conditions, or where animals are moved from one locality to another during production.)*

vi) Further breakdown of data for analysis of antimicrobial use at the regional, local, *herd* and individual veterinarian levels may be possible using veterinary practice computer management software as part of specific targeted surveys or audits. Analysis of this information with the local or regional context could be useful for individual practitioners and practices where specific antimicrobial resistance has been identified and feedback is required.

b) Classes of antimicrobials

Nomenclature of antimicrobials should comply with international standards where available.

Decisions need to be made on what classes of antimicrobials should be considered and what members of various antimicrobial classes should be included in the data collection programme. These decisions should be based on currently known mechanisms of antimicrobial activity and resistance of the particular antimicrobial and its relative potency.

c) Species and production systems

Countries should keep a register of all animal use of antimicrobials for individual food animal species (cattle, sheep, goats, pigs, poultry, horses and fish) and for specific *diseases*. This will help to identify possible nonauthorised usage.

3. Other important information

Breakdown of farm livestock into species and production categories, including total live weights, would be most useful in any *risk analysis* or for comparison of animal antimicrobial use with human medical use within and between countries. For example, the total number of food *animals* by category and their weight in kilograms for food production per year (meat, dairy and draught cattle, and meat, fibre, poultry and dairy sheep) in the country would be essential basic information.

CHAPTER 6.9.

RESPONSIBLE AND PRUDENT USE OF ANTIMICROBIAL AGENTS IN VETERINARY MEDICINE

Article 6.9.1.

Purpose

These recommendations provide guidance for the responsible and prudent use of *antimicrobial agents* in veterinary medicine, with the aim of protecting both animal and human health. The *Competent Authorities* responsible for the registration and control of all groups involved in the production, distribution and use of veterinary antimicrobials have specific obligations.

Prudent use is principally determined by the outcome of the marketing authorisation procedure and by the implementation of specifications when antimicrobials are administered to *animals*.

Article 6.9.2.

Objectives of prudent use

Prudent use includes a set of practical measures and recommendations intended to prevent and/or reduce the selection of antimicrobial-resistant bacteria in *animals* to:

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

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

3. prevent, or reduce, as far as possible, the transfer of micro-organisms (with their resistance determinants) within animal populations;

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

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

6. maintain the efficacy of *antimicrobial agents* used in human medicine and prolong the usefulness of the antimicrobials;

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

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

Article 6.9.3.

Responsibilities of the regulatory authorities

1. Marketing authorisation

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

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

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

3. Market approval

   Regulatory authorities should attempt to expedite the market approval process of a new antimicrobial in order to address a specific need for the treatment of *disease*.

4. Registration procedures

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

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

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

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

   Regulatory authorities of *importing countries* should request the pharmaceutical industry to provide quality certificates prepared by the *Competent Authority* of the exporting and manufacturing country as appropriate. All countries should make every effort to actively combat the manufacture, advertisement, trade, distribution and use of unlicensed and counterfeit bulk active pharmaceutical ingredients and products.

5. Quality control of antimicrobial agents

   Quality controls should be performed:

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

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

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

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

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

6. Assessment of therapeutic efficacy

a) Preclinical trials

i) Preclinical trials should:

- establish the range of activity of *antimicrobial agents* on both pathogens and non-pathogens (commensals);
- assess the ability of the *antimicrobial agent* to select for resistance *in vitro* and *in vivo*, taking into consideration pre-existing resistant strains;
- establish an appropriate dosage regimen necessary to ensure the therapeutic efficacy of the *antimicrobial agent* and limit the selection of antimicrobial resistance. (Pharmacokinetic and pharmacodynamic data and models can assist in this appraisal.)

ii) The activity of *antimicrobial agents* towards the targeted micro-organism should be established by pharmacodynamics. The following criteria should be taken into account:

- spectrum of activity and mode of action;
- minimum inhibitory and bactericidal concentrations;
- time- or concentration-dependent activity or co-dependency;
- activity at the site of *infection*.

iii) The dosage regimens allowing maintenance of effective antimicrobial levels should be established by pharmacokinetics. The following criteria should be taken into account:

- bio-availability according to the route of administration;
- concentration of the antimicrobial at the site of *infection* and its distribution in the treated *animal*;
- metabolism that may lead to the inactivation of antimicrobials;
- excretion routes.

Use of combinations of *antimicrobial agents* should be scientifically supported.

b) Clinical trials

Clinical trials should be performed to confirm the validity of the claimed therapeutic indications and dosage regimens established during the preclinical phase. The following criteria should be taken into account:

i) diversity of the clinical cases encountered when performing multi-centre trials;

ii) compliance of protocols with good clinical practice, such as Veterinary International Cooperation on Harmonisation (VICH) guidelines;

iii) eligibility of studied clinical cases, based on appropriate criteria of clinical and bacteriological diagnoses;

iv) parameters for qualitatively and quantitatively assessing the efficacy of the treatment.

7. Assessment of the potential of antimicrobials to select for resistance

Other studies may be requested in support of the assessment of the potential of antimicrobials to select for resistance. The party applying for market authorisation should, where possible, supply data derived in target animal species under the intended conditions of use.

For this the following may be considered:

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

b) the route and level of human exposure to food-borne or other resistant organisms;

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

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

8. Establishment of acceptable daily intake, maximum residue level and withdrawal periods for antimicrobial compounds

a) When setting the acceptable daily intake (ADI) and MRL for an antimicrobial substance, the safety evaluation should also include the potential biological effects on the intestinal flora of humans.

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

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

i) the MRL established for the *antimicrobial agent* under consideration;

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

iii) the target animal species;

iv) the dosage regimen and the duration of treatment;

v) the route of administration.

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

9. Protection of the environment

An assessment of the impact of the proposed antimicrobial use on the environment should be conducted. Efforts should be made to ensure that the environmental impact of antimicrobial use is restricted to a minimum.

10. Establishment of a summary of product characteristics for each veterinary antimicrobial product

The summary of product characteristics contains the information necessary for the appropriate use of veterinary antimicrobial product (VAP) and constitutes the official reference for their labelling and package insert. This summary should contain the following items:

a) active ingredient and class;

b) pharmacological properties;

c) any potential adverse effects;

d) target animal species and age or production category;

e) therapeutic indications;

f) target micro-organisms;

g) dosage and administration route;

h) withdrawal periods;

i) incompatibilities;

j) shelf-life;

k) operator safety;

l) particular precautions before use;

m) particular precautions for the proper disposal of un-used or expired products;

n) information on conditions of use relevant to the potential for selection of resistance.

11. Post-marketing antimicrobial surveillance

The information collected through existing pharmacovigilance programmes, including lack of efficacy, should form part of the comprehensive strategy to minimise antimicrobial resistance. In addition to this, the following should be considered:

a) General epidemiological surveillance

The surveillance of animal micro-organisms resistant to *antimicrobial agents* is essential. The relevant authorities should implement a programme according to the *Terrestrial Code*.

b) Specific surveillance

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

12. Supply and administration of the antimicrobial agents used in veterinary medicine

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

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

b) supplied only through licensed/authorised distribution systems;

c) administered to *animals* by a *veterinarian* or under the supervision of a *veterinarian* or by other authorised persons.

The relevant authorities should develop effective procedures for the safe collection and destruction of unused or expired VAPs.

13. Control of advertising

All advertising of antimicrobials should be controlled by a code of advertising standards, and the relevant authorities must ensure that the advertising of antimicrobial products:

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

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

14. Training of antimicrobial users

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

a) information on *disease* prevention and management strategies;

b) the ability of antimicrobials to select for resistance in food-producing *animals*;

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

15. Research

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

Article 6.9.4.

Responsibilities of the veterinary pharmaceutical industry

1. Marketing authorisation of VAPs

   The veterinary pharmaceutical industry has responsibilities to:

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

   b) guarantee the quality of this information in compliance with the provisions of good manufacturing, laboratory and clinical practices;

   c) implement a pharmacovigilance programme and on request, specific surveillance for bacterial susceptibility and resistance.

2. Marketing and export of VAPs

   For the marketing and export of VAPs:

   a) only licensed and officially approved VAPs should be sold and supplied, and then only through licensed/authorised distribution systems;

   b) the pharmaceutical industry should provide quality certificates prepared by the *Competent Authority* of the exporting and/or manufacturing countries to the *importing country*;

   c) the national regulatory authority should be provided with the information necessary to evaluate the amount of *antimicrobial agents* marketed.

3. Advertising

   The veterinary pharmaceutical industry should:

   a) disseminate information in compliance with the provisions of the granted authorisation;

   b) ensure that the advertising of antimicrobials directly to the food animal producer is discouraged.

4. Training

   The veterinary pharmaceutical industry should participate in training programmes as defined in point 14 of Article 6.9.3.

5. Research

   The veterinary pharmaceutical industry should contribute to research as defined in point 15 of Article 6.9.3.

Article 6.9.5.

Responsibilities of wholesale and retail distributors

1. Retailers distributing VAPs should only do so on the prescription of a *veterinarian* or other suitably trained person authorised in accordance with the national legislation, and all products should be appropriately labelled.

2. The recommendations on the responsible use of antimicrobials should be reinforced by retail distributors who should keep detailed records of:

   a) date of supply;

   b) name of prescriber;

   c) name of user;

   d) name of product;

   e) batch number;

f) quantity supplied.

3. Distributors should also be involved in training programmes on the responsible use of antimicrobials, as defined in point 14 of Article 6.9.3.

Article 6.9.6.

Responsibilities of veterinarians

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

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

1. Use of antimicrobial agents

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

   a) only prescribe antimicrobials when necessary;

   b) make an appropriate choice of the antimicrobial based on experience of the efficacy of treatment.

2. Choosing an antimicrobial agent

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

      i) the clinical experience of the *veterinarian*;

      ii) the activity towards the pathogens involved;

      iii) the appropriate route of administration;

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

      v) the epidemiological history of the rearing unit, particularly in relation to the antimicrobial resistance profiles of the pathogens involved.

      Should a first-line antimicrobial treatment fail or should the *disease* recur, a second line treatment should ideally be based on the results of diagnostic tests.

      To minimise the likelihood of antimicrobial resistance developing, it is recommended that antimicrobials be targeted to pathogens likely to be the cause of *infection*.

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

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

3. Appropriate use of the antimicrobial chosen

   A prescription for *antimicrobial agents* should indicate precisely the treatment regime, the dose, the treatment intervals, the duration of the treatment, the withdrawal period and the amount of drug to be delivered, depending on the dosage and the number of *animals* to be treated.

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

4. Recording

Records on veterinary antimicrobial drugs should be kept in conformity with the national legislation. Information records should include the following:

a) quantities of medication used;

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

c) a list of medicine withdrawal period;

d) a record of antimicrobial susceptibilities;

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

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

Veterinarians should also periodically review farm records on the use of VAPs to ensure compliance with their directions and use these records to evaluate the efficacy of treatment regimens.

5. Labelling

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

6. Training

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 use of VAPs.

Article 6.9.7.

Responsibilities of food-animal producers

1. Food-animal producers with the assistance of a *veterinarian* are responsible for implementing health and *welfare* programmes on their farms (good farming practice) in order to promote animal health and food safety.

2. Food-animal producers should:

a) draw up a health plan with the attending *veterinarian* that outlines preventative measures (feedlot health plans, mastitis control plans, endo- and ectoparasite control and vaccination programmes, etc.);

b) use *antimicrobial agents* only on prescription, and according to the provisions of the prescription;

c) use *antimicrobial agents* in the species, for the uses and at the dosages on the approved/registered labels and in accordance with product label instructions or the advice of a *veterinarian* familiar with the *animals* and the production site;

d) isolate sick *animals*, when appropriate, to avoid the transfer of pathogens; dispose of dead or dying *animals* promptly under conditions approved by the relevant authorities;

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

f) address hygienic conditions regarding contacts between people (*veterinarians*, breeders, owners, children) and the *animals* treated;

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

h) dispose of surplus antimicrobials under safe conditions for the environment; medicines should only be used within the expiry date, for the condition for which they were prescribed and, if possible, in consultation with the prescribing *veterinarian*;

i) maintain all the laboratory records of bacteriological and susceptibility tests; these data should be made available to the *veterinarian* responsible for treating the *animals*;

j) keep adequate records of all medicines used, including the following:

   i) name of the product/active substance and batch number;

   ii) name of prescriber and/or the supplier;

   iii) date of administration;

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

   v) clinical conditions treated;

   vi) dosage;

   vii) withdrawal periods;

   viii) result of laboratory tests;

   ix) effectiveness of therapy;

k) inform the responsible *veterinarian* of recurrent *disease* problems.

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 OIE Members 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*.

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 resistance determinants from other sources;
- dose, route of administration and duration of treatment;
- pharmacokinetics (metabolism, bioavailability, access to intestinal flora);
- cycling of resistant micro-organisms between humans, *animals* and the environment.

5. Consequence assessment

The following factors should be considered in the consequence assessment:

- dose-response relationships;
- variation in disease susceptibility of exposed populations and subgroups of the populations;
- variation and frequency of animal health effects resulting from loss of efficacy of antimicrobials;
- changes in practices resulting from reduced confidence in antimicrobials;
- associated cost;
- perceived future usefulness of the drug (time reference).

6. Risk estimation

The following factors should be considered in the *risk* estimation:

- number of therapeutic failures due to resistant micro-organisms;
- *animal welfare*;
- economic cost;
- deaths (total per year; probability per year or lifetime for a random member of the population or a member of a specific more exposed sub-population);
- incidence of resistance observed in *animals*.

7. Risk management options and risk communication

Risk management options and *risk communication* have to be continuously monitored and reviewed in order to ensure that the objectives are being achieved.

The relevant recommendations (Articles 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.

ZOONOSES TRANSMISSIBLE FROM NON-HUMAN PRIMATES

Article 6.11.1.

Introduction

There are about 180 different species of non-human primates belonging to two suborders which are split into 12 families. The tree shrew family (previously considered as belonging to the primates) has not been included in these recommendations.

All non-human primate species are included in Appendix I or Appendix II of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) and may be transported internationally only if accompanied by the permits or certificates required under CITES.

Most imported non-human primates are destined for research, educational or breeding purposes.

Public health and safety are the primary issues of concern in the importation and keeping of non-human primates. This is especially true where close contact between humans and animals, their body fluids, faeces and tissues is likely to occur. Minimising the *risk* requires well-trained personnel and the following of stringent personal hygiene standards.

The *risk* of carrying zoonotic pathogens is related to the taxonomic position and the region of origin of the species concerned. It can be considered to increase from prosimians to marmosets and tamarins, then to other New World monkeys, to Old World monkeys and apes. The *risk* of carrying zoonotic agents is also greater in wild-caught non-human primates than in captive-bred animals which have been maintained in a well-defined environment under veterinary supervision. For non-human primates taken from the wild, usually only very limited health related information can be given by the supplier and by the *Veterinary Authority* of the *exporting country*.

Most *diseases* referred to in this chapter are not included in the OIE List, and there is, consequently, no requirement to report them on a regular basis within the OIE animal disease reporting system. However, the requirement to report exceptional epidemiological events remains in effect.

Standards for diagnostic tests are described in the *Terrestrial Manual* (under study).

Article 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 avoid transmission of *disease* (see Chapter 4.15.).

For reasons of public health, *Veterinary Authorities* of *importing countries* should not authorise the import of non-human primates for the purpose of being kept as pets.

In the case of a non-human primate being imported directly from a country within the natural range of the animal's species concerned, and where only limited health guarantees can be given, *Veterinary Authorities* of *importing countries* should place more emphasis on quarantine procedures and less on veterinary certification. As a matter of principle, limited health guarantees given by the supplier or the *Veterinary Authority* of the country of origin should not constitute an obstacle to imports, but very strict post import

quarantine requirements should be imposed. Particularly, the quarantine should meet the standards set in Chapter 6.11., 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 6.11.

