

WORLD ORGANISATION FOR ANIMAL HEALTH

Protecting animals, preserving our future

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HEALTH CODE**

VOLUME I

General provisions

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FOREWORD

The OIE Terrestrial Animal Health Code (hereafter referred to as the Terrestrial Code) establishes standards for the improvement of terrestrial animal health and welfare and veterinary public health worldwide. The health measures in the Terrestrial Code should be used by the Veterinary Authorities of importing and exporting countries to set up measures providing for early detection, reporting and control of pathogenic agents, including zoonotic ones, in terrestrial animals (mammals, birds, reptiles and bees) and preventing their spread via international trade in animals and animal products, while avoiding unjustified sanitary barriers to trade.

The standards in the Terrestrial Code have been formally adopted by the World Assembly of OIE Delegates, which constitutes the organisation's highest decision-making body. This 27th edition incorporates modifications to the Terrestrial Code agreed at the 86th General Session in May 2018.

This edition includes an updated version of the table of contents, User's guide, Glossary and the revised text in the following articles and chapters:

- Diseases, infections and infestations listed by the OIE (Articles 1.3.1., 1.3.2., 1.3.4. and 1.3.5.);
- Procedures for self-declaration and for official recognition by the OIE (Chapter 1.6.);
- Import risk analysis (Articles 2.1.1. and 2.1.3.);
- Criteria applied by the OIE for assessing the safety of commodities (Chapter 2.2.);
- Zoning and compartmentalisation (Chapter 4.3.);
- Collection and processing of oocytes or in vitro derived embryos from livestock and equids (Chapter 4.8.);
- The role of the Veterinary Services in food safety (Chapter 6.2.);
- Harmonisation of national antimicrobial resistance surveillance and monitoring programmes (Chapter 6.8.);
- Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals (Chapter 6.9.);
- Prevention and control of Salmonella in commercial pig production systems (Articles 6.14.2., 6.14.3. and 6.14.16.);
- Introduction to the recommendations for animal welfare (Chapter 7.1.);
- Welfare of working equids (Articles 7.12.7.);
- Infection with bluetongue virus (Chapter 8.3.);
- Infection with *Brucella abortus*, *B. melitensis* and *B. suis* (Article 8.4.10.);
- Infection with rinderpest virus (Article 8.16.2.);
- Infection with lumpy skin disease virus (Articles 11.9.4., 11.9.5., 11.9.6. and 11.9.15.);
- Infection with *Burkholderia mallei* (Glanders) (Chapter 12.10.).

This edition also includes five new chapters on following titles:

- Application for official recognition by the OIE of free status for African horse sickness (Chapter 1.7.);
- Application for official recognition by the OIE of risk status for bovine spongiform encephalopathy (Chapter 1.8.);
- Application for official recognition by the OIE of free status for classical swine fever (Chapter 1.9.);
- Application for official recognition by the OIE of free status for contagious bovine pleuropneumonia (Chapter 1.10.);
- Application for official recognition by the OIE of free status for foot and mouth disease (Chapter 1.11.);
- Application for official recognition by the OIE of free status for peste des petits ruminants (Chapter 1.12.);
- Vaccination (Chapter 4.17.);
- Introduction to recommendations for veterinary public health (Chapter 6.1.);
- Animal welfare and pig production systems (Chapter 7.13.).

The development of these standards and recommendations is the result of the ongoing work by the OIE Terrestrial Animal Health Standards Commission (hereafter referred to as the Code Commission). This Commission, which comprises six elected members, meets twice yearly to address its work programme. The Code Commission draws upon the expertise of internationally renowned specialists to prepare draft texts for new articles of the Terrestrial Code and to revise existing articles. The views of OIE National Delegates are routinely 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 that the recommendations contained in the Terrestrial Code are based upon the latest scientific information.

The World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (hereafter referred to as the SPS Agreement) formally recognises the role of the OIE as the international standard setting organisation for animal health and zoonotic diseases. According to the SPS Agreement, WTO Members should align their import requirements with the recommendations in the relevant standards of the OIE. Where there are no OIE recommendations or if the country chooses a level of protection requiring measures more stringent than the standards of the OIE, these should be based on an import risk analysis conducted in accordance with Chapter 2.1. 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.

We wish to thank the members of the Code Commission, Delegates and the experts participating in Working Groups and ad hoc Groups and other Specialist Commissions for their expert advice. Finally but not least, my thanks go to the staff of the OIE for their dedication in producing this 27th edition of the Terrestrial Code.

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July 2018

USER'S GUIDE

A. Introduction

- 1) The OIE *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code*) establishes standards for the improvement of terrestrial animal health and welfare and veterinary public health worldwide. The purpose of this guide is to advise the Veterinary Authorities of OIE Member Countries on how to use the *Terrestrial Code*.
- 2) Veterinary Authorities should use the standards in the *Terrestrial Code* to set up measures providing for early detection, internal reporting, notification, control or eradication of pathogenic agents, including zoonotic ones, in terrestrial animals (mammals, birds, reptiles and bees) and preventing their spread via international trade in animals and animal products, while avoiding unjustified sanitary barriers to trade.
- 3) The OIE standards are based on the most recent scientific and technical information. Correctly applied, they protect animal health and welfare and veterinary public health during production and trade in animals and animal products, and in the use of animals.
- 4) The absence of chapters, articles or recommendations on particular pathogenic agents or commodities does not preclude the application of appropriate sanitary measures by the Veterinary Authorities, provided they are based on risk analyses conducted in accordance with the *Terrestrial Code*.
- 5) The year that a chapter was first adopted and the year of its last revision are noted at the end of each chapter.
- 6) The complete text of the *Terrestrial Code* is available on the OIE Web site and individual chapters may be downloaded from: <http://www.oie.int>.

B. *Terrestrial Code* content

- 1) Key terms and expressions used in more than one chapter in the *Terrestrial Code* are defined in the Glossary, in the case where common dictionary definitions are not deemed to be adequate. The reader should be aware of the definitions given in the Glossary when reading and using the *Terrestrial Code*. Defined terms appear in italics. In the on-line version of the *Terrestrial Code*, a hyperlink leads to the relevant definition.
- 2) The term '(under study)' is found in some rare instances, with reference to an article or part of an article. This means that this part of the text has not been adopted by the World Assembly of OIE Delegates and the particular provisions are thus not part of the *Terrestrial Code*.
- 3) The standards in the chapters of Section 1 are designed for the implementation of measures for the diagnosis, surveillance and notification of pathogenic agents. The standards include procedures for notification to the OIE, tests for international trade, and procedures for the assessment of the health status of a country, zone or compartment.
- 4) The standards in Section 2 are designed to guide the importing country in conducting import risk analysis in the absence of OIE recommendations on particular pathogenic agents or commodities. The importing country should also use these standards to justify import measures which are more stringent than existing OIE standards.
- 5) The standards in the chapters of Section 3 are designed for the establishment, maintenance and evaluation of Veterinary Services, including veterinary legislation and communication. These standards are intended to assist the Veterinary Services of Member Countries to meet their objectives of improving terrestrial animal health and welfare and veterinary public health, as well as to establish and maintain confidence in their international veterinary certificates.
- 6) The standards in the chapters of Section 4 are designed for the implementation of measures for the prevention and control of pathogenic agents. Measures in this section include animal identification, traceability, zoning, compartmentalisation, disposal of dead animals, disinfection, disinsection and general hygiene precautions. Some chapters address the specific sanitary measures to be applied for the collection and processing of semen and embryos of animals.
- 7) The standards in the chapters of Section 5 are designed for the implementation of general sanitary measures for trade. They address veterinary certification and the measures applicable by the exporting, transit and importing countries. A range of model veterinary certificates is provided to facilitate consistent documentation in international trade.
- 8) The standards in the chapters of Section 6 are designed for the implementation of preventive measures in animal production systems. These measures are intended to assist Member Countries in meeting their veterinary public health objectives. They include ante- and post-mortem inspection, control of hazards in feed, biosecurity at the animal production level, and the control of antimicrobial resistance in animals.

- 9) The standards in the chapters of Section 7 are designed for the implementation of animal welfare measures. The standards cover production, transport, and slaughter or killing, as well as the animal welfare aspects of stray dog population control and the use of animals in research and education.
- 10) The standards in each of the chapters of Sections 8 to 15 are designed to prevent the pathogenic agents of OIE listed diseases, infections or infestations from being introduced into an importing country. The standards take into account the nature of the traded commodity, the animal health status of the exporting country, zone or compartment, and the risk reduction measures applicable to each commodity.

These standards assume that the agent is either not present in the importing country or is the subject of a control or eradication programme. Sections 8 to 15 each relate to the host species of the pathogenic agent: multiple species or single species of Apidae, Aves, Bovidae, Equidae, Leporidae, Caprinae and Suidae. Some chapters include specific measures to prevent and control the infections of global concern. Although the OIE aims to include a chapter for each OIE listed disease, not all OIE listed diseases have been covered yet by a specific chapter. This is work in progress, depending on available scientific knowledge and the priorities set by the World Assembly.

C. Specific issues

1) Notification

Chapter 1.1. describes Member Countries' obligations under OIE Organic Statutes. Listed and emerging diseases, as prescribed in Chapter 1.1., are compulsorily notifiable. Member Countries are encouraged to also provide information to the OIE on other animal health events of epidemiological significance.

Chapter 1.2. describes the criteria for the inclusion of an infection or infestation in the OIE List and Chapter 1.3. gives the current list. Diseases are divided into nine categories based on the host species of the aetiological agents.

2) Diagnostic tests and vaccines

It is recommended that specified diagnostic tests and vaccines in *Terrestrial Code* chapters be used with a reference to the relevant section in the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (hereafter referred to as the *Terrestrial Manual*). Experts responsible for facilities used for disease diagnosis and vaccine production should be fully conversant with the standards in the *Terrestrial Manual*.

3) Freedom from a disease, infection or infestation

Article 1.4.6. provides general principles for declaring a country or zone free from a disease, infection or infestation. This article applies when there are no specific requirements in the listed disease-specific chapter.

4) Prevention and control

Chapters 4.3. and 4.4. describe the measures that should be implemented to establish zones and compartments. Zoning and compartmentalisation should be considered as some of the tools used to control diseases and to facilitate safe trade. Chapters 4.5. to 4.11. describe the measures which should be implemented during collection and processing of semen and embryos of animals, including micromanipulation and cloning, in order to prevent animal health risks, especially when trading these commodities. Although the measures relate principally to OIE listed diseases or infections, general standards apply to all infectious disease risks. Moreover, in Chapter 4.7. diseases that are not listed are marked as such but are included for the information of Member Countries.

Chapter 4.14. addresses the specific issue of the control of bee diseases and some of its trade implications. This chapter should be read in conjunction with the specific bee disease chapters in Section 9.

Chapter 6.5. is designed for the implementation of general biosecurity measures in intensive poultry production. Chapters 6.6., 6.13. and 6.14. provide recommendations for some specific on-farm prevention and control plans for the unlisted food-borne pathogenic agent *Salmonella* as part of the Veterinary Services mission to prevent, eliminate or control food safety hazards in animal production.

Chapter 6.12. deals specifically with the zoonotic risk associated with the movements of non-human primates and gives standards for certification, transportation and import conditions for these animals.