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 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 6.11. for at least 12 weeks; and during this quarantine:
    a) all animals to be monitored daily for signs of illness and, if necessary, be subjected to a clinical examination;
    b) all animals dying for any reason to be subjected to complete post-mortem examination at a laboratory approved for this purpose;
    c) any cause of illness or death to be determinated before the group to which the animals belong is released from quarantine;

d) animals to be subjected to the following diagnostic tests and treatments in accordance with Chapter 4.15.:

Disease/agent	Animal groups	Schedule	Methods
Hepatitis B	Gibbons and great apes	First test during first week; second test after 3 to 4 weeks	Serological tests for anti-hepatitis B core antigen and for hepatitis B surface antigen, and additional parameters as appropriate.
Tuberculosis (*Mycobacterium hominis* and *M. bovis*)	Marmosets and tamarins Prosimians, New World monkeys, Old World monkeys, gibbons and great apes	Two tests at an interval of 2 to 4 weeks At least three tests at intervals of 2 to 4 weeks	Skin test or serology. Of the skin tests, the Mantoux test is the most reliable of all and has the advantage over others in that the size of the reaction to the test is related to the severity of infection. Skin tests in marmosets, tamarins or small prosimians should be performed in the abdominal skin rather than in the eyelid. In some species (e.g. orang utan), skin tests for tuberculosis are notorious for false positive results. Comparative tests using both mammalian and avian PPD, together with cultures, radiography and ELISA may eliminate confusion.
Other bacterial pathogens (*Salmonella*, *Shigella*, *Yersinia* and others as appropriate)	All species	Daily test for 3 days within the first 5 days after arrival, and at least one or two more tests at intervals of 2 to 4 weeks	Faecal culture. The fresh faeces or rectal swabs have to be cultured immediately or to be placed immediately in the transportation medium.
Endo- and ectoparasites	All species	At least two tests, one of which should be at the start, the other towards the end of the quarantine	Testing methods and antiparasitic treatment as appropriate to species of animal and parasitic agent.

In addition, *Veterinary Authorities* of *importing countries* should recognize the public health importance of other *zoonoses* such as measles, hepatitis A, monkey pox, Marburg disease or Ebola/Reston, etc., even though this article does not recommend specific testing or treatment protocols for these agents during the quarantine period. *Veterinary Authorities* should recognize that, if animals are infected, the importation and spread of many such agents will be best controlled by the detection of clinical signs of *disease* during the quarantine period if this is correctly implemented during a 12-week period. For some viral *zoonoses*, e.g. Herpes B, current diagnostic testing is not reliable, and for others, e.g. herpes viruses or retroviruses, which can be latent and relatively ubiquitous, producing life-long *infections* in some species, the diagnosis and exclusion of such infected animals may not be possible for the purposes of importation. Therefore, the precautions described in Article 6.11.7. must be strictly applied when handling such non-human primates in order to protect human health and safety.

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 6.11. for at least 30 days; and during this period:
   a) all animals to be monitored daily for signs of illness and, if necessary, be subjected to a clinical examination;
   b) all animals dying for any reason to be subjected to complete post-mortem examination at a laboratory approved for this purpose;
   c) animals to be subjected to the following diagnostic tests and treatments in accordance with Chapter 4.15.:

Disease/agent	Animal groups	Schedule	Methods
Bacterial pathogens (*Salmonella*, *Shigella*, *Yersinia* and others as appropriate)	All species	Daily test for 3 days within the first 5 days after arrival	Faecal culture. (See further comments in the Table of Article 6.11.4.)
Endo- and ectoparasites	All species	At least two tests, one of which should be at the start, the other towards the end of the quarantine	Testing methods and antiparasitic treatment as appropriate to species of animal and parasitic agent.

Veterinary Authorities of *importing countries* should not normally require any tests for viral *diseases* or for tuberculosis. However, stringent precautions to ensure human health and safety should be followed as recommended in Article 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 *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 tuberculosis 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 determinated before the group to which the *animals* belong is released from quarantine;

d) *animals* to be subjected to the following diagnostic tests and treatments in accordance with Chapter 4.15.:

Disease/agent	Animal groups	Schedule	Methods
Tuberculosis	All species	One test	Skin test or serology. (See further comments in the Table of Article 6.11.4.)
Other bacterial pathogens (*Salmonella*, *Shigella*, *Yersinia* and others as appropriate)	All species	Daily test for 3 days within the first 5 days after arrival, and another test at least one week later	Faecal culture. (See further comments in the Table of Article 6.11.4.)
Endo- and ectoparasites	All species	At least two tests, one of which should be at the start, the other towards the end of the quarantine	Testing methods and antiparasitic treatment as appropriate to species of animal and parasitic agent.

Veterinary Authorities of *importing countries* should not normally require any tests for viral *diseases*. However, stringent precautions to ensure human health and safety should be followed as recommended in Article 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 lifetime as having lifelong *infections* with some zoonotic agents, e.g. macaques with Herpes B virus;
3. to ensure that the staff follows personal hygiene practices, including the use of protective clothing, and the prohibition of eating, drinking and smoking in potentially infective areas;
4. to implement a screening programme for personnel health, including monitoring for tuberculosis, pathogenic enteric bacteria and endoparasites and other agents that are deemed necessary;
5. to implement an immunisation programme as appropriate, including e.g. tetanus, measles, poliomyelitis, rabies, hepatitis A and B, and other *diseases* endemic in the area of origin of the non-human primates;
6. to develop guidelines for the prevention and treatment of *zoonoses* that may be transmitted by bites and scratches, e.g. rabies and herpes viruses;
7. to issue to their staff a card which states that they work with non-human primates or with their body fluids, faeces or tissues, and which may be presented to the medical profession in case of illness;
8. to dispose of carcasses, body fluids, faeces and tissues in a manner which is not detrimental to public health.

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 veterinary treatment, appropriate shelter, management, nutrition, humane handling and humane *slaughter/killing*. *Animal welfare* refers to the state of the *animal*; the treatment that an *animal* receives is covered by other terms such as animal care, animal husbandry, and humane treatment.

Article 7.1.2.

Guiding principles for animal welfare

1. That there is a critical relationship between animal health and *animal welfare*.
2. That the internationally recognised 'five freedoms' (freedom from hunger, thirst and malnutrition; freedom from fear and distress; freedom from physical and thermal discomfort; freedom from pain, injury and *disease*; and freedom to express normal patterns of behaviour) provide valuable guidance in *animal welfare*.
3. That the internationally recognised 'three Rs' (reduction in numbers of *animals*, refinement of experimental methods and replacement of *animals* with non-animal techniques) provide valuable guidance for the use of *animals* in science.
4. That the scientific assessment of *animal welfare* involves diverse elements which need to be considered together, and that selecting and weighing these elements often involves value-based assumptions which should be made as explicit as possible.
5. That the use of *animals* in agriculture and science, and for companionship, recreation and entertainment, makes a major contribution to the wellbeing of people.
6. That the use of *animals* carries with it an ethical responsibility to ensure the *welfare* of such *animals* to the greatest extent practicable.
7. That improvements in farm *animal welfare* can often improve productivity and food safety, and hence lead to economic benefits.
8. That equivalent outcomes based on performance criteria, rather than identical systems based on design criteria, be the basis for comparison of *animal welfare* standards and recommendations.

Article 7.1.3.

Scientific basis for recommendations

1. *Welfare* is a broad term which includes the many elements that contribute to an *animal*'s quality of life, including those referred to in the 'five freedoms' listed above.
2. The scientific assessment of *animal welfare* has progressed rapidly in recent years and forms the basis of these recommendations.
3. Some measures of *animal welfare* involve assessing the degree of impaired functioning associated with injury, *disease*, and malnutrition. Other measures provide information on *animals*' needs and affective states such as hunger, pain and fear, often by measuring the strength of *animals*' preferences, motivations and aversions. Others assess the physiological, behavioural and immunological changes or effects that *animals* show in response to various challenges.
4. Such measures can lead to criteria and indicators that help to evaluate how different methods of managing *animals* influence their *welfare*.

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.

I. Animal behaviour

Animal handlers should be experienced and competent in handling and moving farm livestock and understand the behaviour patterns of *animals* and the underlying principles necessary to carry out their tasks.

The behaviour of individual *animals* or groups of *animals* will vary depending on their breed, sex, temperament and age and the way in which they have been reared and handled. Despite these differences, the following behaviour patterns, which are always present to some degree in domestic *animals*, should be taken into consideration in handling and moving the *animals*.

Most domestic livestock are kept in *herds* and follow a leader by instinct.

Animals which are likely to be hostile to 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*.

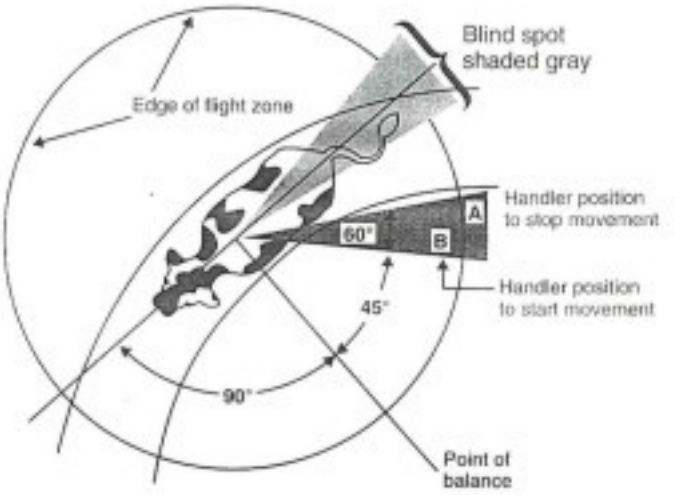
Domestic *animals* will try to escape if any person approaches closer than a certain distance. This critical distance, which defines the flight zone, varies among species and individuals of the same species, and depends upon previous contact with humans. *Animals* reared in close proximity to humans (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.

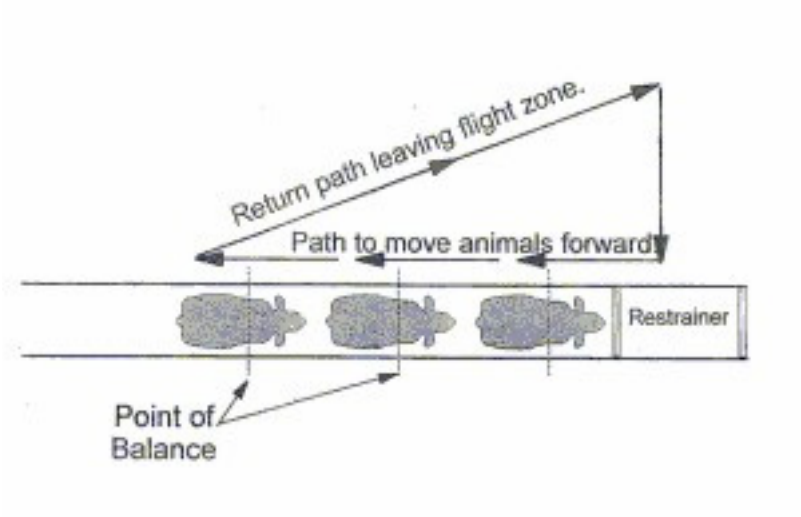
Domestic *animals* have a wide-angle vision but only have a limited forward binocular vision and poor perception of depth. This means that they can detect objects and movements beside and behind them, but can only judge distances directly ahead.

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*.

An example of a flight zone (cattle)



Handler movement pattern to move cattle forward



2. Distractions and their removal

Design of new *loading* and *unloading* facilities or modification of existing facilities should aim to minimise the potential for distractions that may cause approaching *animals* to stop, baulk or turn back. Below are examples of common distractions and methods for eliminating them:

a) reflections on shiny metal or wet floors – move a lamp or change lighting;

b) dark entrances – illuminate with indirect lighting which does not shine directly into the eyes of approaching *animals*;

c) *animals* seeing moving people or equipment up ahead – install solid sides on chutes and races or install shields;

d) dead ends – avoid if possible by curving the passage, or make an illusory passage;

e) chains or other loose objects hanging in chutes or on fences – remove them;

f) uneven floors or a sudden drop in floor levels – avoid uneven floor surfaces or install a solid false floor to provide an illusion of a solid and continuous walking surface;

g) sounds of air hissing from pneumatic equipment – install silencers or use hydraulic equipment or vent high pressure to the external environment using flexible hosing;

h) clanging and banging of metal objects – install rubber stops on gates and other devices to reduce metal to metal contact;

i) air currents from fans or air curtains blowing into the face of *animals* – redirect or reposition equipment.

Article 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.

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*;

vii) give animal consignments priority to allow import procedures to be completed without unnecessary delay.

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*.

Article 7.2.4.

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 provision of non-slippery flooring. The avoidance of injury to *animal handlers* while carrying out their responsibilities should be emphasised.

b) *Vessels* should be properly illuminated to allow *animals* to be observed and inspected.

c) *Vessels* should be designed to permit thorough cleaning and *disinfection*, and the management of faeces and urine.

d) *Vessels* and their fittings should be maintained in good mechanical and structural conditions.

e) *Vessels* should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported. The ventilation system should be effective when the *vessel* is stationary. An emergency power supply should be available to maintain ventilation in the case of primary machinery breakdown.

f) The feeding and watering system should be designed to permit adequate access to feed and water appropriate to the species, size and weight of the *animals*, and to minimise soiling of pens.

g) *Vessels* should be designed so that the faeces or urine from *animals* on upper levels do not soil *animals* on lower levels, or their feed or water.

h) Loading and stowage of feed and bedding should be carried out in such a way to ensure protection from fire hazards, the elements and sea water.

i) Where appropriate, suitable bedding, such as straw or sawdust, should be added to *vessel* floors to assist absorption of urine and faeces, provide better footing for *animals* and protect *animals* (especially young *animals*) from hard or rough flooring surfaces and adverse weather conditions.

j) The above principles apply also to *containers* used for the transport of *animals*.

5. Special provisions for transport in road vehicles on roll-on/roll-off vessels or for containers

a) Road *vehicles* and *containers* should be equipped with a sufficient number of adequately designed, positioned and maintained securing points enabling them to be securely fastened to the *vessel*.

b) Road *vehicles* and *containers* should be secured to the ship before the start of the sea journey to prevent them being displaced by the motion of the *vessel*.

c) *Vessels* should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported, especially where the *animals* are transported in a secondary *vehicle*/*container* on enclosed decks.

d) Due to the risk of limited airflow on certain decks of a *vessel*, a road *vehicle* or *container* may require a forced ventilation system of greater capacity than that provided by natural ventilation.

6. Nature and duration of the journey

The maximum duration of a *journey* should be determined taking into account factors that determine the overall *welfare* of *animals*, such as:

a) the ability of the *animals* to cope with the stress of transport (such as very young, old, lactating or pregnant *animals*);

b) the previous transport experience of the *animals*;

c) the likely onset of fatigue;

d) the need for special attention;

e) the need for feed and water;

f) the increased susceptibility to injury and *disease*;

g) *space allowance* and *vessel* design;

h) weather conditions;

i) *vessel* type used, method of propulsion and risks associated with particular sea conditions.

7. Space allowance

a) The number of *animals* which should be transported on a *vessel* and their allocation to different pens on the *vessel* should be determined before *loading*.

b) The amount of space required, including headroom, depends on the species of *animal* and should allow the necessary thermoregulation. Each *animal* should be able to assume its natural position for transport (including during *loading* and *unloading*) without coming into contact with the roof or upper deck of the *vessel*. When *animals* lie down, there should be enough space for every *animal* to adopt a normal lying posture.

c) Calculations for the *space allowance* for each *animal* should be carried out in reference to a relevant national or international document. The size of pens will affect the number of *animals* in each.

d) The same principles apply when *animals* are transported in *containers*.

8. Ability to observe animals during the journey

Animals should be positioned to enable each *animal* to be observed regularly and clearly by an *animal handler* or other responsible person, during the *journey* to ensure their 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 animal *traceability of animals* to the premises of departure, and, where possible, to the premises of origin;

g) details of any *animals* considered at particular risk of suffering poor *welfare* during transport (point 3e) of Article 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*;

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.

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 *disinfestation* is necessary during travel, it should be carried out with the minimum of stress to the *animals*.

2. Sick or injured animals

a) Sick or injured *animals* should be segregated.

b) Sick or injured *animals* should be appropriately treated or humanely killed, in accordance with a predetermined emergency response plan (Article 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.

Article 7.2.11.

Actions in the event of a refusal to allow the importation of a shipment

1. The *welfare* of the *animals* should be the first consideration in the event of a refusal to import.

2. When *animals* have been refused import, the *Competent Authority* of the *importing country* should make available suitable isolation facilities to allow the *unloading* of *animals* from a *vessel* and their secure holding, without posing a risk to the health of the national *herd*, pending resolution of the situation. In this situation, the priorities should be:

   a) The *Competent Authority* of the *importing country* should provide urgently in writing the reasons for the refusal.

   b) In the event of a refusal for animal health reasons, the *Competent Authority* of the *importing country* should provide urgent access to an OIE-appointed *veterinarian(s)* to assess the health status of the *animals* with regard to the concerns of the *importing country*, and the necessary facilities and approvals to expedite the required diagnostic testing.

   c) The *Competent Authority* of the *importing country* should provide access to allow continued assessment of the ongoing health and *welfare* situation.

   d) If the matter cannot be promptly resolved, the *Competent Authorities* of the *exporting* and *importing countries* should call on the OIE to mediate.

3. In the event that the *animals* are required to remain on the *vessel*, the priorities should be:

   a) The *Competent Authority* of the *importing country* should allow provisioning of the *vessel* with water and feed as necessary.

   b) The *Competent Authority* of the *importing country* should provide urgently in writing the reasons for the refusal.

   c) In the event of a refusal for animal health reasons, the *Competent Authority* of the *importing country* should provide urgent access to an OIE-appointed *veterinarian(s)* to assess the health status of the *animals* with regard to the concerns of the *importing country*, and the necessary facilities and approvals to expedite the required diagnostic testing.

   d) The *Competent Authority* of the *importing country* should provide access to allow continued assessment of the ongoing health and other aspects of the *welfare* of the *animals*, and the necessary actions to deal with any issues which arise.

   e) If the matter cannot be urgently resolved, the *Competent Authorities* of the *exporting* and *importing countries* should call on the OIE to mediate.

4. The OIE should utilise its informal procedure for dispute mediation. to identify a mutually agreed solution which will address the animal health and *welfare* issues in a timely manner.

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 in a bunch as a single *animal* will strive to rejoin the others. Whilst they are usually docile, they have an unnerving habit of spitting in self-defence. During transport, they usually lie down. They frequently extend their front legs forward when lying, so gaps below partitions should be high enough so that their legs are not trapped when the *animals* rise.

Cattle are sociable *animals* and may become agitated if they are singled out. Social order is usually established at about two years of age. When groups are mixed, social order has to be re-established and aggression may occur until a new order is established. Crowding of cattle may also increase aggression as the *animals* try to maintain personal space. Social behaviour varies with age, breed and sex; *Bos indicus* and *B. indicus*-cross *animals* are usually more temperamental than European breeds. Young bulls, when moved in groups, show a degree of playfulness (pushing and shoving) but become more aggressive and territorial with age. Adult bulls have a minimum personal space of six square metres. Cows with young calves can be very protective, and handling calves in the presence of their mothers can be dangerous. Cattle tend to avoid "dead end" in passages.

Goats should be handled calmly and are more easily led or driven than if they are excited. When goats are moved, their gregarious tendencies should be exploited. Activities which frighten, injure or cause agitation to *animals* should be avoided. Bullying is particularly serious in goats. Housing strange goats together could result in fatalities, either through physical violence, or subordinate goats being refused access to food and water.

Horses in this context include all solipeds, donkeys, mules, hinnies and zebra. They have good eyesight and a very wide angle of vision. They may have a history of *loading* resulting in good or bad experiences. Good training should result in easier *loading*, but some horses can prove difficult, especially if they are inexperienced or have associated *loading* with poor transport conditions. In these circumstances, two experienced *animal handlers* can load an *animal* by linking arms or using a strop below its rump. Blindfolding may even be considered. Ramps should be as shallow as possible. Steps are not usually a problem when horses mount a ramp, but they tend to jump a step when descending, so steps should be as low as possible. Horses benefit from being individually stalled, but may be transported in compatible groups. When horses are to travel in groups, their shoes should be removed.

Pigs have poor eyesight, and may move reluctantly in unfamiliar surroundings. They benefit from well lit loading bays. Since they negotiate ramps with difficulty, these should be as level as possible and provided with secure footholds. Ideally, a hydraulic lift should be used for greater heights. Pigs also negotiate steps with difficulty. A good 'rule-of-thumb' is that no step should be higher than the pig's front knee. Serious aggression may result if unfamiliar *animals* are mixed. Pigs are highly susceptible to heat stress.

Sheep are sociable *animals* with good eyesight and tend to "flock together", especially when they are agitated. They should be handled calmly and their tendency to follow each other should be exploited when they are being moved. Sheep may become agitated if they are singled out for attention and will strive to rejoin the group. Activities which frighten, injure or cause agitation to sheep should be avoided. They can negotiate steep ramps.

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.

I. Animal behaviour

Animal handlers should be experienced and competent in handling and moving farm livestock and understand the behaviour patterns of *animals* and the underlying principles necessary to carry out their tasks.

The behaviour of individual *animals* or groups of *animals* will vary depending on their breed, sex, temperament and age and the way in which they have been reared and handled. Despite these differences, the following behaviour patterns, which are always present to some degree in domestic *animals*, should be taken into consideration in handling and moving the *animals*.

Most domestic livestock are kept in 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*.

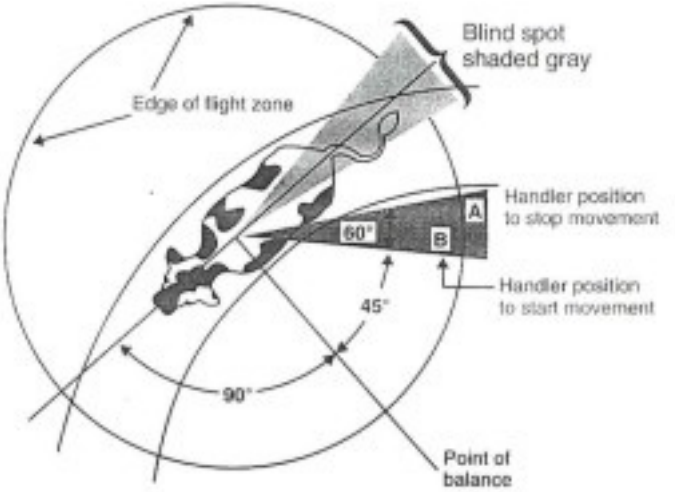
Animal handlers should use the point of balance at the *animal*'s shoulder to move *animals*, adopting a position behind the point of balance to move an *animal* forward and in front of the point of balance to move it backward.

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.

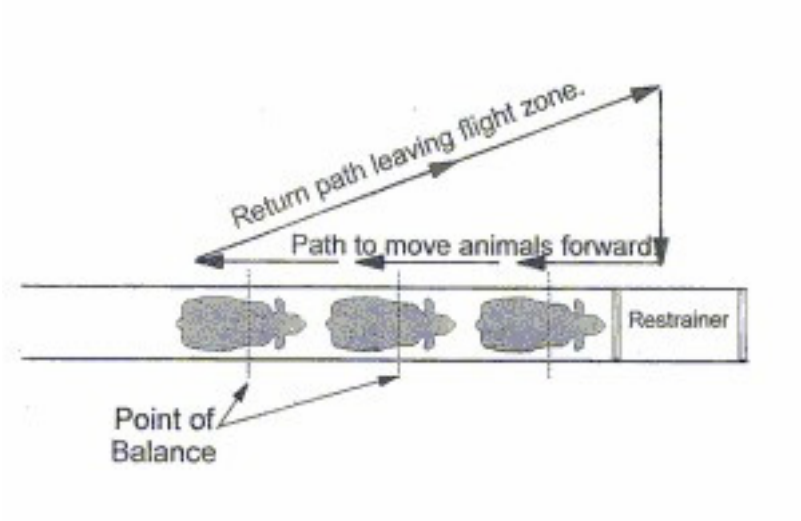
Although domestic *animals* have a highly sensitive sense of smell, they may react differently to the smells encountered during travel. Smells which cause negative responses should be taken into consideration when managing *animals*.

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*.

An example of a flight zone (cattle)



Handler movement pattern to move cattle forward



2. Distractions and their removal

Design of new *loading* and *unloading* facilities or modification of existing facilities should aim to minimise the potential for distractions that may cause approaching *animals* to stop, baulk or turn back. Below are examples of common distractions and methods for eliminating them:

a) reflections on shiny metal or wet floors – move a lamp or change lighting;

b) dark entrances – illuminate with indirect lighting which does not shine directly into the eyes of approaching *animals*;

c) *animals* seeing moving people or equipment up ahead – install solid sides on chutes and races or install shields;

d) dead ends – avoid if possible by curving the passage, or make an illusory passage;

e) chains or other loose objects hanging in chutes or on fences – remove them;

f) uneven floors or a sudden drop in floor levels – avoid uneven floor surfaces or install a solid false floor to provide an illusion of a solid and continuous walking surface;

g) sounds of air hissing from pneumatic equipment – install silencers or use hydraulic equipment or vent high pressure to the external environment using flexible hosing;

h) clanging and banging of metal objects – install rubber stops on gates and other devices to reduce metal to metal contact;

i) air currents from fans or air curtains blowing into the face of *animals* – redirect or reposition equipment.

Article 7.3.3.

Responsibilities

Once the decision to transport the *animals* has been made, the *welfare* of the *animals* during their *journey* is the paramount consideration and is the joint responsibility of all people involved. The individual responsibilities of persons involved will be described in more detail in this article.

The roles of each of those responsible are defined below:

1. The owners and managers of the *animals* are responsible for:

   a) the general health, overall *welfare* and fitness of the *animals* for the *journey*;

   b) ensuring compliance with any required veterinary or other certification;

   c) the presence of an *animal handler* competent for the species being transported during the *journey* with the authority to take prompt action; in case of transport by individual trucks, the truck driver may be the sole *animal handler* during the *journey*;

   d) the presence of an adequate number of *animal handlers* during *loading* and *unloading*;

   e) ensuring that equipment and veterinary assistance are provided as appropriate for the species and the *journey*.

2. Business agents or buying/selling agents are responsible for:

   a) selection of *animals* that are fit to travel;

   b) availability of suitable facilities at the start and at the end of the *journey* for the assembly; *loading*, transport, *unloading* and holding of *animals*, including for any stops at *resting points* during the *journey* and for emergencies.

3. *Animal handlers* are responsible for the humane handling and care of the *animals*, especially during *loading* and *unloading*, and for maintaining a *journey* log. To carry out their responsibilities, they should have the authority to take prompt action. In the absence of a separate *animal handler*, the driver is the *animal handler*.

4. Transport companies, *vehicle* owners and drivers are responsible for planning the *journey* to ensure the care of the *animals*; in particular they are responsible for:

   a) choosing appropriate *vehicles* for the species transported and the *journey*;

   b) ensuring that properly trained staff are available for *loading/unloading* of *animals*;

   c) ensuring adequate competency of the driver in matters of *animal welfare* for the species being transported in case a separate *animal handler* is not assigned to the truck;

d) developing and keeping up-to-date contingency plans to address emergencies (including adverse weather conditions) and minimise stress during transport;

e) producing a *journey* plan which includes a *loading* plan, *journey* duration, itinerary and location of resting places;

f) *loading* only those *animals* which are fit to travel, for their correct *loading* into the *vehicle* and their inspection during the *journey*, and for appropriate responses to problems arising; if its fitness to travel is in doubt, the *animal* should be examined by a *veterinarian* in accordance with point 3a) of Article 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;

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;
      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 3e) 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*.

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 *annimal 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*.

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.

Article 7.3.10.

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*.

Article 7.3.11.

Actions in the event of a refusal to allow the completion of the journey

1. The *welfare* of the *animals* should be the first consideration in the event of a refusal to allow the completion of the *journey*.

2. When the *animals* have been refused import, the *Competent Authority* of the *importing country* should make available suitable isolation facilities to allow the *unloading* of *animals* from a *vehicle* and their secure holding, without posing a risk to the health of national herd or flock, pending resolution of the situation. In this situation, the priorities should be:

a) the *Competent Authority* of the *importing country* should provide urgently in writing the reasons for the refusal;

b) in the event of a refusal for animal health reasons, the *Competent Authority* of the *importing country* should provide urgent access to a *veterinarian*, where possible an OIE *veterinarian(s)* appointed by the Director General, to assess the health status of the *animals* with regard to the concerns of the *importing country*, and the necessary facilities and approvals to expedite the required diagnostic testing;

c) the *Competent Authority* of the *importing country* should provide access to allow continued assessment of the health and other aspects of the *welfare* of the *animals*;

d) if the matter cannot be promptly resolved, the *Competent Authorities* of the *exporting* and *importing countries* should call on the OIE to mediate.

3. In the event that a *Competent Authority* requires the *animals* to remain on the *vehicle*, the priorities should be:

a) to allow provisioning of the *vehicle* with water and feed as necessary;

b) to provide urgently in writing the reasons for the refusal;

c) to provide urgent access to an independent *veterinarian(s)* to assess the health status of the *animals*, and the necessary facilities and approvals to expedite the required diagnostic testing in the event of a refusal for animal health reasons;

d) to provide access to allow continued assessment of the health and other aspects of the *welfare* of the *animals*, and the necessary actions to deal with any animal issues which arise.

4. The OIE should utilise its 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;
- 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.

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:

Females		Maximum number of days since the last service
Horses		300
Cows		250
Deer	(axis, fallow and sika)	170
	(red deer, reindeer)	185
Ewes (sheep)		115
Nannies (goats)		115
Sows (pigs)		90

Where service dates or date of last exposure to a male are not available, the *animals* should be examined by a *veterinarian* to ensure that pregnancy is not so advanced that *animals* are likely to give birth during transport or suffer unnecessarily.

Any *animal* showing udder engorgement and slackening of the pelvic ligament should be refused.

Article 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.

Species	**Weight**	**Density**	**Space/ animal**	**No. of animals per**	**Animals per single tier pallet**		
	kg	kg/m²	m²	10 m²	214x264 cm	214x308 cm	234x308 cm
Calves	50	220	0.23	43	24	28	31
	70	246	0.28	35/6	20	23	25
	80	266	0.30	33	18	21	24
	90	280	0.32	31	17	20	22
Cattle	300	344	0.84	11-12	6	7	8
	500	393	1.27	8	4	5	5
	600	408	1.45	6-7	3-4	4	4-5
	700	400	1.63	6	3	3-4	4
Sheep	25	147	0.17	59	32	37	42
	70	196	0.36	27/8	15	18	20
Pigs	25	172	0.15	67	37	44	48
	100	196	0.51	20	10	12	14

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.