5) Trade requirements

Animal health measures related to international trade should be based on OIE standards. A Member Country may authorise the importation of animals or animal products into its territory under conditions different from those recommended by the *Terrestrial Code*. To scientifically justify more stringent measures, the importing country should conduct a risk analysis in accordance with OIE standards, as described in Chapter 2.1. Members of the WTO should refer to the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

Chapters 5.1. to 5.3. describe the obligations and ethical responsibilities of importing and exporting countries in international trade. Veterinary Authorities and all veterinarians directly involved in international trade should be familiar with these chapters. Chapter 5.3. also describes the OIE informal procedure for dispute mediation.

The OIE aims to include an article listing the commodities that are considered safe for trade without the need for risk mitigation measures specifically directed against a particular listed disease, infection or infestation, regardless of the status of the country or zone of origin for the agent in question, at the beginning of each listed disease-specific chapter in Sections 8 to 15. This is work in progress and some chapters do not yet contain articles listing safe commodities. When a list of safe commodities is present in a chapter, importing countries should not apply trade restrictions to such commodities with respect to the agent in question.

6) International veterinary certificates

An international veterinary certificate is an official document that the Veterinary Authority of an exporting country issues in accordance with Chapters 5.1. and 5.2. It lists animal health requirements and, where appropriate, public health requirements for the exported commodity. The quality of the exporting country's Veterinary Services is essential in providing assurances to trading partners regarding the safety of exported animals and products. This includes the Veterinary Services' ethical approach to the provision of veterinary certificates and their history in meeting their notification obligations.

International veterinary certificates underpin international trade and provide assurances to the importing country regarding the health status of the animals and products imported. The measures prescribed should take into account the health status of both exporting and importing countries, and zones or compartments within them, and be based upon the standards in the *Terrestrial Code*.

The following steps should be taken when drafting international veterinary certificates:

- a) identify the diseases, infections or infestations from which the importing country is justified in seeking protection because of its own health status. Importing countries should not impose measures in regards to diseases that occur in their own territory but are not subject to official control programmes;
- b) for commodities capable of transmitting these diseases, infections or infestations through international trade, the importing country should apply the relevant articles in the listed disease-specific chapters. The application of the articles should be adapted to the disease status of the country, zone or compartment of origin. Such status should be established according to Article 1.4.6. except when articles of the relevant listed disease chapter specify otherwise;
- c) when preparing international veterinary certificates, the importing country should endeavour to use terms and expressions in accordance with the definitions given in the Glossary. International veterinary certificates should be kept as simple as possible and should be clearly worded, to avoid misunderstanding of the importing country's requirements;
- d) Chapters 5.10. to 5.13. provide, as further guidance to Member Countries, model certificates that should be used as a baseline.

7) Guidance notes for importers and exporters

It is recommended that Veterinary Authorities prepare 'guidance notes' to assist importers and exporters understand trade requirements. These notes should identify and explain the trade conditions, including the measures to be applied before and after export and during transport and unloading, and the relevant legal obligations and operational procedures. The guidance notes should advise on all details to be included in the health certification accompanying the consignment to its destination. Exporters should also be reminded of the International Air Transport Association rules governing air transport of animals and animal products.

GLOSSARY

For the purposes of the *Terrestrial Code*:

ANIMAL

means a mammal, reptile, 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 or practical experience.

ANIMAL HEALTH MANAGEMENT

means a system designed to optimise the physical and behavioural health and welfare of *animals*. It includes the prevention, treatment and control of diseases and conditions affecting the individual *animal* and *herd* or *flock*, including the recording of illness, injuries, mortalities and medical treatments where appropriate.

ANIMAL HEALTH STATUS

means the status of a country, *zone* or *compartment* with respect to an *animal* disease in accordance with the criteria listed in the relevant disease-specific chapter or Chapter 1.4. of the *Terrestrial Code*.

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* or owners, the persons responsible for the *animals*, 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 the physical and mental state of an *animal* in relation to the conditions in which it lives and dies.

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*.

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 purposes of transport or isolation.

BIOSECURITY

means a set of management and physical measures designed to reduce the *risk* of introduction, establishment and spread of animal diseases, *infections* or *infestations* to, from and within an animal population.

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.

CASINGS

means intestines and bladders that, after cleaning, have been processed by tissue scraping, defatting and washing, and have been treated with salt.

COLLECTION CENTRE

means a facility approved by the *Veterinary Authority* for the collection of oocytes or embryos 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*, separated from other susceptible *populations* by a common biosecurity management system, and with a specific *animal health status* with respect to one or more *infections* or *infestations* for which the necessary *surveillance*, *biosecurity* and control measures have been applied for the purposes of *international trade* or disease prevention and control in a country or *zone*.

COMPETENT AUTHORITY

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

CONTAINER

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

CONTAINMENT ZONE

means an *infected zone* defined within a previously free country or *zone*, which includes all suspected or confirmed *cases* that are epidemiologically linked and where movement control, *biosecurity* and *sanitary measures* are applied to prevent the spread of, and to eradicate, the *infection* or *infestation*.

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.

DISINFECTION

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

DISINFESTATION

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

EARLY DETECTION SYSTEM

means a system for the timely detection and identification of an incursion or emergence of diseases or *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 paraprofessionals*, 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 occurrence in an *animal* of a disease, *infection* or *infestation*, causing a significant impact on animal or public health resulting from:

- a) a change of a known pathogenic agent or its spread to a new geographic area or species; or
- b) a previously unrecognised pathogenic agent or disease diagnosed for the first time.

EPIDEMIOLOGICAL UNIT

means a group of *animals* with a defined epidemiological relationship that share approximately the same likelihood of exposure to a pathogenic agent. 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 pathogenic agent.

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.

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 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.

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*. A *flock* is usually regarded as an *epidemiological unit*.

FREE COMPARTMENT

means a *compartment* in which the absence of the animal pathogenic agent 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 a specific *infection* or *infestation* in an animal *population* has been demonstrated in accordance with the relevant requirements of the *Terrestrial Code*.

FRESH MEAT

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

GOOD MANUFACTURING PRACTICE

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

GREAVES

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

HATCHING EGGS

means fertilised bird eggs, suitable for incubation and hatching.

HAZARD

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

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: oi@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*. 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 that elapses between the introduction of the pathogenic agent into the *animal* and the occurrence of the first clinical signs of the disease.

INFECTED ZONE

means a *zone* either in which an *infection* or *infestation* has been confirmed, or one that is defined as such in the relevant chapters of the *Terrestrial Code*.

INFECTION

means the entry and development or multiplication of a pathogenic agent in the body of humans or *animals*.

INFECTIVE PERIOD

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

INFESTATION

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

INTERNATIONAL TRADE

means importation, exportation and transit of *commodities*.

INTERNATIONAL VETERINARY CERTIFICATE

means a certificate, issued in accordance with Chapter 5.2., describing the animal health and public health requirements that 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 that 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 DISEASE

means a disease, *infection* or *infestation* listed in Chapter 1.3. after adoption by the World Assembly of OIE Delegates.

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 purposes 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*.

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 disease, *infection* or *infestation* in accordance with Chapter 1.1.

OFFICIAL CONTROL PROGRAMME

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

OFFICIAL VETERINARIAN

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

OFFICIAL VETERINARY CONTROL

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

OUTBREAK

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

OWNED DOG

means a dog for which a person claims responsibility.

PATHOLOGICAL MATERIAL

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

PLACE OF SHIPMENT

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

POPULATION

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

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 purposes of *loading* them.

PREVALENCE

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

PROTECTION ZONE

means a *zone* where specific *biosecurity* and *sanitary measures* are implemented to prevent the entry of a pathogenic agent into a free country or *zone* from a neighbouring country or *zone* of a different *animal health status*.

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'.

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 pathogenic agents outside the establishment while the *animals* are undergoing observation for a specified length of time and, if appropriate, testing or treatment.

REGISTRATION

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

RESPONSIBLE DOG OWNERSHIP

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

RESTING POINT

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

RESTRAINT

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

RISK

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

RISK ANALYSIS

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

RISK ASSESSMENT

means the evaluation of the likelihood and the biological and economic consequences of entry, establishment and spread of a *hazard*.

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*.

SAFE COMMODITY

means a *commodity* that can be traded without the need for *risk* mitigation measures specifically directed against a particular *listed disease*, *infection* or *infestation* and regardless of the status of the country or *zone* of origin for that disease, *infection* or *infestation*.

SANITARY MEASURE

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

SLAUGHTER

means any procedure that 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 a policy designed to eliminate an *outbreak* by carrying out under the authority of the *Veterinary Authority* the following:

- a) the *killing* of the *animals* which are affected and those suspected of being affected in the *herd* or *flock* and, where appropriate, those in other *herds* or *flocks* which have been exposed to *infection* by direct animal to animal contact, or by indirect contact with the causal pathogenic agent; *animals* should be killed in accordance with Chapter 7.6.;
- b) the disposal of carcasses and, where relevant, animal products by rendering, burning or burial, or by any other method described in Chapter 4.12.;
- c) the cleansing and *disinfection* of *establishments* through procedures defined in Chapter 4.13.

STOCKING DENSITY

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

STRAY DOG

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

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

STUNNING

means any mechanical, electrical, chemical or other procedure that 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 in accordance with specific common animal health characteristics.

SURVEILLANCE

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

TERRESTRIAL CODE

means the OIE *Terrestrial Animal Health Code*.

TERRESTRIAL MANUAL

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

TRANSIT COUNTRY

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

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 administration of a vaccine, in accordance with the manufacturer's instructions and the *Terrestrial Manual*, when relevant, with the intention of inducing immunity in an *animal* or group of *animals* against one or more pathogenic agents.

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 *animals*.

VETERINARIAN

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

VETERINARY AUTHORITY

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

VETERINARY LEGISLATION

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

VETERINARY MEDICINAL PRODUCT

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

VETERINARY PARAPROFESSIONAL

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 paraprofessional*) in a territory, and delegated to them under the responsibility and direction of a *veterinarian*. The tasks for each category of *veterinary paraprofessional* should be defined by the *veterinary statutory body* depending on qualifications and training, and in accordance with need.

VETERINARY SERVICES

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

VETERINARY STATUTORY BODY

means an autonomous regulatory body for *veterinarians* and *veterinary paraprofessionals*.

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

means a part of a country defined by the *Veterinary Authority*, containing an animal *population* or *subpopulation* with a specific *animal health status* with respect to an *infection* or *infestation* for the purposes of *international trade* or disease prevention or control.

NB: FIRST ADOPTED IN 1968; MOST RECENT UPDATE ADOPTED IN 2018.

SECTION 1.

**ANIMAL DISEASE DIAGNOSIS, SURVEILLANCE
AND NOTIFICATION**

CHAPTER 1.1.

**NOTIFICATION OF DISEASES, INFECTIONS AND
INFESTATIONS, AND PROVISION OF
EPIDEMIOLOGICAL INFORMATION**

Article 1.1.1.

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

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

Article 1.1.2.