Article 7.4.5.

Disinfection and disinfestation

1. Disinfection

a) Those parts of the interior of the aircraft destined for the carriage of *animals* should be thoroughly cleaned of all foreign matters using methods acceptable to aircraft management before being loaded.

b) These parts should be sprayed with a disinfectant:

i) suitable for the *diseases* which could be carried by the *animals*;

ii) that does not cause problems with the aircraft;

iii) that will not leave a residue hazardous to the *animals* being transported.

If in doubt, the airline should be consulted on the suitability of the disinfectant. A mechanical nebuliser should be used to minimise the amount of disinfectant used.

Suggested disinfectants currently in use are:

iv) 4 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 recognise 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:

a) incineration to an ash;

b) heating at an internal temperature of at least of 100°C for 30 minutes, then disposal in a land fill site;

c) controlled burial in a land fill site.

CHAPTER 7.5.

SLAUGHTER OF ANIMALS

Article 7.5.1.

General principles

1. Object

These recommendations address the need to ensure the *welfare* of food *animals* during pre-slaughter and *slaughter* processes, until they are dead.

These recommendations apply to the *slaughter* in *slaughterhouses* of the following domestic *animals*: cattle, buffalo, bison, sheep, goats, camelids, deer, horses, pigs, ratites, rabbits and *poultry*. Other *animals*, wherever they have been reared, and all *animals* slaughtered outside *slaughterhouses* should be managed to ensure that their *transport*, *lairage*, *restraint* and *slaughter* is carried out without causing undue stress to the *animals*; the principles underpinning these recommendations apply also to these *animals*.

2. Personnel

Persons engaged in the *unloading*, moving, *lairage*, care, *restraint*, *stunning*, *slaughter* and bleeding of *animals* play an important role in the *welfare* of those *animals*. For this reason, there should be a sufficient number of personnel, who should be patient, considerate, competent and familiar with the recommendations outlined in the present chapter and their application within the national context.

Competence may be gained through formal training and/or practical experience. This competence should be demonstrated through a current certificate from the *Competent Authority* or from an independent body accredited by the *Competent Authority*.

The management of the *slaughterhouse* and the *Veterinary Services* should ensure that *slaughterhouse* staff are competent and carry out their tasks in accordance with the principles of *animal welfare*.

3. Animal behaviour

Animal handlers should be experienced and competent in handling and moving farm livestock, and understand the behaviour patterns of *animals* and the underlying principles necessary to carry out their tasks.

The behaviour of individual *animals* or groups of *animals* will vary, depending on their breed, sex, temperament and age and the way in which they have been reared and handled. Despite these differences, the following behaviour patterns which are always present to some degree in domestic *animals*, should be taken into consideration in handling and moving the *animals*.

Most domestic livestock are kept in groups and follow a leader by instinct.

Animals which are likely to harm each other in a group situation should not be mixed at *slaughterhouses*.

The desire of some *animals* to control their personal space should be taken into account in designing facilities.

Domestic *animals* will try to escape if any person approaches closer than a certain distance. This critical distance, which defines the flight zone, varies among species and individuals of the same species, and depends upon previous contact with humans. *Animals* reared in close proximity to humans i.e. tame have a smaller flight zone, whereas those kept in free range or extensive systems may have flight zones which may vary from one metre to many metres. *Animal handlers* should avoid

sudden penetration of the flight zone which may cause a panic reaction which could lead to aggression or attempted escape.

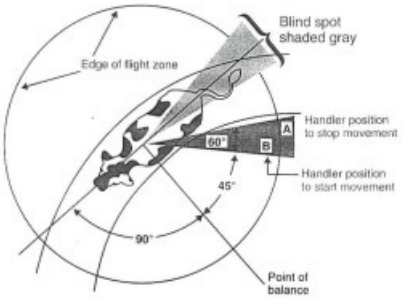
Animal handlers should use the point of balance at the *animal*'s shoulder to move *animals*, adopting a position behind the point of balance to move an *animal* forward and in front of the point of balance to move it backward.

Domestic *animals* have wide-angle vision but only have limited forward binocular vision and poor perception of depth. This means that they can detect objects and movements beside and behind them, but can only judge distances directly ahead.

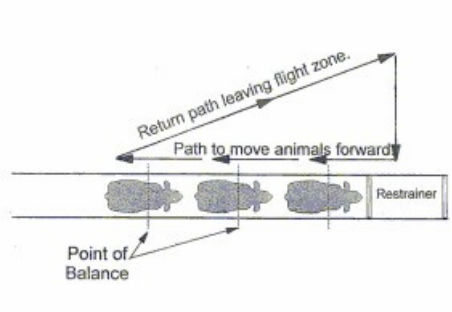
Although most domestic *animals* have a highly sensitive sense of smell, they react in different ways to the smells of *slaughterhouses*. Smells which cause fear or other negative responses should be taken into consideration when managing *animals*.

Domestic *animals* can hear over a greater range of frequencies than humans and are more sensitive to higher frequencies. They tend to be alarmed by constant loud noise and by sudden noises, which may cause them to panic. Sensitivity to such noises should also be taken into account when handling *animals*.

An example of a flight zone (cattle)



Handler movement pattern to move cattle forward



4. Distractions and their removal

Distractions that may cause approaching *animals* to stop, baulk or turn back should be designed out from new facilities or removed from existing ones. Below are examples of common distractions and methods for eliminating them:

a) reflections on shiny metal or wet floors – move a lamp or change lighting;

b) dark entrances to chutes, races, stun boxes or conveyor restrainers – illuminate with indirect lighting which does not shine directly into the eyes of approaching *animals* or create areas of sharp contrast;

c) *animals* seeing moving people or equipment up ahead – install solid sides on chutes and races or install shields;

d) dead ends – avoid if possible by curving the passage, or make an illusory passage;

e) chains or other loose objects hanging in chutes or on fences – remove them;

f) uneven floors or a sudden drop in floor levels at the entrance to conveyor restrainers – avoid uneven floor surfaces or install a solid false floor under the restrainer to provide an illusion of a solid and continuous walking surface;

g) sounds of air hissing from pneumatic equipment – install silencers or use hydraulic equipment or vent high pressure to the external environment using flexible hosing;

h) clanging and banging of metal objects – install rubber stops on gates and other devices to reduce metal to metal contact;

i) air currents from fans or air curtains blowing into the face of *animals* – redirect or reposition equipment.

Article 7.5.2.

Moving and handling animals

1. General considerations

Each *slaughterhouse* should have a dedicated plan for *animal welfare*. The purpose of such plan should be to maintain good level of *animal welfare* at all stages of the handling of *animals* until they are killed. The plan should contain standard operating procedures for each step of animal handling as to ensure that *animal welfare* is properly implemented based on relevant indicators. It also should include specific corrective actions in case of specific risks, like power failures or other circumstances that could negatively affect the *welfare* of *animals*.

Animals should be transported to *slaughter* in a way that minimises adverse animal health and *welfare* outcomes, and the transport should be conducted in accordance with the OIE recommendations for the transportation of *animals* (Chapters 7.2. and 7.3.).

The following principles should apply to *unloading animals*, moving them into *lairage* pens, out of the *lairage* pens and up to the *slaughter* point:

a) The conditions of the *animals* should be assessed upon their arrival for any *animal welfare* and health problems.

b) Injured or sick *animals*, requiring immediate *slaughter*, should be killed humanely and without delay, in accordance with the recommendations of the OIE.

c) *Animals* should not be forced to move at a speed greater than their normal walking pace, in order to minimise injury through falling or slipping. Performance standards should be established where numerical scoring of the prevalence of *animals* slipping or falling is used to evaluate whether animal moving practices and/or facilities should be improved. In properly designed and constructed facilities with competent *animal handlers*, it should be possible to move 99 percent of *animals* without their falling.

d) *Animals* for *slaughter* should not be forced to walk over the top of other *animals*.

e) *Animals* should be handled in such a way as to avoid harm, distress or injury. Under no circumstances should *animal handlers* resort to violent acts to move *animals*, such as crushing or breaking tails of *animals*, grasping their eyes or pulling them by the ears. *Animal handlers* should never apply an injurious object or irritant substance to *animals* and especially not to sensitive areas such as eyes, mouth, ears, anogenital region or belly. The throwing or dropping of *animals*, or their lifting or dragging by body parts such as their tail, head, horns, ears, limbs, wool, hair or feathers, should not be permitted. The manual lifting of small *animals* is permissible.

f) When using goads and other aids, the following principles should apply:

i) *Animals* that have little or no room to move should not be subjected to physical force or goads and other aids which compel movement. Electric goads and prods should only be used in extreme cases and not on a routine basis to move *animals*. The use and the power output should be restricted to that necessary to assist movement of an *animal* and only when an *animal* has a clear path ahead to move. Goads and other aids should not be used repeatedly if the *animal* fails to respond or move. In such cases it should be investigated whether some physical or other impediment is preventing the *animal* from moving.

ii) The use of such devices should be limited to battery-powered goads on the hindquarters of pigs and large ruminants, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets.

iii) Useful and permitted goads include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and metallic rattles; they should be used in a manner sufficient to encourage and direct movement of the *animals* without causing undue stress.

iv) Painful procedures (including whipping, kicking, tail twisting, use of nose twitches, pressure on eyes, ears or external genitalia), or the use of goads or other aids which cause pain and suffering (including large sticks, sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts), should not be used to move *animals*.

v) Excessive shouting at *animals* or making loud noises (e.g. through the cracking of whips) to encourage them to move should not occur, as such actions may make the *animals* agitated, leading to crowding or falling.

vi) *Animals* should be grasped or lifted in a manner which avoids pain or suffering and physical damage (e.g. bruising, fractures, dislocations). In the case of quadrupeds, manual lifting by a person should only be used in young *animals* or small species, and in a manner appropriate to the species; grasping or lifting such *animals* only by their wool, hair, feathers, feet, neck, ears, tails, head, horns, limbs causing pain or suffering should not be permitted, except in an emergency where *animal welfare* or human safety may otherwise be compromised.

vii) Conscious *animals* should not be thrown, dragged or dropped.

g) Performance standards should be established to evaluate the use of such instruments. Numerical scoring may be used to measure the percentage of *animals* moved with an electric instrument and the percentage of *animals* slipping or falling at a point in the *slaughterhouse*. Any risk of compromising *animal welfare*, for example slippery floor, should be investigated immediately and the defect rectified to eliminate the problem. In addition to resource-based measures, outcome-based measures (e.g. bruises, lesions, behaviour, and mortality) should be used to monitor the level of *welfare* of the *animals*.

2. Specific considerations for poultry

Stocking density in transport crates should be optimum to suit climatic conditions and to maintain species-specific thermal comfort within *containers*.

Care is especially necessary during *loading* and *unloading* to avoid body parts being caught on crates, leading to dislocated or broken bones in conscious birds. Such injuries will adversely affect *animal welfare*, carcass and *meat* quality.

Modular systems that involve tipping of live birds are not conducive to maintaining good *animal welfare*. These systems, when used, should be incorporated with a mechanism to facilitate birds sliding out of the transport system, rather than being dropped or dumped on top of each other from heights of more than a metre.

Birds may get trapped or their wings or claws may get caught in the fixtures, mesh or holes in poorly designed, constructed or maintained transport systems. Under this situation, operators *unloading* birds should ensure gentle release of trapped birds.

Drawers in modular systems and crates should be stacked and de-stacked carefully so as to avoid injury to birds.

Birds should have sufficient space so that all can lie down at the same time without being on top of each other.

Birds with broken bones and/or dislocated joints should be humanely killed before being hung on shackles for processing.

The number of *poultry* arriving at the processing plant with broken bones and/or dislocated joints should be recorded in a manner that allows for verification. For *poultry*, the percentage of chickens with broken or dislocated wings should not exceed 2 percent, with less than 1 percent being the goal (under study).

3. Provisions relevant to animals delivered in containers

   a) *Containers* in which *animals* are transported should be handled with care, and should not be thrown, dropped or knocked over. Where possible, they should be horizontal while being loaded and unloaded mechanically, and stacked to ensure ventilation. In any case they should be moved and stored in an upright position as indicated by specific marks.

   b) *Animals* delivered in *containers* with perforated or flexible bottoms should be unloaded with particular care in order to avoid injury. Where appropriate, *animals* should be unloaded from the *containers* individually.

   c) *Animals* which have been transported in *containers* should be slaughtered as soon as possible; mammals and ratites which are not taken directly upon arrival to the place of *slaughter* should have drinking water available to them from appropriate facilities at all times. Delivery of *poultry* for *slaughter* should be scheduled such that they are not deprived of water at the premises for longer than 12 hours. *Animals* which have not been slaughtered within 12 hours of their arrival should be fed, and should subsequently be given moderate amounts of food at appropriate intervals.

4. Provisions relevant to restraining and containing animals

   a) Provisions relevant to *restraining animals* for *stunning* or *slaughter* without *stunning*, to help maintain *animal welfare*, include:

      i) provision of a non-slippery floor;

      ii) avoidance of excessive pressure applied by *restraining* equipment that causes struggling or vocalisation in *animals*;

      iii) equipment engineered to reduce noise of air hissing and clanging metal;

      iv) absence of sharp edges in *restraining* equipment that would harm *animals*;

      v) avoidance of jerking or sudden movement of *restraining* device.

   b) Methods of *restraint* causing avoidable suffering should not be used in conscious *animals* because they cause severe pain and stress:

      i) suspending or hoisting *animals* (other than *poultry*) by the feet or legs;

      ii) indiscriminate and inappropriate use of *stunning* equipment;

      iii) mechanical clamping of the legs or feet of the *animals* (other than shackles used in *poultry* and ostriches) as the sole method of *restraint*;

      iv) breaking legs, cutting leg tendons or blinding *animals* in order to immobilise them;

      v) severing the spinal cord, for example using a puntilla or dagger, to immobilise *animals* 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*.

g) *Animal handlers* should be positioned alongside races and passageways on the inside radius of any curve, to take advantage of the natural tendency of *animals* to circle an intruder. Where one-way gates are used, they should be of a design which avoids bruising. Races should be horizontal but where there is a slope, they should be constructed to allow the free movement of *animals* without injury.

h) In *slaughterhouses* with high throughput, there should be a waiting pen, with a level floor and solid sides, between the holding pens and the race leading to the point of *stunning* or *slaughter*, to ensure a steady supply of *animals* for *stunning* or *slaughter* and to avoid having *animal handlers*

trying to rush *animals* from the holding pens. The waiting pen should preferably be circular, but in any case, so designed that *animals* cannot be trapped or trampled.

i) Ramps or lifts should be used for the *loading* and *unloading* of *animals* where there is a difference in height or a gap between the floor of the *vehicle* and the *unloading* area. Unloading ramps should be designed and constructed so as to permit *animals* to be unloaded from *vehicles* on the level or at the minimum gradient achievable. Lateral side protection should be available to prevent *animals* escaping or falling. They should be well drained, with secure footholds and adjustable to facilitate easy movement of *animals* without causing distress or injury.