- 1) Member Countries shall make available to other Member Countries, through the OIE, whatever information is necessary to minimise the spread of important animal diseases, and their pathogenic agents, and to assist in achieving better worldwide control of these diseases.
- 2) To achieve this, Member Countries shall comply with the *notification* requirements specified in Articles 1.1.3. and 1.1.4.
- 3) For the purposes of this chapter, an 'event' means a single *outbreak* or a group of epidemiologically related *outbreaks* of a given disease, *infection* or *infestation* that is the subject of a *notification*. An event is specific to a pathogenic agent and strain, when appropriate, and includes all related *outbreaks* reported from the time of the immediate *notification* through to the final report. Reports of an event include susceptible species, number and geographical distribution of affected animals and *epidemiological units*.
- 4) To assist in the clear and concise exchange of information, reports shall conform as closely as possible to the OIE disease reporting format.
- 5) The detection of the pathogenic agent of a *listed disease* in an *animal* should be reported, even in the absence of clinical signs. Recognising that scientific knowledge concerning the relationship between diseases and their pathogenic agents is constantly developing and that the presence of a pathogenic agent does not necessarily imply the presence of a disease, Member Countries shall ensure, through their reports, that they comply with the spirit and intention of point 1) above.
- 6) In addition to notifying new findings in accordance with Articles 1.1.3. and 1.1.4., Member Countries shall also provide information on the measures taken to prevent the spread of diseases, *infections* and *infestations*. Information shall include quarantine measures and restrictions applied to the movement of *animals*, animal products, biological products and other miscellaneous objects which could by their nature be responsible for the transmission of diseases, *infections* or *infestations*. In the case of diseases transmitted by *vectors*, the measures taken against such *vectors* shall also be specified.

Article 1.1.3.

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

- 1) in accordance with relevant provisions in the disease-specific chapters, *notification*, through the World Animal Health Information System (WAHIS) or by fax or email within 24 hours, of any of the following events:
 - a) first occurrence of a *listed disease, infection or infestation* in a country, a *zone* or a *compartment*;
 - b) recurrence of a *listed disease, infection or infestation* in a country, a *zone* or a *compartment* following the final report that declared the *outbreak* ended;
 - c) first occurrence of a new strain of a pathogenic agent of a *listed disease, infection or infestation* in a country, a *zone* or a *compartment*;
 - d) a sudden and unexpected change in the distribution or increase in incidence or virulence of, or morbidity or mortality caused by, the pathogenic agent of a *listed disease, infection or infestation* present within a country, a *zone* or a *compartment*;
 - e) occurrence of a *listed disease, infection or infestation* in an unusual host species;
- 2) weekly reports subsequent to a *notification* under point 1) above, to provide further information on the evolution of the event which justified the *notification*. These reports should continue until the disease, *infection* or *infestation* has been eradicated or the situation has become sufficiently stable so that six-monthly reporting under point 3) will satisfy the obligation of the Member Country; for each event notified, a final report should be submitted;
- 3) six-monthly reports on the absence or presence and evolution of *listed diseases, infections or infestations* and information of epidemiological significance to other Member Countries;
- 4) annual reports concerning any other information of significance to other Member Countries.

Article 1.1.4.

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

- 1) a *notification* through WAHIS or by fax or email, when an *emerging disease* has been detected in a country, a *zone* or a *compartment*;
- 2) periodic reports subsequent to a *notification* of an *emerging disease*:
 - a) for the time necessary to have reasonable certainty that:
 - i) the disease, *infection* or *infestation* has been eradicated; or
 - ii) the situation has become stable;OR
 - b) until sufficient scientific information is available to determine whether it meets the criteria for inclusion in the OIE list as described in Chapter 1.2.;
- 3) a final report once point 2 a) or b) above is complied with.

Article 1.1.5.

- 1) The *Veterinary Authority* of a country in which an *infected zone* is located shall inform the *Headquarters* when this zone or the entire country becomes free from the disease, *infection* or *infestation*.
- 2) A country or *zone* may be considered to have regained freedom from a specific disease, *infection* or *infestation* when all relevant conditions given in the *Terrestrial Code* have been fulfilled.
- 3) The *Veterinary Authority* of a Member Country which establishes one or several *free zones* shall inform the *Headquarters* giving necessary details, including the criteria on which the free status is based, the requirements for maintaining the status and indicating clearly the location of the *zones* on a map of the territory of the Member Country.

Article 1.1.6.

- 1) Although Member Countries are only required to notify *listed diseases, infections and infestations* and *emerging diseases*, they are encouraged to provide the OIE with other important animal health information.
- 2) The *Headquarters* shall communicate by email or through the interface of WAHIS to *Veterinary Authorities* all *notifications* received as provided in Articles 1.1.2. to 1.1.5. and other relevant information.

NB: FIRST ADOPTED IN 1968; MOST RECENT UPDATE ADOPTED IN 2016.

CHAPTER 1.2.

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

Article 1.2.1.

Introduction

This chapter describes the criteria for the inclusion of diseases, *infections* and *infestations* in Chapter 1.3.

The objective is to support Member Countries by providing information needed to take appropriate action to prevent the transboundary spread of important animal diseases, including zoonoses. This is achieved through transparent, timely and consistent *notification*.

Each *listed disease* normally has a corresponding chapter that assists Member Countries in the harmonisation of disease detection, prevention and control and provides standards for safe *international trade* in *animals* and their products.

The requirements for *notification* are detailed in Chapter 1.1.

Principles and methods of validation of diagnostic tests are described in Chapter 1.1.5. of the *Terrestrial Manual*.

Article 1.2.2.

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

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

AND

- 2) At least one country has demonstrated freedom or impending freedom from the disease, *infection* or *infestation* in populations of susceptible *animals*, based on the provisions of Chapter 1.4.

AND

- 3) Reliable means of detection and diagnosis exist and a precise *case* definition is available to clearly identify *cases* and allow them to be distinguished from other diseases, *infections* or *infestations*.

AND

4)

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

OR

- b) The disease has been shown to have a significant impact on the health of domestic *animals* at the level of a country or a *zone* taking into account the occurrence and severity of the clinical signs, including direct production losses and mortality.

OR

- c) The disease has been shown to, or scientific evidence indicates that it would, have a significant impact on the health of *wildlife* taking into account the occurrence and severity of the clinical signs, including direct economic losses and mortality, and any threat to the viability of a *wildlife* population.

NB: FIRST ADOPTED IN 2004; MOST RECENT UPDATE ADOPTED IN 2017.

CHAPTER 1.3.

DISEASES, INFECTIONS AND INFESTATIONS LISTED BY THE OIE

Preamble

The diseases, *infections* and *infestations* in this chapter have been assessed in accordance with Chapter 1.2. and constitute the OIE list of terrestrial animal diseases.

In case of modifications of this list adopted by the World Assembly of OIE Delegates, the new list comes into force on 1 January of the following year.

Article 1.3.1.

The following are included within the category of multiple species diseases, *infections* and *infestations*:

- Anthrax
- Crimean Congo hemorrhagic fever
- Equine encephalomyelitis (Eastern)
- Heartwater
- Infection with Aujeszky's disease virus
- Infection with bluetongue virus
- Infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis*
- Infection with *Echinococcus granulosus*
- Infection with *Echinococcus multilocularis*
- Infection with epizootic hemorrhagic disease virus
- Infection with foot and mouth disease virus
- Infection with *Mycobacterium tuberculosis* complex
- Infection with rabies virus
- Infection with Rift Valley fever virus
- Infection with rinderpest virus
- Infection with *Trichinella* spp.
- Japanese encephalitis
- New World screwworm (*Cochliomyia hominivorax*)
- Old World screwworm (*Chrysomya bezziana*)
- Paratuberculosis
- Q fever
- Surra (*Trypanosoma evansi*)
- Tularemia
- West Nile fever.

Article 1.3.2.

The following are included within the category of cattle diseases and *infections*:

- Bovine anaplasmosis
- Bovine babesiosis
- Bovine genital campylobacteriosis
- Bovine spongiform encephalopathy
- Bovine viral diarrhoea

- Enzootic bovine leukosis
- Haemorrhagic septicaemia
- Infection with lumpy skin disease virus
- Infection with *Mycoplasma mycoides* subsp. *mycoides* SC (Contagious bovine pleuropneumonia)
- Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
- Theileriosis
- Trichomonosis
- Trypanosomosis (tsetse-transmitted).

Article 1.3.3.

The following are included within the category of sheep and goat diseases and *infections*:

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

Article 1.3.4.

The following are included within the category of equine diseases and *infections*:

- Contagious equine metritis
- Dourine
- Equine encephalomyelitis (Western)
- Equine infectious anaemia
- Equine influenza
- Equine piroplasmiasis
- Infection with *Burkholderia mallei* (Glanders)
- Infection with African horse sickness virus
- Infection with equid herpesvirus-1 (EHV-1)
- Infection with equine arteritis virus
- Venezuelan equine encephalomyelitis.

Article 1.3.5.

The following are included within the category of swine diseases and *infections*:

- Infection with African swine fever virus
- Infection with classical swine fever virus
- Infection with porcine reproductive and respiratory syndrome virus
- Infection with *Taenia solium* (Porcine cysticercosis)
- Nipah virus encephalitis
- Transmissible gastroenteritis.

Article 1.3.6.

The following are included within the category of avian diseases and *infections*:

- Avian chlamydiosis
- Avian infectious bronchitis
- Avian infectious laryngotracheitis
- Avian mycoplasmosis (*Mycoplasma gallisepticum*)
- Avian mycoplasmosis (*Mycoplasma synoviae*)
- Duck virus hepatitis
- Fowl typhoid
- Infection with avian influenza viruses
- Infection with influenza A viruses of high pathogenicity in birds other than *poultry* including wild birds
- Infection with Newcastle disease virus
- Infectious bursal disease (Gumboro disease)
- Pullorum disease
- Turkey rhinotracheitis.

Article 1.3.7.

The following are included within the category of lagomorph diseases and *infections*:

- Myxomatosis
- Rabbit haemorrhagic disease.

Article 1.3.8.

The following are included within the category of bee diseases, *infections* and *infestations*:

- Infection of honey bees with *Melissococcus plutonius* (European foulbrood)
- Infection of honey bees with *Paenibacillus larvae* (American foulbrood)
- Infestation of honey bees with *Acarapis woodi*
- Infestation of honey bees with *Tropilaelaps* spp.
- Infestation of honey bees with *Varroa* spp. (Varroosis)
- Infestation with *Aethina tumida* (Small hive beetle).

Article 1.3.9.

The following are included within the category of other diseases and *infections*:

- Camel pox
- Leishmaniasis.

NB: FIRST ADOPTED IN 1976; MOST RECENT UPDATE ADOPTED IN 2018.

CHAPTER 1.4.

ANIMAL HEALTH SURVEILLANCE

Article 1.4.1.

Introduction and objectives

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

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

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

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

Article 1.4.2.

Definitions

The following definitions apply for the purposes of this chapter:

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

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

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

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

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

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

'**Specificity**': means the proportion of truly negative units that are correctly identified as negative by a test.

'**Study population**': means the population from which *surveillance* data are derived. This may be the same as the target population or a subset of it.

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

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

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

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

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

Article 1.4.3.

Principles of surveillance

1. Types of surveillance

- a) *Surveillance* may be based on many different data sources and can be classified in a number of ways, including:
- i) the means by which data are collected (active versus passive *surveillance*);
 - ii) the disease focus (pathogen-specific versus general *surveillance*); and
 - iii) the way in which units for observation are selected (structured surveys versus non-random data sources).
- b) In this chapter, *surveillance* activities are classified as being based on:
- EITHER
- i) structured population-based surveys, such as:
 - systematic sampling at *slaughter*;
 - random surveys;
 - surveys for *infection* in clinically normal *animals*, including *wildlife*;
- OR
- ii) structured non-random *surveillance* activities, such as:
 - disease reporting or notifications;
 - control programmes or health schemes;
 - targeted testing or screening;
 - ante-mortem and post-mortem inspections;
 - laboratory investigation records;
 - biological specimen banks;
 - sentinel units;
 - field observations;
 - farm production records;
 - *wildlife* disease data.
- c) In addition, *surveillance* data should be supported by related information, such as:
- i) data on the epidemiology of the disease or *infection*, including environmental, host population distribution, and climatic information;
 - ii) data on animal movements, including transhumance and natural *wildlife* migrations;
 - iii) trading patterns for *animals* and animal products;
 - iv) national animal health regulations, including information on compliance with them and their effectiveness;
 - v) history of imports of potentially infected material;
 - vi) biosecurity measures in place; and
 - vii) the likelihood and consequence of disease or *infection* introduction.
- d) The sources of evidence should be fully described. In the case of a structured survey, this should include a description of the sampling strategy used for the selection of units for testing. For structured non-random data sources, a full description of the system is required including the sources 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* (See 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 units* 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* or *flock*, a cluster of pens in a building, or a cluster of farms in a *compartment*). Clustering should be taken into account in the design of *surveillance* activities and the statistical analysis of *surveillance* data, at least at what is judged to be the most significant level of clustering for the particular animal population and *infection*.

e) Case definition

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

f) Analytical methodologies

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

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

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

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

g) Testing

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

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

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

h) Quality assurance

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

i) Validation

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

j) Data collection and management

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

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

Article 1.4.4.

Structured population-based surveys

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

1. Types of surveys

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

- a) non-probability based sampling methods, such as:
 - i) convenience;
 - ii) expert choice;
 - iii) quota;
- b) probability based sampling methods, such as:
 - i) simple random selection;
 - ii) cluster sampling;
 - iii) stratified sampling;
 - iv) systematic sampling.

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

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

2. Survey design

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

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

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

3. Sampling

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

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

4. Sampling methods

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

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

5. Sample size

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

Article 1.4.5.

Structured non-random surveillance

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

1. Common non-random surveillance sources

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

a) Disease reporting or notification systems

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

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

b) Control programmes and health schemes

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

c) Targeted testing and screening

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

d) Ante-mortem and post-mortem inspections

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

- i) the training, experience and number of the inspection staff;
- ii) the involvement of the *Competent Authority* in the supervision of ante-mortem and post-mortem inspections;
- iii) the quality of construction of the *slaughterhouse/abattoir*, speed of the slaughter chain, lighting quality, etc.; and
- iv) staff morale and motivation for efficient performance.

Slaughterhouse/abattoir inspections are likely to provide good coverage for particular age groups and geographical areas only. *Slaughterhouse/abattoir 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* or *flock*-level coverage, there should be, if possible, an effective identification system that relates *animals* in the *slaughterhouse/abattoir* 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 *slaughterhouse/abattoir* inspections, there needs to be a mechanism to relate specimens to the farm of origin.

f) Biological specimen banks

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

g) Sentinel units

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

h) Field observations

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

i) Farm production records

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

j) Wildlife data

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

2. Critical elements for structured non-random surveillance

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

3. Analytical methodologies

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

4. Combination of multiple sources of data

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

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

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

Article 1.4.6.

Surveillance to demonstrate freedom from disease or infection

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

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

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

- in the absence of disease and *vaccination*, the animal population would become susceptible over a period of time;
- the pathogenic 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 or *infection* can affect both domestic *animals* and *wildlife*;
- the absence of disease or *infection* over a long period of time in a susceptible population can be substantiated by effective disease investigation and reporting by a Member Country.

a) Historically free

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

- i) there has never been occurrence of disease, or
- ii) eradication has been achieved or the disease or *infection* has ceased to occur for at least 25 years, provided that for at least the past 10 years:
- iii) the disease has been a *notifiable disease*;
- iv) an early detection system has been in place for all relevant species;
- v) measures to prevent disease or *infection* introduction have been in place; no *vaccination* against the disease has been carried out unless otherwise provided for in the *Terrestrial Code*;
- vi) *infection* is not known to be established in *wildlife* within the country or *zone*. A country or *zone* cannot apply for historical freedom if there is any evidence of *infection* in *wildlife*.

b) Last occurrence within the previous 25 years

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

- i) the disease has been a *notifiable disease*;
- ii) an early detection system has been in place;
- iii) measures to prevent the introduction of the disease or *infection* introduction have been in place;
- iv) no *vaccination* against the disease has been carried out unless otherwise provided for in the *Terrestrial Code*;
- v) *infection* is not known to be established in *wildlife* within the country or *zone*. A country or *zone* cannot apply for recognition of freedom if there is any evidence of *infection* in *wildlife*.

2. Recommendations for the discontinuation of pathogen-specific screening after recognition of freedom from infection

A country, *zone* or *compartment* that has been recognised as free from *infection* following the provisions of the *Terrestrial Code* may discontinue pathogen-specific screening while maintaining the infection-free status provided that:

- a) the disease is a *notifiable disease*;
- b) an early detection system is in place;
- c) measures to prevent the introduction of the disease or *infection* are in place;
- d) *vaccination* against the disease is not applied;
- e) *infection* is known not to be established in *wildlife*. It can be difficult to collect sufficient epidemiological data to prove absence of disease or *infection* in *wild animal* populations. In such circumstances, a range of supporting evidence should be used to make this assessment.

3. Self declaration of freedom from disease or infection

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

4. International recognition of disease or infection free status

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

5. Demonstration of freedom from infection

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

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

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

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

Article 1.4.7.

Surveillance for distribution and occurrence of infection

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

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

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

NB: FIRST ADOPTED IN 2005; MOST RECENT UPDATE ADOPTED IN 2012.

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 *vectors* and the disease status of a country/*zone*, and also that the apparent absence of *vectors* does not by itself confirm *vector*-free status.

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

Article 1.5.2.

Objectives

The objective of these recommendations is to provide methods for:

- 1) gathering up-to-date information on the spatial and temporal distribution and abundance of *vectors* of the arthropod-borne *listed diseases* and *emerging diseases*;
- 2) monitoring changes in the spatial and temporal distribution and abundance of these *vectors*;
- 3) collecting relevant data to inform *risk assessment* (including *vector* competency) and *risk management* of these *vector*-borne diseases;
- 4) detecting the presence of specific *vectors* or confirming their absence;
- 5) understanding pathways of entry for *vectors* and *vector*-borne pathogenic agents.

Article 1.5.3.

Sampling methodology

1. Sampling plan

- a) The objective of the *surveillance* programme should be determined and stated before planning begins.
- b) Available historical data on the *vector* or the disease for the country or *zone* should be collated and assessed.
- c) The sampling plan should consider the following:
 - i) the biology and ecology of the *vectors*,
 - ii) the presence, distribution and abundance of the *vectors*' host animal populations,
 - 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 *vectors* 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 diseases of concern,
 - areas of known *vector* occurrences,
 - fringe *zones* around areas of known *vector* occurrences or other high *risks* areas for *vector* introduction, such as ports,
 - areas in which the diseases or *vectors* 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 in accordance with 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 in accordance with the disease/*vector* system under consideration.

- a) The collection methods used should be adapted as required to ensure reasonable confidence of collecting the *vectors* of concern.

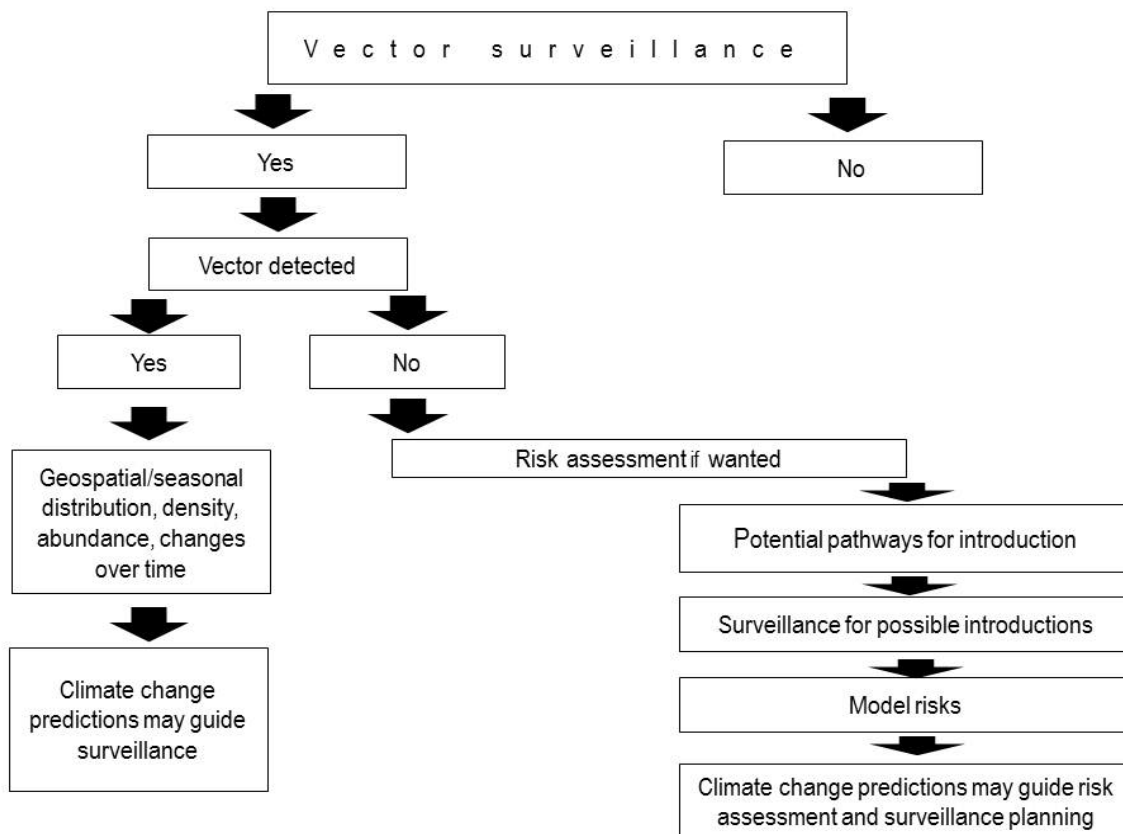
- b) Collection methods should obtain the various developmental stages (such as eggs, larvae, nymphs, adults) and adult age categories, as appropriate to the species in question and the objectives of the *surveillance*. For example, if a *vector* is not believed to be present, collection methods should 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 *vectors* in a manner suitable for their morphological identification or identification with molecular techniques. Where the purpose of sampling is to detect or isolate pathogenic agents, 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.

Fig. 1. Decision tree for vector surveillance



NB: FIRST ADOPTED IN 2009; MOST RECENT UPDATE ADOPTED IN 2010.