3. Construction of lairage

a) *Lairages* should be constructed and maintained so as to provide protection from unfavourable climatic conditions, using strong and resistant materials such as concrete and metal which has been treated to prevent corrosion. Surfaces should be easy to clean. There should be no sharp edges or protuberances which may injure the *animals*.

b) Floors should be well drained and not slippery; they should not cause injury to the feet of the *animals*. Where necessary, floors should be insulated or provided with appropriate bedding. Drainage grids should be placed at the sides of pens and passageways and not where *animals* would have to cross them. Discontinuities or changes in floor, wall or gate colours, patterns or texture which could cause baulking in the movement of *animals* should be avoided.

c) *Lairages* should be provided with adequate lighting, but care should be taken to avoid harsh lights and shadows, which frighten the *animals* or affect their movement. The fact that *animals* will move more readily from a darker area into a well-lit area might be exploited by providing for lighting that can be regulated accordingly.

d) *Lairages* should be adequately ventilated to ensure that waste gases (e.g. ammonia) do not build up and that draughts at animal height are minimised. Ventilation should be able to cope with the range of expected climatic conditions and the number of *animals* the *lairage* will be expected to hold.

e) Care should be taken to protect the *animals* from excessively or potentially disturbing noises, for example by avoiding the use of noisy hydraulic or pneumatic equipment, and muffling noisy metal equipment by the use of suitable padding, or by minimising the transmission of such noises to the areas where *animals* are held and slaughtered.

f) Where *animals* are kept in outdoor *lairages* without natural shelter or shade, they should be protected from the effects of adverse weather conditions.

Article 7.5.4.

Care of animals in lairages

Animals in *lairages* should be cared for in accordance with the following recommendations:

1. As far as possible, established groups of *animals* should be kept together and each *animal* should have enough space to stand up, lie down and turn around. *Animals* hostile to each other should be separated.

2. Where tethers, ties or individual stalls are used, they should allow *animals* to stand up and lie down without causing injury or distress.

3. Where bedding is provided, it should be maintained in a condition that minimises risks to the health and safety of the *animals*, and sufficient bedding should be used so that *animals* do not become soiled with manure.

4. *Animals* should be kept securely in the *lairage*, and care should be taken to prevent them from escaping and from predators.

5. Suitable drinking water should be available to the *animals* on their arrival and at all times to *animals* in *lairages* unless they are to be slaughtered without delay.

6. Waiting time should be minimised and should not exceed 12 hours. If *animals* are not to be slaughtered within this period, suitable feed should be available to the *animals* on arrival and at intervals appropriate to the species. Unweaned *animals* should be slaughtered as soon as possible.

7. In order to prevent heat stress, *animals* subjected to high temperatures, particularly pigs and *poultry*, should be cooled by the use of water sprays, fans or other suitable means. However, the potential for water sprays to reduce the ability of *animals* to thermoregulate (especially *poultry*) should be considered in any decision to use water sprays. The risk of *animals* being exposed to very cold temperatures or sudden extreme temperature changes should also be considered.

8. The *lairage* area should be well lit in order to enable the *animals* to see clearly without being dazzled. During the night, the lights should be dimmed. Lighting should also be adequate to permit inspection of all *animals*. Subdued lighting, and for example blue light, may be useful in *poultry lairages* in helping to calm birds.

9. The condition and state of health of the *animals* in a *lairage* should be inspected at least every morning and evening by a *veterinarian* or, under the *veterinarian*'s responsibility, by another competent person, such as an *animal handler*. *Animals* which are sick, weak, injured or showing visible signs of distress should be separated, and veterinary advice should be sought immediately regarding treatment or the *animals* should be humanely killed immediately if necessary.

10. Lactating dairy *animals* should be slaughtered as soon as possible. Dairy *animals* with obvious udder distension should be milked to minimise udder discomfort.

11. *Animals* which have given birth during the *journey* or in the *lairage* should be slaughtered as soon as possible or provided with conditions which are appropriate for suckling for their *welfare* and the *welfare* of the newborn. Under normal circumstances, *animals* which are expected to give birth during a *journey* should not be transported.

12. *Animals* with horns, antlers or tusks capable of injuring other *animals*, if aggressive, should be penned separately.

13. *Poultry* awaiting *slaughter* should be protected from adverse weather conditions and provided with adequate ventilation.

14. *Poultry* in transport *containers* should be examined at the time of arrival. *Containers* should be stacked with sufficient space between the stacks to facilitate inspection of birds and air movement.

15. Forced ventilation or other cooling systems may be necessary under certain conditions to avoid build up of temperature and humidity. Temperature and humidity should be monitored at appropriate intervals.

Recommendations for specific species are described in detail in Articles 7.5.5. to 7.5.9.

Article 7.5.5.

Management of foetuses during slaughter of pregnant animals

Under normal circumstances, pregnant *animals* that would be in the final 10 percent of their gestation period at the planned time of *unloading* at the *slaughterhouse* should be neither transported nor slaughtered. If such an event occurs, an *animal handler* should ensure that females are handled separately, and the specific procedures described below are applied. In all cases, the *welfare* of foetuses and dams during *slaughter* should be safeguarded.

Foetuses should not be removed from the uterus sooner than 5 minutes after the maternal neck or chest cut, to ensure absence of consciousness. A foetal heartbeat will usually still be present and foetal movements may occur at this stage, but these are only a cause for concern if the exposed foetus successfully breathes air.

If a live mature foetus is removed from the uterus, it should be prevented from inflating its lungs and breathing air (e.g. by clamping the trachea).

When uterine, placental or foetal tissues, including foetal blood, are not to be collected as part of the post-*slaughter* processing of pregnant *animals*, all foetuses should be left inside the unopened uterus until they are dead. When uterine, placental or foetal tissues are to be collected, where practical, foetuses should not be removed from the uterus until at least 15–20 minutes after the maternal neck or chest cut.

If there is any doubt about consciousness, the foetus should be killed with a captive bolt of appropriate size or a blow to the head with a suitable blunt instrument.

The above recommendations do not refer to foetal rescue. Foetal rescue, the practice of attempting to revive foetuses found alive at the evisceration of the dam, should not be attempted during normal commercial *slaughter* as it may lead to serious *welfare* complications in the newborn *animal*. These include impaired brain function resulting from oxygen shortage before rescue is completed, compromised breathing and body heat production because of foetal immaturity, and an increased incidence of infections due to a lack of colostrum.

Article 7.5.6.

Summary analysis of handling and restraining methods and the associated animal welfare issues

	Presentation of animals	**Specific procedure**	**Specific purpose**	**Animal welfare concerns/ implications**	**Key animal welfare requirements**	**Applicable species**
No restraint	Animals are grouped	Group container	Gas stunning	Specific procedure is suitable only for gas stunning	Competent animal handlers in lairage; facilities; stocking density	Pigs, poultry
		In the field	Free bullet	Inaccurate targeting and inappropriate ballistics not achieving outright kill with first shot	Operator competence	Deer
		Group stunning pen	Head-only electrical Captive bolt	Uncontrolled movement of animals impedes use of hand operated electrical and mechanical stunning methods	Competent animal handlers in lairage and at stunning point	Pigs, sheep, goats, calves
	Individual animal confinement	Stunning pen/box	Electrical and mechanical stunning methods	Loading of animal; accuracy of stunning method, slippery floor and animal falling down	Competent animal handlers	Cattle, buffalo, sheep, goats, horses, pigs, deer, camelids, ratites
Restraining methods	Head restraint, upright	Halter/ head collar/bridle	Captive bolt Free bullet	Suitable for halter-trained animals; stress in untrained animals	Competent animal handlers	Cattle, buffalo, horses, camelids

	Presentation of animals	Specific procedure	Specific purpose	Animal welfare concerns/ implications	Key animal welfare requirements	Applicable species
Restraining methods (contd)	Head restraint, upright	Neck yoke	Captive bolt Electrical-head only Free bullet Slaughter without stunning	Stress of loading and neck capture; stress of prolonged restraint, horn configuration; unsuitable for fast line speeds, animals struggling and falling due to slippery floor, excessive pressure	Equipment; competent animal handlers, prompt stunning or slaughter	Cattle
	Leg restraint	Single leg tied in flexion (animal standing on 3 legs)	Captive bolt Free bullet	Ineffective control of animal movement, misdirected shots	Competent animal handler	Breeding pigs (boars and sows)
	Upright restraint	Beak holding	Captive bolt Electrical-head only	Stress of capture	Sufficient competent animal handlers	Ostriches
		Head restraint in electrical stunning box	Electrical-head only	Stress of capture and positioning	Competent animal handler	Ostriches
	Holding body upright- manual	Manual restraint	Captive bolt Electrical-head only Slaughter without stunning	Stress of capture and restraint; accuracy of stunning/ slaughter	Competent animal handlers	Sheep, goats, calves, ratites, small camelids, poultry
	Holding body upright mechanical	Mechanical clamp / crush / squeeze/ V-restrainer (static)	Captive bolt Electrical methods Slaughter without stunning	Loading of animal and overriding; excessive pressure	Proper design and operation of equipment	Cattle, buffalo, sheep, goats, deer, pigs, ostriches
	Lateral restraint – manual or mechanical	Restrainer/ cradle/crush	Slaughter without stunning	Stress of restraint	Competent animal handlers	Sheep, goats, calves, camelids, cattle
	Upright restraint mechanical	Mechanical straddle (static)	Slaughter without stunning Electrical methods Captive bolt	Loading of animal and overriding	Competent animal handlers	Cattle, sheep, goats, pigs
	Upright restraint – manual or mechanical	Wing shackling	Electrical	Excessive tension applied prior to stunning	Competent animal handlers	Ostriches
Restraining and /or conveying methods	Mechanical – upright	V–restrainer	Electrical methods Captive bolt Slaughter without stunning	Loading of animal and overriding; excessive pressure, size mismatch between restrainer and animal	Proper design and operation of equipment	Cattle, calves, sheep, goats, pigs

	Presentation of animals	Specific procedure	Specific purpose	Animal welfare concerns/ implications	Key animal welfare requirements	Applicable species
Restraining and /or conveying methods (contd)	Mechanical – upright	Mechanical straddle – band restrainer (moving)	Electrical methods Captive bolt Slaughter without stunning	Loading of animal and overriding, size mismatch between restrainer and animal	Competent animal handlers, proper design and layout of restraint	Cattle, calves, sheep, goats, pigs
	Mechanical – upright	Flat bed/deck Tipped out of containers on to conveyors	Presentation of birds for shackling prior to electrical stunning Gas stunning	Stress and injury due to tipping in dump-module systems height of tipping conscious poultry broken bones and dislocations	Proper design and operation of equipment	Poultry
	Suspension and/or inversion	Poultry shackle	Electrical stunning Slaughter without stunning	Inversion stress; pain from compression on leg bones	Competent animal handlers; proper design and operation of equipment	Poultry
	Suspension and/or inversion	Cone	Electrical – head-only Captive bolt Slaughter without stunning	Inversion stress	Competent animal handlers; proper design and operation of equipment	Poultry
	Upright restraint	Mechanical leg clamping	Electrical – head-only	Stress of resisting restraint in ostriches	Competent animal handlers; proper equipment design and operation	Ostriches
Restraining by inversion	Rotating box	Fixed side(s) (e.g. Weinberg pen)	Slaughter without stunning	Inversion stress; stress of resisting restraint, prolonged restraint, inhalation of blood and ingesta Keep restraint as brief as possible	Proper design and operation of equipment	Cattle
		Compressible side(s)	Slaughter without stunning	Inversion stress, stress of resisting restraint, prolonged restraint Preferable to rotating box with fixed sides Keep restraint as brief as possible	Proper design and operation of equipment	Cattle
Body restraint	Casting/ hobbling	Manual	Mechanical stunning methods Slaughter without stunning	Stress of resisting restraint; animal temperament; bruising. Keep restraint as short as possible	Competent animal handlers	Sheep, goats, calves, small camelids, pigs

	Presentation of animals	Specific procedure	Specific purpose	Animal welfare concerns/ implications	Key animal welfare requirements	Applicable species
Leg restraints		Rope casting	Mechanical stunning methods Slaughter without stunning	Stress of resisting restraint; prolonged restraint, animal temperament; bruising Keep restraint as short as possible	Competent animal handlers	Cattle, camelids
		Tying of 3 or 4 legs	Mechanical stunning methods Slaughter without stunning	Stress of resisting restraint; prolonged restraint, animal temperament; bruising Keep restraint as short as possible	Competent animal handlers	Sheep, goats, small camelids, pigs

Article 7.5.7.

Stunning methods

1. General considerations

The competence of the operators, and the appropriateness, and effectiveness of the method used for *stunning* and the maintenance of the equipment are the responsibility of the management of the *slaughterhouse*, and should be checked regularly by a *Competent Authority*.

Persons carrying out *stunning* should be properly trained and competent, and should ensure that:

a) the *animal* is adequately restrained;

b) *animals* in *restraint* are stunned as soon as possible;

c) the equipment used for *stunning* is maintained and operated properly in accordance with the manufacturer's recommendations, in particular with regard to the species and size of the *animal*;

d) the equipment is applied correctly;

e) stunned *animals* are bled out (slaughtered) as soon as possible;

f) *animals* are not stunned when *slaughter* is likely to be delayed; and

g) backup *stunning* devices are available for immediate use if the primary method of *stunning* fails. Provision of a manual inspection area and simple intervention like captive bolt or cervical dislocation for *poultry* would help prevent potential *welfare* problems.

In addition, such persons should be able to recognise when an *animal* is not correctly stunned and should take appropriate action.

2. Mechanical stunning

A mechanical device should be applied usually to the front of the head and perpendicular to the bone surface. For a more detailed explanation on the different methods for mechanical *stunning*, see Chapter 7.6. and Articles 7.6.6., 7.6.7. and 7.6.8. The following diagrams illustrate the proper application of the device for certain species.

Cattle

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

The optimum position for cattle is at the intersection of two imaginary lines drawn from the rear of the eyes to the opposite horn buds.

Pigs

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

The optimum position for pigs is on the midline just above eye level, with the shot directed down the line of the spinal cord.

Sheep

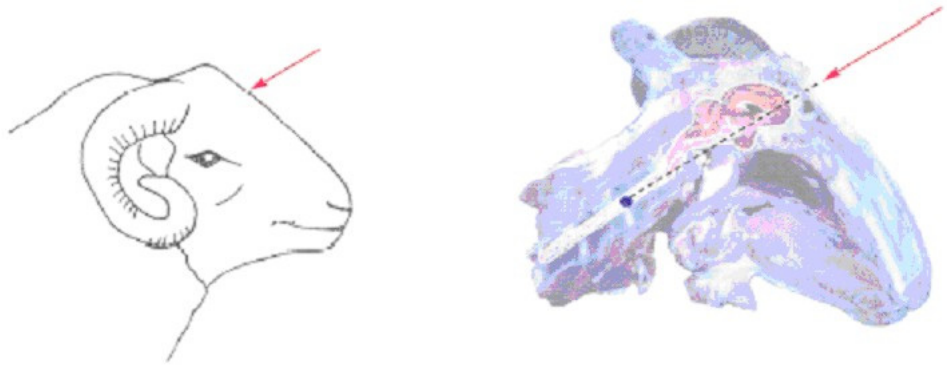


Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

The optimum position for hornless sheep and goats is on the midline.

Goats

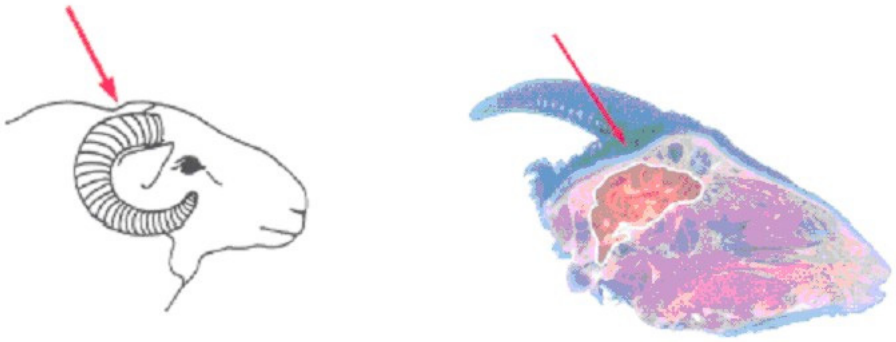


Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

The optimum position for heavily horned sheep and horned goats is behind the poll, aiming towards the angle of the jaw.