CHAPTER 1.6.

PROCEDURES FOR SELF DECLARATION AND FOR OFFICIAL RECOGNITION BY THE OIE

Article 1.6.1.

General principles

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

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

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

The OIE does not grant official recognition for other diseases.

In these cases, Member Countries should present documentation setting out the compliance of their *Veterinary Services* with 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 or requesting endorsement by the OIE of an *official control programme*, the Member Country should submit to the OIE Status Department a dossier providing the information requested in the following chapters (as appropriate): 1.7., 1.8., 1.9., 1.10., 1.11. or 1.12.

The OIE framework for the official recognition and maintenance of disease status is described in Resolution N° XV (administrative procedures) and Resolution N° XVI (financial obligations) adopted during the 83rd General Session in May 2015.

NB: FIRST ADOPTED IN 2009; MOST RECENT UPDATE ADOPTED IN 2018.

CHAPTER 1.7.

APPLICATION FOR OFFICIAL RECOGNITION BY THE OIE OF FREE STATUS FOR AFRICAN HORSE SICKNESS

Article 1.7.1.

Country free from infection with African horse sickness virus

The following information should be provided by OIE Member Countries to support applications for official recognition of status as a country free from *infection* with African horse sickness (AHS) virus in accordance with Chapter 12.1. of the *Terrestrial Code*.

The dossier provided to the OIE should address concisely all the topics under the headings provided to describe the actual situation in the country and the procedures currently applied, explaining how these comply with the *Terrestrial Code*.

The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

All annexes should be provided in one of the OIE official languages.

The Delegate of the Member Country applying for recognition of AHS freedom for a country must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Article 12.1.2. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that:

- 1) there has been no *case of infection* with AHS virus for at least the past two years;
- 2) no routine *vaccination* against AHS has been carried out during the past year;
- 3) and that any equids imported have been done so in accordance with Chapter 12.1.

In addition, the Delegate of the Member Country applying for recognition of historical freedom must also submit documentary evidence that the provisions of point 1 a) of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.

1. Introduction

- a) Geographical features (rivers, mountain ranges, etc.). Provide a general description of the country and, where relevant, of the region, including physical, geographical and other factors that are relevant to introduction of *infection* and spread of AHS virus, taking into account the countries sharing common borders and other

epidemiologic pathways for the potential introduction of *infection*. Provide maps identifying the features above. Specify whether the application includes any noncontiguous territories.

- b) Demographics of domestic equids. Describe the composition of the equine *population* by species (e.g. horses, donkeys, mules, zebras, etc.) within the various sectors.

Equine sectors are defined as equids (including donkeys, mules, hinnies and zebras) used for breeding stock, competition, leisure, exhibition, working (including transport) and production. How are the equine sectors distributed (e.g. density, etc.) throughout the country? Provide tables and maps as appropriate.

- c) Equine sectors. Provide a general description of the relative economic importance of the equine sectors in the country. Consider the below-mentioned sector groupings and outline any recent significant changes observed within the sector groupings (attach relevant documents if available):

i) breeding stock equids;

ii) competition horses;

iii) leisure equids;

iv) exhibition equids;

v) working, transport and production equids (including donkeys, mules and hinnies).

- d) *Wildlife* demographics. What *captive wild*, *wild* or *feral* equids are present in the country? Provide estimates of *population* sizes and geographic distribution.

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation, regulations and *Veterinary Authority* directives in relation to AHS and a brief description of the relevance of each. The table should include, but not be limited to, the legislation on disease control measures and compensation systems.

- b) *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, control, enforce and monitor all AHS-related activities. Provide maps, figures and tables wherever possible.

- c) Provide information on any OIE PVS evaluation conducted in the country and follow-up steps within the PVS Pathway and highlight the results relevant to AHS and the susceptible species.

- d) Provide a description of the involvement and the participation of industry, producers, farmer, including subsistence and small-scale producers, keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in AHS *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, including the number of *veterinarians* and their distribution, in AHS *surveillance* and control. Include a description of continuing education and awareness programmes on AHS at all relevant levels.

- e) *Animal identification*, registration, traceability and movement control. Are equids identified (individually or at a group level)? Provide a description of the traceability system, including methods of *animal identification* and *establishment* or *herd* registration, applicable to all equine sectors. How are movements of equids controlled in the country for all equine sectors? Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months. Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g. seasonal migration).

Describe the actions available under national legislation. Provide information on illegal movements detected in the past 24 months and the action taken.

- f) Leisure, exhibition and competition movements of equids. How are movements of these types of equids controlled in the country? Provide information on systems including any use of registration. Provide information on any events that include international movements of equids.

- g) Describe the market systems for the sale of, or transfer of ownership of, equids in the country, including where the international movement of equids occurs.

3. AHS eradication

- a) History. If *infection* has never occurred in the country, or has not occurred within the past 25 years, state explicitly whether or not the country is applying for recognition of historical freedom according to point 1 a) of Article 1.4.6. of the *Terrestrial Code*.

If *infection* has occurred in the country within the past 25 years, provide a description of the AHS history in the country, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, and the date of last *case* or *eradication* in the country.

- b) Strategy. Describe how AHS was controlled and eradicated (e.g. isolation of *cases*, *stamping-out policy*, zoning, movement control, protection of equids against *vectors*). Provide the time frame for *eradication*. Describe and justify the corrective actions that have been implemented to prevent future *outbreaks* of AHS in response to any past incursions of AHS virus.

- c) Vaccines and *vaccination*. Briefly answer the following:

- i) Is there any legislation that prohibits *vaccination*? If so:

- Provide the date when *vaccination* was formally prohibited;
- Provide information on cases of detection of illegal *vaccination* during the reporting period and actions taken in response to the detection.

- ii) Was *vaccination* ever used in the country? If so:

- Provide the date when the last *vaccination* was carried out;
- What type of vaccine was used?
- What species were vaccinated?
- How were vaccinated animals identified?
- What was the fate of those animals?

- iii) In addition, if *vaccination* was applied during the past 24 months, provide a description and justification of the *vaccination* strategy and programme, including the following:

- the vaccine strains;
- the species vaccinated;
- identification of vaccinated animals;
- the way in which the *vaccination* of animals was certified or reported and the records maintained;
- evidence that the vaccine used complies with Chapter 2.5.1. of the *Terrestrial Manual*.

- d) Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. AHS diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 2.5.1. of the *Terrestrial Manual* are applied. The following points should be addressed:

- a) Is AHS *laboratory* diagnosis carried out in the country? If so, provide an overview of the AHS-approved *laboratories* in the country, including the following:

- i) How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for reporting results;

- ii) Details of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of AHS tests performed in the past 24 months in national *laboratories* and in *laboratories* in other countries, if relevant;

- iii) Procedures for quality assurance and for the official accreditation of *laboratories*. Give details of formal internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;

- iv) Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;

- v) Provide details of the handling of live pathogenic agent, including a description of the biosecurity and biosafety measures applied;

- vi) Provide a table identifying the tests carried out by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.

- b) If AHS *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

5. AHS surveillance

Provide documentary evidence that *surveillance* for AHS in the country complies with Articles 12.1.11. to 12.1.13. of the *Terrestrial Code*, and Chapter 2.5.1. of the *Terrestrial Manual*. The following information should be included:

- a) What are the criteria for raising a suspicion of AHS? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?
- b) Describe how clinical *surveillance* is conducted, including which equine sectors are included in clinical *surveillance*, such as *establishments*, markets, fairs, *slaughterhouses/abattoirs*, check points, etc.

Provide a summary table indicating, for the past 24 months, the number of suspected cases, the number of samples tested for AHS, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude AHS. Provide details of follow-up actions taken on all suspicious and positive results.

- c) Other *surveillance*. Is *surveillance* undertaken as described in Article 12.1.13., specifically:
- i) Serological *surveillance*.
 - ii) Virological *surveillance* including genome or antigen detection.
 - iii) Sentinel animals.
 - iv) Vector *surveillance*.

If so, provide detailed information on the target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 12.1.11. and 12.1.13. of the *Terrestrial Code*. How frequently are they conducted? Which equine species are included? Are *wildlife* species included? If not, explain the rationale.

Provide a summary table and maps indicating detailed results for at least the past 24 months. Provide details of follow-up actions taken on all suspicious and positive results and how these findings are acted upon. Provide criteria for selection of *populations* for targeted *surveillance* and numbers of equids examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the *surveillance* programme including indicators.

- d) Provide information on risks in the different equine sectors, and provide evidence that targeted studies are implemented to address gaps (e.g. targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.). Provide evidence of how the knowledge acquired through these activities assisted in more effective implementation of control measures.
- e) Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical, serological, virological and other *surveillance*, and the approaches used to increase community involvement in AHS *surveillance* programmes.

6. AHS prevention

Describe the procedures in place to prevent the introduction of AHS into the country, including details of:

- a) Coordination with other countries. Describe any relevant factors in neighbouring countries that should be taken into account (e.g. size, distance from the border to affected *herds* or animals, wind currents and possible *vector* spread)? Describe coordination, collaboration and information-sharing activities with other countries in the same region or ecosystem.

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

Are *protection zones* in place? If so, provide details of the measures that are applied (e.g. *vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the *zones*.

- b) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the spread of the pathogenic agent within the country. Provide evidence that measures to reduce transmission of AHS are in place at markets, such as enhancing awareness of AHS transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity*, hygiene and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).

c) Import control procedures

Provide information on countries, *zones* or *compartments* from which the country authorises the import of susceptible animals or their products into the country. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied to entry of such animals and products, and subsequent internal movement. Describe the import measures (e.g. quarantine) 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 *international veterinary certificates* are required.

Describe any other procedures used for assessing the *risks* posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic equids.

- i) Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border posts*, and between *border posts*.
- ii) Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the country or their final destination, concerning the import and follow-up of the following:
 - equids;
 - genetic material (semen, oocytes and embryos of the equine species);
 - equine derived (by-)products;
 - *veterinary medicinal products*.

7. Control measures and contingency planning

- a) List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of AHS. The contingency plan should be attached as an annex in one of the OIE official languages. If not available, provide a brief summary of what is covered. Provide information on any simulation exercise for AHS that was conducted in the country in the past five years.
- b) In the event of a suspected or confirmed AHS *outbreak*:
 - i) Are quarantine measures imposed on *establishments* with suspected *cases*, pending final diagnosis? What other procedures are followed with respect to suspected *cases* (e.g. standstills)?
 - ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the pathogenic agent;
 - iii) Describe the actions that would be taken to control the disease situation in and around the *establishments* where the *outbreak* is confirmed;
 - iv) Provide a detailed description of the control or *eradication* procedures (e.g. forward and backward tracing, movement control, *disinfection* of *establishments*, *vehicles* and equipment, including verification methods, *vaccination*, *stamping-out policy*, *vector-protected stabling*, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;
 - v) Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;
 - vi) Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;
 - vii) Describe how control efforts, including *vaccination* and *biosecurity*, would target critical risk control points.

8. Recovery of free status

Member Countries applying for recognition of recovery of free status for a country should comply with the provisions of Article 12.1.5. of the *Terrestrial Code* and provide detailed information as specified in Sections 4 a), 4 b), 4 c) and 6, and Sections 1-7 (inclusive) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Article 1.7.2.