Horses

Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

The optimum position for horses is at right angles to the frontal surface, well above the point where imaginary lines from eyes to ears cross.

Signs of correct *stunning* using a mechanical instrument are as follows:

a) the *animal* collapses immediately and does not attempt to stand up;

b) the body and muscles of the *animal* become tonic (rigid) immediately after the shot;

c) normal rhythmic breathing stops; and

d) the eyelid is open with the eyeball facing straight ahead and is not rotated.

Poultry

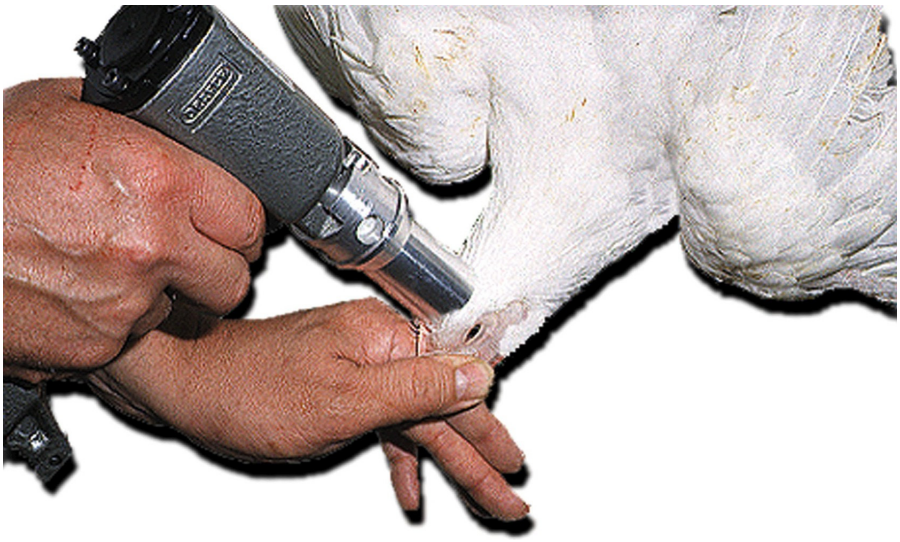


Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Poultry

Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Captive bolts powered by cartridges, compressed air or spring can be used for *poultry*. The optimum position for *poultry* species is at right angles to the frontal surface.

Firing of a captive bolt according to the manufacturers' instructions should lead to immediate destruction of the skull and the brain and, as a result, immediate *death*.

5. Electrical stunning

a) General considerations

An electrical device should be applied to the *animal* in accordance with the following recommendations.

Electrodes should be designed, constructed, maintained and cleaned regularly to ensure that the flow of current is optimal and in accordance with manufacturing specifications. They should be placed so that they span the brain. The application of electrical currents which bypass the brain is unacceptable unless the *animal* has been stunned. The use of a single current leg-to-leg is unacceptable as a *stunning* method.

If, in addition, it is intended to cause cardiac arrest, the electrodes should either span the brain and immediately thereafter the heart, on the condition that it has been ascertained that the *animal* is adequately stunned, or span brain and heart simultaneously.

Electrical *stunning* equipment should not be applied on *animals* as a means of guidance, movement, *restraint* or immobilisation, and shall not deliver any shock to the *animal* before the actual *stunning* or *killing*.

Electrical *stunning* apparatus should be tested prior to application on *animals* using appropriate resistors or dummy loads to ensure the power output is adequate to stun *animals*.

The electrical *stunning* apparatus should incorporate a device that monitors and displays voltage (true RMS) and the applied current (true RMS) and that such devices are regularly calibrated at least annually.

Appropriate measures, such as removing excess wool or wetting the skin only at the point of contact, can be taken to minimise impedance of the skin and facilitate effective *stunning*.

The *stunning* apparatus should be appropriate for the species. Apparatus for electrical *stunning* should be provided with adequate power to achieve continuously the minimum current level recommended for *stunning* as indicated in the table below.

In all cases, the correct current level shall be attained within one second of the initiation of stun and maintained at least for between one and three seconds and in accordance with the manufacturer's instructions. Minimum current levels for head-only *stunning* are shown in the following table.

Species	Minimum current levels for head-only stunning
Cattle	1.5 amps
Calves (bovines of less than 6 month of age)	1.0 amps
Pigs	1.25 amps
Sheep and goats	1.0 amps
Lambs	0.7 amps
Ostriches	0.4 amps

b) Electrical stunning of birds using a waterbath

There should be no sharp bends or steep gradients in the shackle line and the shackle line should be as short as possible consistent with achieving acceptable line speeds, and ensuring that birds have settled by the time they reach the water bath. A breast comforter can be used effectively to reduce wing flapping and calm birds. The angle at which the shackle line approaches the entrance to the water bath, and the design of the entrance to the water bath, and the draining of excess 'live' water from the bath are all important considerations in ensuring birds are calm as they enter the bath, do not flap their wings, and do not receive pre-stun electric shocks.

In the case of birds suspended on a moving line, measures should be taken to ensure that the birds are not wing flapping at the entrance of the stunner. The birds should be secure in their shackle, but there should not be undue pressure on their shanks. The shackle size should be appropriate to fit the size of the shanks (metatarsal bones) of birds.

Birds should be hung on shackles by both legs.

Birds with dislocated or broken legs or wings should be humanely killed rather than shackled.

The duration between hanging on shackles and *stunning* should be kept to the minimum. In any event, the time between shackling and *stunning* should not exceed one minute.

Waterbaths for *poultry* should be adequate in size and depth for the type of bird being slaughtered, and their height should be adjustable to allow for the head of each bird to be immersed. The electrode immersed in the bath should extend the full length of the waterbath. Birds should be immersed in the bath up to the base of their wings.

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:

Species	Current (milliamperes per bird)
Broilers	100
Layers (spent hens)	100
Turkeys	150
Ducks and geese	130

Minimum current for *stunning poultry* when using high frequencies is as follows:

	Minimum current (milliamperes per bird)	
Frequency (Hz)	Chickens	Turkeys
From 50 to 200 Hz	100 mA	250 mA
From 200 to 400 Hz	150 mA	400 mA
From 400 to 1500 Hz	200 mA	400 mA

6. Gas stunning (under study)

a) *Stunning* of pigs by exposure to carbon dioxide (CO_2)

The concentration of CO_2 for *stunning* should be preferably 90 percent by volume but in any case no less than 80 percent by volume. After entering the *stunning* chamber, the *animals* should be conveyed to the point of maximum concentration of the gas as rapidly as possible and be kept until they are dead or brought into a state of insensibility which lasts until *death* occur due to bleeding. Ideally, pigs should be exposed to this concentration of CO_2 for 3 minutes. Sticking should occur as soon as possible after exit from the gas chamber.

In any case, the concentration of the gas should be such that it minimises as far as possible all stress of the *animal* prior to loss of consciousness.

The chamber in which *animals* are exposed to CO_2 and the equipment used for conveying them through it shall be designed, constructed and maintained in such a way as to avoid injury or unnecessary stress to the *animals*. The animal density within the chamber should be such to avoid stacking *animals* on top of each others.

The conveyor and the chamber shall be adequately lit to allow the *animals* to see their surroundings and, if possible, each other.

It should be possible to inspect the CO_2 chamber whilst it is in use, and to have access to the *animals* in emergency cases.

The chamber shall be equipped to continuously measure and display register at the point of *stunning* the CO_2 concentration and the time of exposure, and to give a clearly visible and audible warning if the concentration of CO_2 falls below the required level.

Emergency *stunning* equipment should be available at the point of exit from the *stunning* chamber and used on any pigs that do not appear to be completely stunned.

b) Inert gas mixtures for stunning pigs

Inhalation of high concentration of carbon dioxide is aversive and can be distressing to *animals*. Therefore, the use of non-aversive gas mixtures is being developed.

Such gas mixtures include:

i) a maximum of 2 percent by volume of oxygen in argon, nitrogen or other inert gases, or

ii) to a maximum of 30 percent by volume of carbon dioxide and a maximum of 2 percent by volume of oxygen in mixtures with carbon dioxide and argon, nitrogen or other inert gases.

Exposure time to the gas mixtures should be sufficient to ensure that no pigs regain consciousness before *death* supervenes through bleeding or cardiac arrest is induced.

c) Gas stunning of poultry

The main objective of gas *stunning* is to avoid the pain and suffering associated with shackling conscious *poultry* under water bath *stunning* and *killing* systems. Therefore, gas *stunning* should be limited to birds contained in crates or on conveyors only. The gas mixture should be non-aversive to *poultry*.

Live *poultry* contained within transport modules or crates may be exposed to gradually increasing concentrations of CO_2 until the birds are properly stunned. No bird should recover consciousness during bleeding.

Gas *stunning* of *poultry* in their transport *containers* will eliminate the need for live birds' handling at the processing plant and all the problems associated with the electrical *stunning*. Gas *stunning* of *poultry* on a conveyor eliminates the problems associated with the electrical water bath *stunning*.

Live *poultry* should be conveyed into the gas mixtures either in transport crates or on conveyor belts.

The following gas procedures have been properly documented for chickens and turkeys but do not necessarily apply for other domestic birds. In any case the procedure should be designed as to ensure that all *animals* are properly stunned without unnecessary suffering. Some monitoring points for gas *stunning* could be the following:

- ensure smooth entry and passage of crates or birds through the system;
- avoid crowding of birds in crates or conveyors;
- monitor and maintain gas concentrations continuously during operation;
- provide visible and audible alarm systems if gas concentrations are inappropriate to the species;
- calibrate gas monitors and maintain verifiable records;
- ensure that duration of exposure is adequate to prevent recovery of consciousness;
- make provision to monitor and deal with recovery of consciousness;

- ensure that blood vessels are cut to induce *death* in unconscious birds;
- ensure that all birds are dead before entering scalding tank;
- provide emergency procedures in the event of system failure.

i) Gas mixtures used for stunning *poultry* include:

- a minimum of 2 minutes exposure to 40 percent carbon dioxide, 30 percent oxygen and 30 percent nitrogen, followed by a minimum of one minute exposure to 80 percent carbon dioxide in air; or
- a minimum of 2 minutes exposure to any mixture of argon, nitrogen or other inert gases with atmospheric air and carbon dioxide, provided that the carbon dioxide concentration does not exceed 30 percent by volume and the residual oxygen concentration does not exceed 2 percent by volume; or
- a minimum of 2 minutes exposure to argon, nitrogen, other inert gases or any mixture of these gases in atmospheric air with a maximum of 2 percent residual oxygen by volume; or
- a minimum of 2 minutes exposure to a minimum of 55 percent carbon dioxide in air; or
- a minimum of one minute exposure to 30 percent carbon dioxide in air, followed by a minimum of one minute exposure to at least 60 percent carbon dioxide in air.

ii) Requirements for effective use are as follows:

- Compressed gases should be vaporised prior to administration into the chamber and should be at room temperature to prevent any thermal shock; under no circumstances, should solid gases with freezing temperatures enter the chamber.
- Gas mixtures should be humidified.
- Appropriate gas concentrations of oxygen and carbon dioxide should be monitored and displayed continuously at the level of the birds inside the chamber to ensure that anoxia ensues.

Under no circumstances, should birds exposed to gas mixtures be allowed to regain consciousness. If necessary, the exposure time should be extended.

7. Bleeding

From the point of view of *animal welfare*, *animals* which are stunned with a reversible method should be bled without delay. Maximum stun-stick interval depends on the parameters of the *stunning* method applied, the species concerned and the bleeding method used (full cut or chest stick when possible). As a consequence, depending on those factors, the *slaughterhouse* operator should set up a maximum stun-stick interval that ensures that no *animals* recover consciousness during bleeding. In any case the following time limits should be applied.

Stunning method	**Maximum – stun stick interval**
Electrical methods and non-penetrating captive bolt	20 seconds
CO_2	60 seconds (after leaving the chamber)

All *animals* should be bled out by incising both carotid arteries, or the vessels from which they arise (e.g. chest stick). However, when the *stunning* method used causes cardiac arrest, the incision of all of these vessels is not necessary from the point of view of *animal welfare*.

It should be possible for staff to observe, inspect and access the *animals* throughout the bleeding period. Any *animal* showing signs of recovering consciousness should be re-stunned.

After incision of the blood vessels, no scalding carcass treatment or dressing procedures should be performed on the *animals* for at least 30 seconds, or in any case until all brain-stem reflexes have ceased.

Article 7.5.8.

Summary analysis of stunning methods and the associated animal welfare issues

Method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements applicable	Species	Comment
Mechanical	Free bullet	Inaccurate targeting and inappropriate ballistics	Operator competence; achieving outright kill with first shot	Cattle, calves, buffalo, deer, horses, pigs (boars and sows)	Personnel safety
	Captive bolt – penetrating	Inaccurate targeting, velocity and diameter of bolt	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, buffalo, sheep, goats, deer, horses, pigs, camelids, ratites, poultry	(Unsuitable for specimen collection from TSE suspects). A back-up gun should be available in the event of an ineffective shot
	Captive bolt – non-penetrating	Inaccurate targeting, velocity of bolt, potentially higher failure rate than penetrating captive bolt	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats, deer, pigs, camelids, ratites, poultry	Presently available devices are not recommended for young bulls and animals with thick skull. This method should only be used for cattle and sheep when alternative methods are not available.
	Manual percussive blow	Inaccurate targeting; insufficient power; size of instrument	Competent animal handlers; restraint; accuracy. Not recommended for general use	Young and small mammals, ostriches and poultry	Mechanical devices potentially more reliable. Where manual percussive blow is used, unconsciousness should be achieved with single sharp blow delivered to central skull bones
Electrical	Split application: 1. across head then head to chest; 2. across head then across chest	Accidental pre-stun electric shocks; electrode positioning; application of a current to the body while animal conscious; inadequate current and voltage	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats and pigs, ratites and poultry	Systems involving repeated application of head-only or head-to-leg with short current durations (<1 second) in the first application should not be used.
	Single application: 1. head only; 2. head to body; 3. head to leg	Accidental pre-stun electric shocks; inadequate current and voltage; wrong electrode positioning; recovery of consciousness	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats, pigs, ratites, poultry	
	Waterbath	Restraint, accidental pre-stun electric shocks; inadequate current and voltage; recovery of consciousness	Competent operation and maintenance of equipment	Poultry only	

Method (contd)	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements applicable	Species	Comment
Gaseous	CO_2 air/O_2 mixture; CO_2 inert gas mixture	Aversiveness of high CO_2; respiratory distress; inadequate exposure	Concentration; duration of exposure; design, maintenance and operation of equipment; stocking density management	Pigs, poultry	
	Inert gases	Recovery of consciousness	Concentration; duration of exposure; design, maintenance and operation of equipment; density management	Pigs, poultry	

Article 7.5.9.

Summary analysis of slaughter methods and the associated animal welfare issues

Slaughter methods	Specific method	Animal welfare concerns/ implications	Key requirements	Species	Comments
Bleeding out by severance of blood vessels in the neck without stunning	Full frontal cutting across the throat	Failure to cut both common carotid arteries; occlusion of cut arteries; pain during and after the cut	High level of operator competency. A very sharp blade or knife of sufficient length so that the point of the knife remains outside the incision during the cut; the point of the knife should not be used to make the incision. The incision should not close over the knife during the throat cut.	Cattle, buffalo, horses, camelids, sheep, goats, poultry, ratites	No further procedure should be carried out before the bleeding out is completed (i.e. at least 30 seconds for mammals). The practice to remove hypothetical blood clots just after the bleeding should be discouraged since this may increase animal suffering.
Bleeding with prior stunning	Full frontal cutting across the throat	Failure to cut both common carotid arteries; occlusion of cut arteries; pain during and after the cut.	A very sharp blade or knife of sufficient length so that the point of the knife remains outside the incision during the cut; the point of the knife should not be used to make the incision. The incision should not close over the knife during the throat cut.	Cattle, buffalo, horses, camelids, sheep, goats	

Slaughter methods (contd)	Specific method	Animal welfare concerns/ implications	Key requirements	Species	Comments
Bleeding with prior stunning (contd)	Neck stab followed by forward cut	Ineffective stunning; failure to cut both common carotid arteries; impaired blood flow; delay in cutting after reversible stunning	Prompt and accurate cutting	Camelids, sheep, goats, poultry, ratites	
	Neck stab alone	Ineffective stunning; failure to cut both common carotid arteries; impaired blood flow; delay in cutting after reversible stunning	Prompt and accurate cutting	Camelids, sheep, goats, poultry, ratites	
	Chest stick into major arteries or hollow-tube knife into heart	Ineffective stunning; inadequate size of stick wound inadequate length of sticking knife; delay in sticking after reversible stunning	Prompt and accurate sticking	Cattle, sheep, goats, pigs	
	Neck skin cut followed by severance of vessels in the neck	Ineffective stunning; inadequate size of stick wound; inadequate length of sticking knife; delay in sticking after reversible stunning	Prompt and accurate cutting of vessels	Cattle	
	Automated mechanical cutting	Ineffective stunning; failure to cut and misplaced cuts. Recovery of consciousness following reversible stunning systems	Design, maintenance and operation of equipment; accuracy of cut; manual back-up	Poultry only	
	Manual neck cut on one side	Ineffective stunning; recovery of consciousness following reversible stunning systems	Prior non-reversible stunning	Poultry only	N.B. slow induction of unconsciousness under slaughter without stunning
	Oral cut	Ineffective stunning; recovery of consciousness following reversible stunning systems	Prior non-reversible stunning	Poultry only	N.B. slow induction of unconsciousness in non-stun systems
Other methods without stunning	Decapitation with a sharp knife	Pain due to loss of consciousness not being immediate		Sheep, goats, poultry	This method is only applicable to Jhatka slaughter
	Manual neck dislocation and decapitation	Pain due to loss of consciousness not being immediate; difficult to achieve in large birds	Neck dislocation should be performed in one stretch to sever the spinal cord	Poultry only	Slaughter by neck dislocation should be performed in one stretch to sever the spinal cord. Acceptable only when slaughtering small numbers of small birds.

Slaughter methods (contd)	Specific method	Animal welfare concerns/ implications	Key requirements	Species	Comments
Cardiac arrest in a waterbath electric stunner	Bleeding by evisceration		Induction of cardiac arrest	Quail	
	Bleeding by neck cutting			Poultry	

Article 7.5.10.

Methods, procedures or practices unacceptable on animal welfare grounds

1. The restraining methods which work through electro-immobilisation or immobilisation by injury such as breaking legs, leg tendon cutting, and severing the spinal cord (e.g. using a puntilla or dagger) cause severe pain and stress in *animals*. Those methods are not acceptable in any species.
2. The use of the electrical *stunning* method with a single application leg to leg is ineffective and unacceptable in any species.
3. The *slaughter* method of brain stem severance by piercing through the eye socket or skull bone without prior *stunning* is not acceptable in any species.

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.

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 7.5. on the *slaughter* of *animals* should be followed;
3. the species, number, age and size of *animals* to be killed, and the order of *killing* them;
4. methods of *killing* the *animals*, and their cost;
5. housing, husbandry, location of the *animals* as well as accessibility of the farm;
6. the availability and effectiveness of equipment needed for *killing* of the *animals*, as well as the time necessary to kill the required number of *animals* using such methods;
7. the facilities available on the premises that will assist with the *killing* including any additional facilities that may need to be brought on and then removed from the premises;
8. biosecurity and environmental issues;
9. the health and safety of personnel conducting the *killing*;
10. any legal issues that may be involved, for example where restricted veterinary drugs or poisons may be used, or where the process may impact on the environment;
11. the presence of other nearby premises holding *animals*;
12. possibilities for removal, disposal and destruction of carcasses.

The plan should minimise the negative *welfare* impacts of the *killing* by taking into account the different phases of the procedures to be applied for *killing* (choice of the *killing* sites, *killing* methods, etc.) and the measures restricting the movements of the *animals*.

Competences and skills of the personnel handling and *killing animals*.

In designing a *killing* plan, it is essential that the method chosen be consistently reliable to ensure that all *animals* are humanely and quickly killed.

Article 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.

Species	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
Cattle	all	free bullet	no	non-lethal wounding	7.6.6.
	all except neonates	penetrating captive bolt - followed by pithing or bleeding	yes	ineffective stunning	7.6.7.
	adults only	non-penetrating captive bolt, followed by bleeding	yes	ineffective stunning, regaining of consciousness before killing	7.6.8.
	calves only	electrical, two-stage application	yes	pain associated with cardiac arrest after ineffective stunning	7.6.10.
	calves only	electrical, single application (method 1)	yes	ineffective stunning	7.6.11.
	all	injection with barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	7.6.15.
Sheep and goats	all	free bullet	no	non-lethal wounding	7.6.6.
	all except neonates	penetrating captive bolt, followed by pithing or bleeding	yes	ineffective stunning, regaining of consciousness before death	7.6.7.
	all except neonates	non-penetrating captive bolt, followed by bleeding	yes	ineffective stunning, regaining of consciousness before death	7.6.8.
	neonates	non-penetrating captive bolt	yes	non-lethal wounding	7.6.8.
	all	electrical, two-stage application	yes	pain associated with cardiac arrest after ineffective stunning	7.6.10.
	all	electrical, single application (method 1)	yes	ineffective stunning	7.6.11.
	neonates only	CO_2 / air mixture	yes	slow induction of unconsciousness, aversiveness of induction	7.6.12.
	neonates only	nitrogen and/or inert gas mixed with CO_2	yes	slow induction of unconsciousness, aversiveness of induction	7.6.13.
	neonates only	nitrogen and/or inert gases	yes	slow induction of unconsciousness	7.6.14.
	all	injection of barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	7.6.15.
Pigs	all, except neonates	free bullet	no	non-lethal wounding	7.6.6.
	all except neonates	penetrating captive bolt, followed by pithing or bleeding	yes	ineffective stunning, regaining of consciousness before death	7.6.7.
	neonates only	non-penetrating captive bolt	yes	non-lethal wounding	7.6.8.

Species (contd)	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
Pigs (contd)	all[1]	electrical, two-stage application	yes	pain associated with cardiac arrest after ineffective stunning	7.6.10.
	all	electrical, single application (method 1)	yes	ineffective stunning	7.6.11.
	neonates only	CO_2 / air mixture	yes	slow induction of unconsciousness, aversiveness of induction	7.6.12.
	neonates only	nitrogen and/or inert gas mixed with CO_2	yes	slow induction of unconsciousness, aversiveness of induction	7.6.13.
	neonates only	nitrogen and/or inert gases	yes	slow induction of unconsciousness	7.6.14.
	all	injection with barbiturates and other	yes	non-lethal dose, pain associated with injection site	7.6.15.
Poultry	adults only	non-penetrating captive bolt	yes	ineffective stunning	7.6.8.
	day-olds and eggs only	maceration	no	non-lethal wounding, non-immediacy	7.6.9.
	adults only	electrical, single application (method 2)	yes	ineffective stunning	7.6.11.
	adults only	electrical, single application, followed by killing (method 3)	yes	ineffective stunning; regaining of consciousness before death	7.6.11.
	all	CO_2 / air mixture Method 1 Method 2	 yes no	slow induction of unconsciousness, aversiveness of induction	7.6.12.
	all	nitrogen and/or inert gas mixed with CO_2	yes	slow induction of unconsciousness, aversiveness of induction	7.6.13.
	all	nitrogen and/or inert gases	yes	slow induction of unconsciousness	7.6.14.
	all	injection of barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	7.6.15.
	all	cervical dislocation	no		Point 1 of 7.6.17.
	all	decapitation	no		Point 2 of 7.6.17.
	adults only	addition of anaesthetics to feed or water, followed by an appropriate killing method	no	ineffective or slow induction of unconsciousness	7.6.16.

Article 7.6.6.

Free bullet

1. Introduction

   a) A free bullet is a projectile fired from a shotgun, rifle, handgun or purpose-made humane killer.

   b) The most commonly used firearms for close range use are:

      i) humane killers (specially manufactured/adapted single-shot weapons);

      ii) shotguns (12, 16, 20, 28 bore and .410);

      iii) rifles (.22 rimfire);

      iv) handguns (various calibres from .32 to .45).

   c) The most commonly used firearms for long range use are rifles (.22, .243, .270 and .308).

   d) A free bullet used from long range should be aimed to penetrate the skull or soft tissue at the top of the neck of the *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 source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Figure 2. The optimum position for hornless sheep and goats is on the midline.

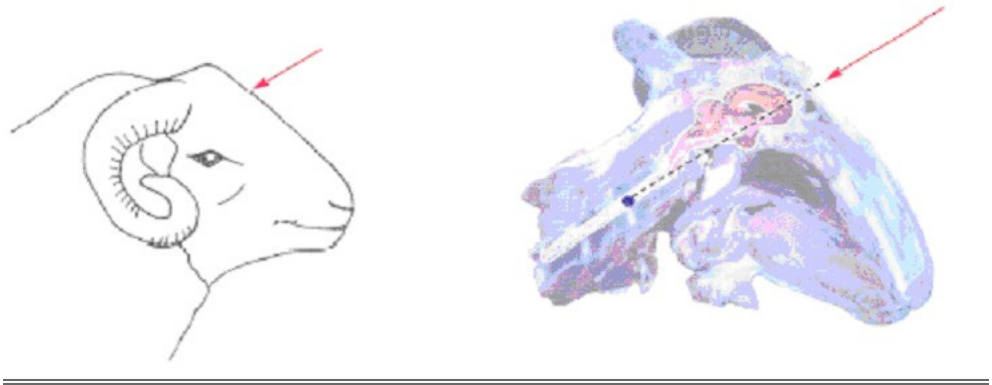


Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Figure 3. The optimum shooting position for heavily horned sheep and horned goats is behind the poll aiming towards the angle of the jaw.

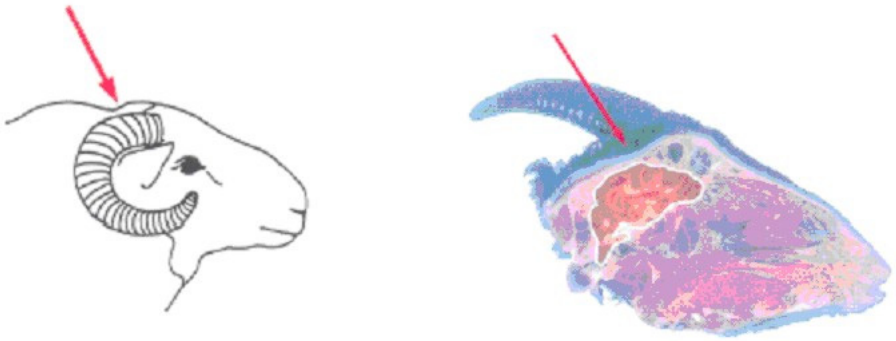


Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Figure 4. The optimum shooting position for pigs is just above eye level, with the shot directed down the line of the spinal cord.

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Article 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. of the *Terrestrial Code*.

2. Requirements for effective use

   a) For cartridge powered and compressed air guns, the bolt velocity and the length of the bolt should be appropriate to the species and type of *animal*, in accordance with the recommendations of the manufacturer.

b) Captive bolt guns should be frequently cleaned and maintained in good working condition.

c) More than one gun may be necessary to avoid overheating, and a back-up gun should be available in the event of an ineffective shot.

d) *Animals* should be restrained; at a minimum, they should be penned for cartridge powered guns and in a race for compressed air guns.

e) The operator should ensure that the head of the *animal* is accessible.

f) The operator should fire the captive bolt at right angles to the skull in the optimal position (see figures 1, 3 & 4. The optimum shooting position for hornless sheep is on the highest point of the head, on the midline and aim towards the angle of the jaw).

g) To ensure the *death* of the *animal*, pithing or bleeding should be performed as soon as possible after *stunning*.

h) *Animals* should be monitored continuously after *stunning* until *death* to ensure the absence of brain stem reflexes.

3. Advantages

a) Mobility of cartridge powered equipment reduces the need to move *animals*.

b) The method induces an immediate onset of a sustained period of unconsciousness.

4. Disadvantages

a) Poor gun maintenance and misfiring, and inaccurate gun positioning and orientation may result in poor *animal welfare*.

b) Post stun convulsions may make pithing difficult and hazardous.

c) The method is difficult to apply in agitated *animals*.

d) Repeated use of a cartridge powered gun may result in over-heating.

e) Leakage of bodily fluids may present a biosecurity risk.

f) Destruction of brain tissue may preclude diagnosis of some *diseases*.

5. Conclusions

The method is suitable for *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.

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.

Article 7.6.9.

Maceration

1. Introduction

Maceration, utilising a mechanical apparatus with rotating blades or projections, causes immediate fragmentation and *death* in day-old *poultry* and embryonated eggs.

2. Requirements

a) Maceration requires specialised equipment which should be kept in excellent working order.

b) The rate of introducing the birds should not allow the equipment to jam, birds to rebound from the blades or the birds to suffocate before they are macerated.

3. Advantages

a) Procedure results in immediate *death*.

b) Large numbers can be killed quickly.

4. Disadvantages

a) Specialised equipment is required.

b) Macerated tissues may present biosecurity or human health risks.

c) The cleaning of the equipment can be a source of contamination.

5. Conclusion

The method is suitable for *killing* day-old poultry and embryonated eggs.

Article 7.6.10.

Electrical – two-stage application

1. Introduction

A two-stage application of electric current comprises firstly an application of current to the head by scissor-type tongs, immediately followed by an application of the tongs across the chest in a position that spans the heart.

The application of sufficient electric current to the head will induce 'tonic/clonic' epilepsy and unconsciousness. Once the *animal* is unconscious, the second stage will induce ventricular fibrillation (cardiac arrest) resulting in *death*. The second stage (the application of low frequency current across the chest) should only be applied to unconscious *animals* to prevent unacceptable levels of pain.

2. Requirements for effective use

a) The stunner control device should generate a low frequency (AC sine wave 50 Hz) current with a minimum voltage and current as set out in the following table:

Animal	Minimum voltage (V)	Minimum current (A)
Cattle	220	1.5
Sheep	220	1.0
Pigs over 6 weeks of age	220	1.3
Pigs less than 6 weeks of age	125	0.5

b) Appropriate protective clothing (including rubber gloves and boots) should be worn.

c) *Animals* should be restrained, at a minimum free-standing in a pen, close to an electrical supply.

d) Two team members are required, the first to apply the electrodes and the second to manipulate the position of the *animal* to allow the second application to be made.

e) A *stunning* current should be applied via scissor-type *stunning* tongs in a position that spans the brain for a minimum of 3 seconds; immediately following the application to the head, the electrodes should be transferred to a position that spans the heart and the electrodes applied for a minimum of 3 seconds.

f) Electrodes should be cleaned regularly and after use, to enable optimum electrical contact to be maintained.

g) *Animals* should be monitored continuously after *stunning* until *death* to ensure the absence of brain stem reflexes.

h) Electrodes should be applied firmly for the intended duration of time and pressure not released until the stun is complete.