Zone free from infection with African horse sickness virus

The following information should be provided by OIE Member Countries to support applications for official recognition of status as a *zone* free from *infection* with African horse sickness virus in accordance with Chapter 12.1. of the *Terrestrial Code*.

The dossier provided to the OIE should address concisely all the topics under the headings provided to describe the actual situation in the country and the procedures currently applied, explaining how these comply with the *Terrestrial Code*.

The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

All annexes should be provided in one of the OIE official languages.

The Delegate of the Member Country applying for recognition of AHS freedom for a *zone* must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Article 12.1.2. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that:

- 1) there has been no *case of infection* with AHS virus for at least the past two years in the *zone*;
- 2) no routine *vaccination* against AHS has been carried out during the past year in the *zone*;
- 3) and that any equids imported into the *zone* have been done so in accordance with Chapter 12.1.

In addition, the Delegate of the Member Country applying for recognition of historical freedom must also submit documentary evidence that the provisions of point 1 a) of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.

1. Introduction

- a) Geographical features (rivers, mountain ranges, etc.). Provide a general description of the country and the *zone*, and where relevant of the region, including physical, geographical and other factors that are relevant to introduction of *infection* and spread of AHS virus, taking into account the countries or *zones* sharing common borders and other epidemiologic pathways for the potential introduction of *infection*.

The boundaries of the *zone* must be clearly defined, including a *protection zone* if applied. Provide maps identifying the features above, including a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zone*.

- b) Demographics of domestic equids. Describe the composition of the equine *population* by species (e.g. horses, donkeys, mules, zebras, etc.) within the various sectors in the country and the *zone*.

Equine sectors are defined as equids (including donkeys, mules, hinnies and zebras) used for breeding stock, competition, leisure, exhibition, working (including transport) and production. How are the equine sectors distributed (e.g. density, etc.) throughout the country and the *zone*? Provide tables and maps as appropriate.

- c) Equine sectors. Provide a general description of the relative economic importance of the equine sectors in the country and the *zone*. Consider the below-mentioned sector groupings and outline any recent significant changes observed within the sector groupings (attach relevant documents if available):

- i) breeding stock equids;
- ii) competition horses;
- iii) leisure equids;
- iv) exhibition equids;
- v) working, transport and production equids (including donkeys, mules and hinnies).

- d) *Wildlife* demographics. What *captive wild*, *wild* or *feral* equids are present in the country and the *zone*? Provide estimates of *population* sizes and geographic distribution.

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation, regulations and *Veterinary Authority* directives in relation to AHS and a brief description of the relevance of each. The table should include, but not be limited to, the legislation on disease control measures and compensation systems.
- b) *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, control, enforce and monitor all AHS-related activities. Provide maps, figures and tables wherever possible.
- c) Provide information on any OIE PVS evaluation conducted in the country and follow-up steps within the PVS Pathway and highlight the results relevant to AHS and the susceptible species.
- d) Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in AHS *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, including the number of *veterinarians* and their distribution, in AHS *surveillance* and control. Include a description of continuing education and awareness programmes on AHS at all relevant levels.
- e) *Animal identification*, registration, traceability and movement control. Are equids identified (individually or at a group level)? Provide a description of the traceability system, including methods of *animal identification* and *establishment* or *herd* registration, applicable to all equine sectors. How are movements of equids controlled in and between *zones* of the same or different status for all equine sectors? Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months. Provide information on pastoralism, transhumance and related paths of movement.
Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g. seasonal migration).
Describe the actions available under national legislation. Provide information on illegal movements detected in the past 24 months and the action taken.
- f) Leisure, exhibition and competition movements of equids. How are movements of these types of equids controlled in the country and the *zones*? Provide information on systems including any use of registration. Provide information on any events that include international movements of equids.
- g) Describe the market systems for the sale of, or transfer of ownership of, equids in the country and the *zones*, including where the international movement of equids occurs.

3. AHS eradication

- a) History. If *infection* has never occurred in the country, or has not occurred within the past 25 years, state explicitly whether or not the *zone* is applying for recognition of historical freedom according to point 1 a) of Article 1.4.6. of the *Terrestrial Code*.
If *infection* has occurred in the *zone* within the past 25 years, provide a description of the AHS history in the country and *zone*, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, and the date of last case or *eradication* in the *zone*.
- b) Strategy. Describe how AHS was controlled and eradicated in the *zone* (e.g. isolation of cases, *stamping-out policy*, zoning, movement control, protection of equids against *vectors*). Provide the time frame for *eradication*. Describe and justify the corrective actions that have been implemented to prevent future *outbreaks* of AHS in response to any past incursions of AHS virus.
- c) Vaccines and *vaccination*. Briefly answer the following:
 - i) Is there any legislation that prohibits *vaccination*? If so:
 - Provide the date when *vaccination* was formally prohibited;
 - Provide information on cases of detection of illegal *vaccination* during the reporting period and actions taken in response to the detection.
 - ii) Was *vaccination* ever used in the country? If so:
 - Provide the date when the last *vaccination* was carried out;
 - What type of vaccine was used in the *zone* and the rest of the country?
 - What species were vaccinated?
 - How were vaccinated animals identified?
 - What was the fate of those animals?

- iii) In addition, if *vaccination* was applied during the past 24 months, provide a description and justification of the *vaccination* strategy and programme, including the following:
- the vaccine strains;
 - the species vaccinated;
 - identification of vaccinated animals;
 - the way in which the *vaccination* of animals was certified or reported and the records maintained;
 - evidence that the vaccine used complies with Chapter 2.5.1. of the *Terrestrial Manual*.
- d) Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. AHS diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 2.5.1. of the *Terrestrial Manual* are applied. The following points should be addressed:

- a) Is AHS *laboratory* diagnosis carried out in the country? If so, provide an overview of the AHS-approved *laboratories* in the country. Indicate the *laboratories* where samples originating from the *zone* are diagnosed. Address the following points:
- i) How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for reporting results;
 - ii) Details of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of AHS tests performed in the past 24 months in national *laboratories* and in *laboratories* in other countries, if relevant;
 - iii) Procedures for quality assurance and for the official accreditation of *laboratories*. Give details of formal internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;
 - iv) Provide details of performance in inter-*laboratory* validation tests (ring tests), including the most recent results and, if applicable, the corrective measures applied;
 - v) Provide details of the handling of live pathogenic agent, including a description of the biosecurity and biosafety measures applied;
 - vi) Provide a table identifying the tests carried out by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.
- b) If AHS *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

5. AHS surveillance

Provide documentary evidence that *surveillance* for AHS in the *zone* complies with Articles 12.1.11. to 12.1.13. of the *Terrestrial Code*, and Chapter 2.5.1. of the *Terrestrial Manual*. The following information should be included:

- a) What are the criteria for raising a suspicion of AHS? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?
- b) Describe how clinical *surveillance* is conducted, including which equine sectors are included in clinical *surveillance*, such as *establishments*, markets, fairs, *slaughterhouses/abattoirs*, check points, etc.

Provide a summary table indicating, for the past 24 months, the number of suspected cases, the number of samples tested for AHS, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude AHS. Provide details of follow-up actions taken on all suspicious and positive results.

- c) Other *surveillance*. Is *surveillance* undertaken as described in Article 12.1.13., specifically:
- i) Serological *surveillance*.
 - ii) Virological *surveillance* including genome or antigen detection.
 - iii) Sentinel animals.
 - iv) Vector *surveillance*.

If so, provide detailed information on the target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 12.1.11. and 12.1.13. of the *Terrestrial Code*. How frequently are they conducted? Which equine species are included? Are *wildlife* species included? If not, explain the rationale.

Provide a summary table and maps indicating detailed results for at least the past 24 months. Provide details of follow-up actions taken on all suspicious and positive results and how these findings are acted upon. Provide criteria for selection of *populations* for targeted *surveillance* and numbers of equids examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the *surveillance* programme including indicators.

- d) Provide information on risks in the different equine sectors, and provide evidence that targeted studies are implemented to address gaps (e.g. targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.). Provide evidence of how the knowledge acquired through these activities assisted in more effective implementation of control measures.
- e) Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in AHS *surveillance* programmes.

6. AHS prevention

Describe the procedures in place to prevent the introduction of AHS into the country or *zone*, including details of:

- a) Coordination with other countries. Describe any relevant factors in neighbouring countries and *zones* that should be taken into account (e.g. size, distance from the border to affected *herds* or animals, wind currents and possible *vector* spread)? Describe coordination, collaboration and information-sharing activities with other countries and *zones* in the same region or ecosystem.

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

Are *protection zones* in place? If so, indicate whether or not the *protection zones* are included in the proposed free *zones*. Provide details of the measures that are applied (e.g. *vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the *zones*.

- b) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the spread of the pathogenic agent within the country or *zone*. Provide evidence that measures to reduce transmission of AHS are in place at markets, such as enhancing awareness of AHS transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity*, hygiene and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).
- c) Import control procedures

Provide information on countries, *zones* or *compartments* 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, *zones* or *compartments*, the controls applied to entry of such animals and products, and subsequent internal movement. Describe the import measures (e.g. quarantine) 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 *international veterinary certificates* are required.

Describe any other procedures used for assessing the *risks* posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past

24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country or *zone*. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic equids.

- i) Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border posts*, and between *border posts*.
- ii) Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the *zone* or their final destination, concerning the import and follow-up of the following:
 - equids;
 - genetic material (semen, oocytes and embryos of the equine species);
 - equine derived (by-)products;
 - *veterinary medicinal products*.

7. Control measures and contingency planning

- a) List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of AHS. The contingency plan should be attached as an annex in one of the OIE official languages. If not available, provide a brief summary of what is covered. Provide information on any simulation exercise for AHS that was conducted in the country in the past five years.
- b) In the event of a suspected or confirmed AHS *outbreak*:
 - i) Are quarantine measures imposed on *establishments* with suspected *cases*, pending final diagnosis? What other procedures are followed with respect to suspected *cases* (e.g. standstills)?
 - ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the pathogenic agent;
 - iii) Describe the actions that would be taken to control the disease situation in and around the *establishments* where the *outbreak* is confirmed;
 - iv) Provide a detailed description of the control or *eradication* procedures (e.g. forward and backward tracing, movement control, *disinfection* of *establishments*, *vehicles* and equipment, including verification methods, *vaccination*, *stamping-out policy*, *vector-protected stabling*, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;
 - v) Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;
 - vi) Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;
 - vii) Describe how control efforts, including *vaccination* and *biosecurity*, would target critical risk control points.

8. Recovery of free status

Member Countries applying for recognition of recovery of free status for a *zone* should comply with the provisions of Article 12.1.5. of the *Terrestrial Code* and provide detailed information as specified in Sections 4 a), 4 b), 4 c) and 6, and Sections 1-7 (inclusive) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

NB: FIRST ADOPTED IN 2009; MOST RECENT UPDATE ADOPTED IN 2018.

CHAPTER 1.8.

APPLICATION FOR OFFICIAL RECOGNITION BY THE OIE OF RISK STATUS FOR BOVINE SPONGIFORM ENCEPHALOPATHY

Article 1.8.1.

The following information should be provided by OIE Member Countries to support applications for official recognition of risk status for bovine spongiform encephalopathy (BSE) in accordance with Chapter 11.4. of the *Terrestrial Code*.

The Delegate of the Member Country submitting documentation of the legislation under which the *Veterinary Services* are mandated should provide a description of the content of the relevant legal acts (in one of the three official languages of OIE), as well as the dates of official publication and implementation.

The dossier provided to the OIE should address concisely all the topics under the headings provided to describe the actual situation in the country and the procedures currently applied, explaining how these comply with the *Terrestrial Code*.

The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

All annexes should be provided in one of the OIE official languages.

The Delegate of the Member Country applying for official recognition of BSE risk status must submit documentary evidence that the provisions of Article 11.4.2. and Article 11.4.3. or Article 11.4.4. have been properly implemented and supervised.

1. Introduction

Provide a general description of the bovine (*Bos taurus* and *B. indicus*) husbandry and slaughtering practices in the country. Provide figures and tables as appropriate.

2. Veterinary system

- a) Describe how the *Veterinary Services* of the country comply with the provisions of Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code*;
- b) describe how the *Veterinary Services* supervise, control, enforce and monitor all BSE-related activities;
- c) provide maps, figures and tables wherever possible;
- d) provide information on any OIE PVS evaluation conducted in the country and follow-up actions within the PVS Pathway highlighting the results relevant to BSE and the susceptible species;
- e) provide a description of the structure (including number and distribution) and role of private veterinary sector in BSE *surveillance* and control.

Article 1.8.2.

BSE risk status requirements: Section 1: risk assessment (see point 1) of Article 11.4.2.)

Article 11.4.2. of the *Terrestrial Code* Chapter on BSE prescribes the criteria to determine the BSE risk status of the cattle population of a country or *zone*. The Delegate of the Member Country applying for recognition of a claim for negligible risk status (Article 11.4.3.) or controlled risk status (Article 11.4.4.) must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate must submit documentary evidence that the provisions of Article 11.4.3. or Article 11.4.4. have been properly implemented and complied with.

1. Introduction

The Delegate of the Member Country applying for official recognition by the OIE of BSE risk status of the cattle population of the country or *zone* should submit documentary evidence demonstrating that a *risk assessment* based on Section 2 and Chapter 11.4. of the *Terrestrial Code* has been carried out.

2. Entry assessment

- a) The potential for the entry of the classical BSE agent through importation of meat-and-bone meal or greaves (including of non-ruminant origin)

Knowledge of the origin of *meat-and-bone meal*, *greaves* or *feed ingredients* containing either *meat-and-bone meal* or *greaves*, is necessary to assess the risk of entry of classical BSE agent. *meat-and-bone meal* and *greaves* originating in countries of undetermined or controlled BSE risk pose a higher likelihood of entry than that from negligible risk countries.

Has *meat-and-bone meal*, *greaves* (including of non-ruminant origin) or *feed ingredients* containing either, been imported within the past eight years? If not, provide documentary evidence, including supporting legislation, where relevant:

- i) to support claims that *meat-and-bone meal* (including of non-ruminant origin), *greaves* or *feed ingredients* containing either *meat-and-bone meal* or *greaves* have not been imported, OR

If *meat-and-bone meal*, *greaves* (including of non-ruminant origin) or *feed ingredients* containing either, has been imported within the past eight years, provide documentary evidence of the following:

- ii) official statistics on annual volume, by country of origin, of *meat-and-bone meal* (including of non-ruminant origin), *greaves* or *feed ingredients* containing them;
iii) the species composition of the *meat-and-bone meal*, *greaves* or *feed ingredients*;
iv) the method used to reduce BSE infectivity complies with Article 11.4.19.

- b) The potential for the entry of the classical BSE agent through the importation of potentially infected live cattle
The likelihood of entry is dependent on:

- the BSE status of the country or *zone* of origin;
- dairy versus meat breeds, where there are differences in exposure in the country or *zone* of origin because feeding practices result in greater exposure of one category;
- age of animals imported for *slaughter*;
- the effective implementation of the ban on feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants in the country or *zone* of origin before the birth of the imported animals.

Have live cattle been imported within the past seven years? Provide documentary evidence of the following:

- i) to support claims that live cattle have not been imported including supporting legislation, OR
ii) the country or *zone* of origin and volume of imports, official statistics, where relevant, in table form, and evidence of compliance with the requirements of Articles 11.4.6. to 11.4.9.

- c) The potential for the entry of the classical BSE agent through the importation of potentially infected products of ruminant origin

The likelihood of entry is dependent on:

- the BSE status of the country or *zone* of origin and whether these products contain tissues known to contain BSE infectivity (Article 11.4.13.);
- dairy versus meat breeds, where there are differences in exposure in the country or *zone* of origin because feeding practices result in greater exposure of one category;
- age at *slaughter*.

What products of ruminant origin have been imported within the past seven years? This includes all products of ruminant origin that are not considered as *safe commodities* in Article 11.4.1., in particular products listed in points 1 a) v), vi) and vii) of Article 11.4.2. Provide documentary evidence of the following:

- i) the country or *zone* of origin and volume of imports, in table form, of all products of ruminant origin that are not considered as *safe commodities* in Article 11.4.1.;
- ii) evidence of compliance with the requirements of Article 11.4.26.

3. Exposure assessment

- a) The origin of ruminant carcasses, by-products and slaughterhouses/abattoir waste, the parameters of the rendering processes

The overall risk of BSE in the cattle population of a country or *zone* is proportional to the potential for recycling and amplification of the infectivity through rendering practices. For the *risk assessment* to conclude that the cattle population of a country or *zone* is of negligible or controlled BSE risk, it must have demonstrated that appropriate measures have been taken to manage any risks identified. If potentially infected cattle or contaminated materials are rendered, there is a risk that the resulting *meat-and-bone meal* could retain BSE infectivity.

Rendering is a process by which inedible animal by-products and *slaughter* waste, including bones and fallen stock, are transformed into *meat-and-bone meal*.

How have ruminant carcasses, by-products and *slaughterhouses/abattoir* waste been processed over the past eight years? Provide the following:

- i) A description of the collection and disposal of fallen stock, inedible animal by-products, and materials condemned as unfit for human consumption. If by-products derived from imported cattle are managed differently, describe the process.
- ii) A description of the definition, collection and disposal of material listed in Article 11.4.14.
- iii) A description of the rendering industry and processes and parameters used to produce ruminant *meat-and-bone meal* and *greaves*.
- iv) Documentation describing monitoring and enforcement of the above.
- v) Information in a table (see below), including the audit findings in rendering plants processing material of ruminant origin (including mixed species containing ruminant material) and only material of non-ruminant origin (e.g., fish, *poultry*, pig, horse), related to the prohibition of the feeding to ruminants of *meat-and-bone meal* and *greaves*. The sampling objectives to detect whether material of non-ruminant origin could have been contaminated with ruminant material.

Year (information should be provided for each of the eight years for which effectiveness is claimed)	Type of renderers	Number of plants	Number of plants in (A) inspected under Competent Authority supervision	Number of inspections in (B) in total	Total number of plants in (B) with infractions	Total number of plants in (B) inspected under Competent Authority supervision with sampling	Total number of plants in (E) with positive test results
		(A)	(B)	(C)	(D)	(E)	(F)
Year 1	Material of ruminant origin (or mixed species)		(e.g.: < or = to A)	(e.g.: > or = to B)	(e.g.: < or = to B)	Not applicable for the purpose of the dossier	Not applicable for the purpose of the dossier
	Only material of non-ruminant origin		(e.g.: < or = to A)	(e.g.: > or = to B)	(e.g.: < or = to B)	(e.g.: < or = to B)	(e.g.: < or = to E)
Year 2, etc.	Material of ruminant origin (or mixed species)					Not applicable for the purpose of the dossier	Not applicable for the purpose of the dossier
	Only material of non-ruminant origin						

- vi) Information in a table (see below) on each rendering plant referred to above processing material of ruminant origin (including mixed species containing ruminant material) and only material of

non-ruminant origin (e.g., fish, *poultry*, pig, horse) with infractions, specifying the type of infraction (columns D and F of the table above) and the method of resolution.

Year (information should be provided for each of the eight years for which effectiveness is claimed)	Type of renderers	Plant ID	Nature of infraction	Method of resolution	Follow-up results
Year 1	Material of ruminant origin (or mixed species)	ID 1			
		ID 2			
		ID 3, etc.			
	Only material of non-ruminant origin	ID 1			
		ID 2			
		ID 3, etc.			
Year 2, etc.	Material of ruminant origin (or mixed species)				
	Only material of non-ruminant origin				

- b) The potential for the exposure of cattle to the classical and atypical BSE agents through consumption of meat-and-bone meal or greaves of ruminant origin

The overall risk of BSE in the cattle population of a country or *zone* is proportional to the level of known or potential exposure to BSE infectivity. If cattle have not been fed products of ruminant origin (other than *milk* or blood) potentially containing *meat-and-bone meal* or *greaves* of ruminant origin within the past eight years, *meat-and-bone meal* and *greaves* can be dismissed as a risk. Where *meat-and-bone meal* is utilised in the production of any ruminant *feed*, a risk of cross-contamination exists.

Countries applying for negligible risk status will be required to demonstrate that the ruminant *feed* ban has been effective for at least eight years.

Feed mills are processing plants where different *feed ingredients* are mixed and processed together to produce compound *feed* for animals. This should include on-farm *feed* producers that keep cattle.

Has *meat-and-bone meal* or *greaves* of ruminant origin been fed to cattle within the past eight years (Articles 11.4.3. and 11.4.4. in the *Terrestrial Code*)? Describe the following:

- i) the *feed* industry, including repartition between *feed* mills producing *feed* for ruminant only, *feed* for non-ruminant only and *feed* for both;
- ii) methods of animal *feed* production, including details of *ingredients* used, the extent of use of *meat-and-bone meal* (including of non-ruminant origin) in any livestock *feed*;
- iii) the use of imported *meat-and-bone meal* and *greaves* (including of non-ruminant origin), their country or *zone* of origin, including the feeding of any animal species;
- iv) the use made of *meat-and-bone meal* and *greaves* produced from ruminants, including the feeding of any animal species;
- v) the measures taken to control cross-contamination of ruminant *feed ingredients* with the *meat-and-bone meal* and *greaves* including the risk of cross-contamination during production, transport, storage and feeding;
- vi) provide details in a table, on the audit findings in *feed* mill processing *feed* for ruminant only, for non-ruminant only and for both, related to the prohibition of the feeding to ruminants of *meat-and-bone*

meal and *greaves*. The sampling aims to detect whether material of ruminant origin could have contaminated *feed* intended to ruminant;

Year (information should be provided for each of the eight years for which effectiveness is claimed)	Type of feed mill	Number of feed mills	Number of feed mills in (A) inspected under Competent Authority supervision	Number of inspections in (B) in total	Total number of feed mills in (B) with infractions	Total number of inspected feed mills in (B) with sampling	Total number of feed mills in (E) with positive test results
		(A)	(B)	(C)	(D)	(E)	(F)
Year 1	For ruminant only						
	For non-ruminant only					Not applicable for the purpose of the dossier	Not applicable for the purpose of the dossier
	For both						
Year 2, etc.	For ruminant only						
	For non-ruminant only					Not applicable for the purpose of the dossier	Not applicable for the purpose of the dossier
	For both						

- vii) details in a table, on each *feed* mill processing *feed* for ruminant only, for non-ruminant only and for both, with infractions, specifying the type of infraction (columns D and F of the table above) and the method of resolution;

Year (information should be provided for each of the eight years for which effectiveness is claimed)	Type of feed mills	Feed mills ID	Nature of infraction	Method of resolution	Follow-up results
Année 1	For ruminant only	ID 1 ID 2 ID 3, etc.			
	For non-ruminant only	ID 1 ID 2 ID 3, etc.			
	For both	ID 1 ID 2 ID 3, etc.			
Année 2, etc.	For ruminant only	ID 1 ID 2 ID 3, etc.			
	For non-ruminant only	ID 1 ID 2 ID 3, etc.			
	For both	ID 1 ID 2 ID 3, etc.			