3. Advantages

a) The application of the second stage minimises post-stun convulsions and therefore the method is particularly effective with pigs.

b) Non-invasive technique minimises biosecurity risk.

4. Disadvantages

a) The method requires a reliable supply of electricity.

b) The electrodes 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 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 (CO_2) induces respiratory and metabolic acidosis and hence reduces the pH of cerebrospinal fluid (CSF) and neurones thereby causing unconsciousness and, after prolonged exposure, *death*. Exposure to carbon dioxide does not induce immediate loss of consciousness, therefore the aversive nature of gas mixtures containing high concentrations of CO_2 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) CO_2 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 CO_2 concentrations.

iii) No immediate loss of consciousness.

iv) The risk of suffocation due to overcrowding.

v) Difficulty in verifying *death* while the *animals* are in the *container* or apparatus.

d) Conclusion

Method 1 is suitable for use in poultry, and neonatal sheep, goats and pigs.

3. Method 2

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 (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 CO_2 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 CO_2 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) CO_2 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 CO_2. 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, CO_2 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 CO_2, 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 CO_2 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) CO_2 is readily available.

iii) Gradual raising of CO_2 concentration minimises the aversiveness of the induction of unconsciousness.

c) Disadvantages

i) It is difficult to determine volume of gas required to achieve adequate concentrations of CO_2 in some poultry houses.

ii) It is difficult to verify *death* while the birds are in the poultry house.

The extremely low temperature of liquid CO_2 entering the house and formation of solid CO_2 (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, CO_2 is likely to cause a period of distress in the birds before they lose consciousness.

Article 7.6.13.

Nitrogen and/or inert gas mixed with CO2

1. Introduction

CO_2 may be mixed in various proportions with nitrogen or an inert gas (e.g. argon), and the inhalation of such mixtures leads to hypercapnic-hypoxia and *death* when the oxygen concentration by volume is ≤2 percent, or ≤5 percent for chickens. Various mixtures of CO_2 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 CO_2 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 CO_2 and the respiratory distress occurring during the induction phase, are important *animal welfare* considerations.

Pigs and poultry appear not to find low concentrations of CO_2 strongly aversive, and a mixture of nitrogen or argon with ≤30 percent CO_2 by volume and ≤2 percent O_2 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.

a) Requirements for effective use

i) *Containers* or apparatus should allow the required gas concentrations to be maintained, and the O_2 and CO_2 concentrations accurately measured during the *killing* procedure.

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 O_2), 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 CO_2 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.

Figure source: Department of Clinical Veterinary Science, University of Bristol, United Kingdom.

Figure source: Department of Clinical Veterinary Science, University of Bristol, United Kingdom.

Article 7.6.14.

Nitrogen and/or inert gases

1. Introduction

   This method involves the introduction of *animals* into a *container* or apparatus containing nitrogen or an inert gas such as argon. The controlled atmosphere produced leads to unconsciousness and *death* from hypoxia.

   Research has shown that hypoxia is not aversive to pigs and poultry, and it does not induce any signs of respiratory distress prior to loss of consciousness.

2. Requirements for effective use

   a) *Containers* or apparatus should allow the required gas concentrations to be maintained, and the O_2 concentration accurately measured.

b) When *animals* are exposed to the gases individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the *animals* and allow them to be observed.

c) *Animals* should be introduced into the *container* or apparatus after it has been filled with the required gas concentrations (with ≤2 percent O_2), and held in this atmosphere until *death* is confirmed.

d) Team members should ensure that there is sufficient time allowed for each batch of *animals* to die before subsequent ones are introduced into the *container* or apparatus.

e) *Containers* or apparatus should not be overcrowded, and measures are needed to avoid *animals* suffocating by climbing on top of each other.

3. Advantages

Animals are unable to detect nitrogen or inert gases, and the induction of hypoxia by this method is not aversive to *animals*.

4. Disadvantages

a) A properly designed *container* or apparatus is needed.

b) It is difficult to verify *death* while the *animals* are in the *container* or apparatus.

c) There is no immediate loss of consciousness.

d) Exposure times required to kill are considerable.

5. Conclusion

The method is suitable for poultry and neonatal sheep, goats and pigs.

Article 7.6.15.

Lethal injection

1. Introduction

A lethal injection using high doses of anaesthetic and sedative drugs causes CNS depression, unconsciousness and *death*. In practice, barbiturates in combination with other drugs are commonly used.

2. Requirements for effective use

a) Doses and routes of administration that cause rapid loss of consciousness followed by *death* should be used.

b) Prior sedation may be necessary for some *animals*.

c) Intravenous administration is preferred, but intraperitoneal or intramuscular administration may be appropriate, especially if the agent is non-irritating.

d) *Animals* should be restrained to allow effective administration.

e) *Animals* should be monitored to ensure the absence of brain stem reflexes.

3. Advantages

a) The method can be used in all species.

b) *Death* can be induced smoothly.

4. Disadvantages

a) *Restraint* and/or sedation may be necessary prior to injection.

b) Some combinations of drug type and route of administration may be painful, and should only be used in unconscious *animals*.

c) Legal requirements and skill/training required may restrict use to veterinarians.

d) Contaminated carcasses may present a risk to other *wild 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.

Article 7.6.18.

Pithing and bleeding

1. Pithing

   a) Introduction

   Pithing is a method of *killing animals* which have been stunned by a penetrating captive bolt, without immediate *death*. Pithing results in the physical destruction of the brain and upper regions of the spinal cord, through the insertion of a rod or cane through the bolt hole.

   b) Requirements for effective use

      i) Pithing cane or rod is required.

      ii) An access to the head of the *animal* and to the brain through the skull is required.

      iii) *Animals* should be monitored continuously until *death* to ensure the absence of brain stem reflexes.

   c) Advantages

   The technique is effective in producing immediate *death*.

   d) Disadvantages

      i) A delayed and/or ineffective pithing due to convulsions may occur.

      ii) The working area is contaminated with body fluids, which increases biosecurity risks.

2. Bleeding

   a) Introduction

   Bleeding is a method of *killing animals* through the severance of the major blood vessels in the neck or chest that results in a rapid fall in blood pressure, leading to cerebral ischaemia and *death*.

   b) Requirements for effective use

      i) A sharp knife is required.

      ii) An access to the neck or chest of the *animal* is required.

      iii) *Animals* should be monitored continuously until *death* to ensure the absence of brain stem reflexes.

   c) Advantages

   The technique is effective in producing *death* after an effective *stunning* method which does not permit pithing.

   d) Disadvantages

      i) A delayed and/or ineffective bleeding due to convulsions may occur.

      ii) The working area is contaminated with body fluids, which increases biosecurity risks.

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1 The only preclusion against the use of this method for neonates is the design of the stunning tongs that may not facilitate their application across such a small-sized head/body.

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.).

Owned dog: means a dog for which a person claims responsibility.

Person: this can include more than one individual, and could comprise family/household members or an organisation.

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.

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

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

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.

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;

   g) central-state or province-local partnerships.

Article 7.7.6.

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.

c) 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 8.10. 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) Restraint

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

- Electrocution 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. CO_2, CO, N_2, 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 used for euthanasia of dogs

Euthanasia method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements	Considerations relating to operator security	Advantages	Disadvantages
Chemical via infection	Barbiturates	Correct restraint is needed. IP is slow and may be irritant. IC injection is a painful procedure.	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.	Correct restraint is needed. Administered under veterinary supervision and requires trained personnel.	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.	These drugs persist in the carcass and may cause sedation or death in animals that consume the cadaver.
	Embutramide +Mebezonium +Tetracaine	Muscle paralysis may occur before lost of consciousness if injection given rapidly.	Use slow IV injection with sedation to permit slow rate of injection.	Correct restraint is needed. To be administered under veterinary supervision and by trained personnel.	Quite low cost.	Unavailable/ unlicensed in some countries.
	Anaesthetic agent overdose (thiopentone or propofenol)	Underdosing may lead to recovery.	IV injection of a sufficient dose.	Correct restraint is needed. To be administered under veterinary supervision and by trained personnel.	Generally quick action and minimal discomfort to animal.	Large volume required (cost implications).
	Potassium chloride (KCl)	K+ is cardiotoxic and very painful if used without anaesthetic agent.	Only use on anaesthetised animals, IV injection.	Requires trained personnel.	Readily available without veterinary control.	Prior need for anaesthetic (cost and availability implications).

Table 1. Summary analysis of methods used for euthanasia of dogs (contd)

Mechanical	Free bullet	Can be inhumane if shot is inaccurate and dog is only wounded; dog may also escape.	Skilled operator essential.	Risk of injury to operators and spectators.	Not necessary to handle or capture dog.	Brain tissue may be unavailable for rabies diagnosis. Risk of injury to bystanders. Legal constraints on use of firearms.
	Penetrating captive bolt followed by pithing where necessary to ensure death	Can be inhumane if shot is inaccurate and dog is only wounded.	Skilled operator essential.	Animal should be restrained. Skilled operator essential.	No risk to operator (see free bullet) unless risk of dog infected with rabies, due to potential contact with brain tissue.	Brain tissue may be unavailable for rabies diagnosis. Legal constraints on use of firearms. May raise aesthetic objections.
	Exsanguination	Onset of hypovolaemia may cause dog to become anxious.	Only use on unconscious animal.	Danger to operator through use of sharp instrument.	Material requirements minimal.	Need to render animal unconscious. Aesthetically objectionable.

Table 1. Summary analysis of methods used for euthanasia of dogs (contd)

Gaseous	Carbon monoxide (CO)	Inadequate concentration of CO is not lethal and can cause suffering. Signs of distress (convulsions, vocalization and agitation) may occur.	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.	Very hazardous for operator - gas is odourless and causes toxicity at both acute high levels and chronic low levels.	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%.	
	Carbon dioxide (CO_2)	Gas is aversive. Inadequate concentration of CO_2 is not lethal and can cause suffering. CO_2 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.	Compressed CO_2 gas chamber is the only acceptable method because the concentration can be monitored and regulated.	Minimal hazard to operator when properly designed equipment used.	Gas is not flammable or explosive and causes quite rapid anaesthesia when correct concentrations used. Low cost. Readily available as compressed gas.	Unconscious-ness can occur in minutes, but death may take some time. Likelihood of suffering before unconscious-ness.
	Inert gas (nitrogen, N_2 argon, Ar)	Loss of consciousness is preceded by hypoxemia and ventilatory stimulation, which may be distressing to the dog. Re-establishing a low concentration of O_2 (i.e. greater than or equal to 6%) in the chamber before death will allow immediate recovery.	Concentration above 98% should be achieved rapidly and maintained. Properly designed equipment should be used.	Minimal hazard to operator when properly designed equipment used.	Gas is not flammable or explosive and is odourless. Readily available as compressed gas.	High cost. Little data on animal welfare implications in dogs.
	Anaesthetic gas overdose (halothane or enflurane)	Animal may struggle and become anxious during induction. Vapours may be irritating and can induce excitement.	Supplementa-tion with air or O_2 required to avoid hypoxemia during induction phase.	Some gases may be hazardous, especially for pregnant women. General recommen-dation: avoid human exposure to greater than or equal to 2 ppm to avoid narcosis.	Gas is not flammable or explosive. Valuable for use with small animals (<7 kgs) and animals that are already anesthetised with gas.	High cost. Anaesthetic and euthanasia properties of the gas used should be known. Isoflurane has a pungent odour. Methoxyflu-rane's action is slow and dog may become agitated.

Table 1. Summary analysis of methods used for euthanasia of dogs (contd)

Electrical	Electrocution	Cardiac fibrillation occurs before onset of unconscious-ness, 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.	Only use on unconscious dogs. This can be accomplished by electrical stunning (current 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.	May be hazardous for operator, who should use protective equipment (boots and gloves).	Low cost.	Need to render animal unconscious. May raise aesthetic objections.

KEY to abbreviations used in Table 1:

IV: intravenous

IP: intraperitoneal

IC: intracardiac

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);

   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 OIE Members to follow when formulating regulatory requirements, or other form of oversight, for the use of live *animals* in research and education[1]. A system of animal use oversight should be implemented in each country. The system will, in practice, vary from country to country and according to cultural, economic, religious and social factors. However, the OIE recommends that Members address all the essential elements identified in this chapter in formulating a regulatory framework that is appropriate to their local conditions. This framework may be delivered through a combination of national, regional and institutional jurisdictions and both public sector and private sector responsibilities should be clearly defined.

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

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

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

The OIE 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 well as provide cognitive stimulation.

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

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

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

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

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

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

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

Article 7.8.2.

Scope

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

Article 7.8.3.

The Three Rs

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

1. replacement refers to the use of methods 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;

   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 minimized;

   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 action to ensure compliance.

Article 7.8.5.

Assurance of training and competency

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

1. Scientific staff

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

2. Veterinarians

It is important that *veterinarians* working in an animal research environment have veterinary medical knowledge and experience in the species used. Furthermore, they should be educated and experienced in the normal behaviour, behavioural needs, stress reponses 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 advice on measures that may be taken in the animal facility to minimize the risk of transmission, e.g. personal protective equipment, appropriate *désinfection* procedures, air pressure differentials in animal holding rooms, etc. *Animals* brought into the institution may carry *diseases* that require notification to government officials. It is important that the *veterinarian* be aware of, and comply with, these requirements.

5. Advice on surgery and postoperative care

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

6. Advice on analgesia, anaesthesia and euthanasia

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

7. Advice on humane endpoints

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

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

Article 7.8.7.

Source of animals

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

1. Animal procurement

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

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

2. Documentation

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

3. Animal health status

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

4. Genetically defined animals

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

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

A genetically altered *animal* 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 status, with care to ensure appropriate physical containment of the *animals* as well as exclusion of contaminants. The amount of time *animals* spend on a journey should be kept to a minimum. It is important to ensure that there is a well constructed journey plan, with key staff identified who have responsibility for the *animals* and that relevant documentation accompanies *animals* during transport to avoid unnecessary delays during the journey from the sender to the receiving institution.

9. Risks to biosecurity

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

Article 7.8.8.

Physical facility and environmental conditions

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

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

1. Ventilation

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

2. Temperature and humidity

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

3. Lighting

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

4. Noise

Separation of human and animal areas minimises disturbance to animal occupants of the facility. Noisy *animals*, such as dogs, pigs, goats and nonhuman primates, should be housed in a manner which ensures they do not adversely affect the *welfare* of quieter *animals*, such as rodents, rabbits and cats. Consideration should be given to insulating holding rooms and procedure rooms to mitigate the

effects of noise sources. Many species are sensitive to high frequency sounds and thus the location of potential sources of ultrasound should be considered.

Article 7.8.9.

Husbandry

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

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

1. Transportation

   Transportation is a typically stressful experience. Therefore, every precaution should be taken to avoid unnecessary stress through inadequate ventilation, exposure to extreme temperatures, lack of feed and water, long delays, etc. Consignments of *animals* should be accepted into the facility without avoidable delay and, after inspection, should be transferred to clean cages or pens and be supplied with feed and water as appropriate. Social *animals* should be transported in established pairs or groups and maintained in these on arrival.

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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1 Wherever the term "research" is used, it includes basic and applied research, testing and the production of biological materials; "education" includes teaching and training.

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