- viii) why, in light of the findings displayed in the preceding four tables (of Sections 4 and 5), 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 ruminant origin;
- ix) husbandry practices (multiple species farms) which could lend themselves to cross-contamination of ruminant *feed* with *meat-and-bone meal* and *greaves* destined to other species.

Article 1.8.3.

BSE risk status requirements: Section 2: other requirements (see points 2) to 4) of Article 11.4.2.)

1. Awareness programme (see point 2) of Article 11.4.2.)

An awareness programme is essential in ensuring detection and reporting of BSE, especially in countries of low prevalence and competing differential diagnoses. Provide documentary evidence of the following:

- a) when the awareness programme was implemented and its continuous application and geographical coverage;
- b) the number and occupation of persons who have participated in the awareness programme (farmers, livestock owners, *animal handlers*, *veterinarians*, workers at livestock markets or auctions, workers at *slaughterhouses/abattoirs*, etc.);
- c) a description of the materials used in the awareness programme (the manual, supportive documents, or other teaching materials) (Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.);
- d) contingency plans or preparedness plans to deal with an occurrence of BSE.

2. Compulsory notification and investigation (see point 3) of Article 11.4.2.)

In order to ensure appropriate detection and follow-up of any BSE cases, appropriate legislation to support BSE control and *eradication* and effective regulatory controls and verification should be in place.

The socioeconomic implications of BSE require that there be incentives and obligations to notify and investigate suspected cases.

- a) Describe the guidance given to farmers, livestock owners, *animal handlers*, *veterinarians*, workers at livestock markets or auctions, workers at *slaughterhouses/abattoirs*, etc. in terms of the criteria that would initiate the investigation of an *animal* suspected as being a case of BSE. Have these criteria evolved and, if so, how?
- b) What was the date and content of the legal act making notification of suspected cases of BSE compulsory?
- c) Describe the measures in place to stimulate notification, such as compensation payments or penalties for not notifying a suspected case.

3. Examination in an approved laboratory of brain or other tissues collected within the framework of the surveillance system described above (see point 4) of Article 11.4.2.)

Provide documentary evidence that the relevant provisions of Chapter 2.4.5. of the *Terrestrial Manual* are applied, including the following:

- a) if BSE *laboratory* diagnosis carried out in the country provide an overview of the approved *laboratories* where samples of cattle tissues from the country or *zone* are examined for BSE;
- b) if BSE *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results;
- c) that these diagnostic procedures and methods have been applied through the entire *surveillance* period.

Article 1.8.4.

Section 3: BSE surveillance and monitoring systems (see point 1 b) iv) and point 4) of Article 11.4.2.)

Articles 11.4.20.. to 11.4.22.. 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.

1) Does the BSE *surveillance* programme comply with the guidelines in Articles 11.4.20. to 11.4.22. of the *Terrestrial Code*? Provide documentary evidence of the following:

- a) that the samples collected are representative of the distribution of the cattle population in the country or *zone*, including by age and *subpopulations* as described in Article 11.4.21.;
- b) the methods applied to assess the ages of animals sampled and the proportions for each method (individual identification, dentition, other methods to be specified);
- c) the means and procedures whereby samples were assigned to the cattle *subpopulations* described in Article 11.4.21., including the specific provisions applied to ensure that animals described as clinical met the conditions of point 1) of Article 11.4.21. and that at least three of the four *subpopulations* have been sampled.

- 2) In a table (see below), provide details of all clinically suspected cases notified complying with the definition in point 1) of Article 11.4.21.

Laboratory identification number	Age	Description of observed clinical signs	Point of detection (farm, market channels, slaughterhouse)	Final diagnosis

- 3) In a table (see below), provide details of the number of target points applicable to the country or zone and its BSE surveillance requirements (type A or type B surveillance as a result of the risk assessment of Section 1) are met as described in Articles 11.4.21. and 11.4.22..

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								

- 4) Provide the number of adult cattle (over 24 months of age) in the country or zone.

Article 1.8.5.

Section 4: BSE history of the country or zone (see Articles 11.4.3. and 11.4.4.)

The categorisation of a country or zone as either negligible or controlled risk is dependent upon, the outcome of the risk assessment described in Section 1, compliance with the provisions described in Section 2, the results of surveillance described in Section 3, and the history of BSE in the country or zone. Describe the BSE history in the country or zone by providing documentary evidence of the following:

- 1) Whether a case of BSE has ever been diagnosed in the country or zone.
- 2) In the case of positive BSE findings:
 - a) the numbers of BSE cases (classical and atypical), the origin of each BSE case in respect to the country or zone. Indicate the birth date and place of birth;
 - b) the most recent year of birth of the classical BSE cases;
 - c) that the case(s); and
 - d) all cattle which, during their first year of life, were reared with the BSE cases during their first year of life, and which investigation could not rule out consumption of the same potentially contaminated feed during that period; or
 - e) 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; and

- f) if alive in the country or *zone*, how they are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.

Article 1.8.6.

Recovery of BSE risk status

Member Countries applying for recognition of recovery of BSE risk status for a country or *zone* should comply with the provisions of Article 11.4.2. and Article 11.4.3. or Article 11.4.4. of the *Terrestrial Code* and provide detailed information as specified in this questionnaire.

NB: FIRST ADOPTED IN 2018.

CHAPTER 1.9.

APPLICATION FOR OFFICIAL RECOGNITION BY THE OIE OF FREE STATUS FOR CLASSICAL SWINE FEVER

Article 1.9.1.

Country or zone free from infection with classical swine fever virus

The following information should be provided by OIE Member Countries to support applications for official recognition of status as a country or *zone* free from *infection* with classical swine fever (CSF) virus in accordance with Chapter 15.2. of the *Terrestrial Code*.

The dossier provided to the OIE should address concisely all the following topics under the headings provided to describe the actual situation in the country and the procedures currently applied, explaining how these comply with the *Terrestrial Code*.

The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

All annexes should be provided in one of the OIE official languages.

The Delegate of the Member Country applying for recognition of CSF freedom for a country or *zone* must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Articles 15.2.2. and 15.2.3. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that:

- 1) there has been no *outbreak* of CSF or evidence of CSFV *infection* in domestic and *captive wild* pigs in the country or *zone* during the past 12 months;
- 2) no *vaccination* against CSF has been carried out in domestic and *captive wild* pigs in the country or *zone* during the past 12 months; or, if *vaccination* is carried out, vaccinated and infected pigs can be distinguished by a means validated according to Chapter 2.8.3. of the *Terrestrial Manual*;
- 3) imported pigs and pig *commodities* comply with the relevant requirements in Chapter 15.2.

In addition, the Delegate of the Member Country applying for recognition of historical freedom must also submit documentary evidence that the provisions of point 1 a) of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.

1. Introduction

- a) Geographical features (rivers, mountain ranges, etc.). Provide a general description of the country and the *zone*, and where relevant of the region, including physical, geographical and other factors that are relevant to introduction of *infection* and spread of CSF virus, taking into account the countries or *zones* sharing common borders and other epidemiologic pathways for the potential introduction of *infection*.

The boundaries of the country or *zone* must be clearly defined, including a *protection zone* if applied. Provide maps identifying the features above, including a digitalised, geo-referenced map with a precise text

description of the geographical boundaries of the country or *zone*. Specify whether the application includes any noncontiguous territories.

- b) Pig industry. Describe the composition of the domestic and *captive wild* pig industry in the country and the *zone*. In particular, describe:
- i) the types of production systems in the country and the *zone*;
 - ii) the number of *herds*;
 - iii) their geographical distribution;
 - iv) *herd* density;
 - v) the degree of integration and role of producer organisations in the different production systems;
 - vi) any recent significant changes observed in the production (attach relevant documents if available).
- Provide tables and maps.
- c) *Wildlife* demographics. What *captive wild*, *wild* or *feral* pigs 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 *captive wild* pigs, and *wild* and *feral* pig *populations*?
- d) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g. fairs, shows, competitions). Where are the major pig marketing or collection centres? What are the patterns of pig movement for marketing within the country or *zone*, and between *zones* of the same or different status? How are the pigs sourced, transported and handled during these transactions? What proportions of slaughtered pigs are subjected to meat inspection in different production systems? Provide maps as appropriate.

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation, regulations and *Veterinary Authority* directives in relation to CSF and a brief description of the relevance of each. The table should include, but not be limited to, the legislation on disease control measures and compensation systems.
- b) *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, control, enforce and monitor all CSF-related activities. Provide maps, figures and tables wherever possible.
- c) Provide information on any OIE PVS evaluation conducted in the country and follow-up steps within the PVS Pathway and highlight the results relevant to CSF and pigs.
- d) Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in CSF *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, including number of *veterinarians* and their distribution, in CSF *surveillance* and control. Include a description of continuing education and awareness programmes on CSF at all relevant levels.
- e) *Animal identification*, registration, traceability and movement control. Are pigs identified (individually or at a group level)? Provide a description of the traceability system, including methods of *animal identification* and *establishment* or *herd* registration, applicable to all susceptible species. How are pig movements controlled in the country or *zone*, or between *zones* of the same or different status for all susceptible species? Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, origin and destination of the pigs and their products moved within the country in the past 24 months. Describe the *risk management* strategy for uncontrolled movements of pigs. Describe the actions available under national legislation. Provide information on illegal movements detected in the past 24 months and the action taken.

3. CSF eradication

- a) History. If *infection* has never occurred in the country, or has not occurred within the past 25 years, state explicitly whether or not the country or *zone* is applying for recognition of historical freedom according to point 1 a) of Article 1.4.6. of the *Terrestrial Code*.

If *infection* has occurred in the country or *zone* within the past 25 years, provide a description of the CSF history in the country and *zone*, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the pigs involved, and the date of last *case* or *eradication* in the country or *zone*.

- b) Strategy. Describe how CSF was controlled and eradicated in the country or zone (e.g. *stamping-out policy*, movement control, zoning). Provide the time frame for *eradication*. Describe and justify the corrective actions that have been implemented to prevent future *outbreaks* of CSF in response to any past incursions of CSF virus.
- c) Vaccines and *vaccination*. Briefly answer the following:
- i) Is there any legislation that prohibits *vaccination*? If so:
 - Provide the date when *vaccination* was formally prohibited;
 - Provide information on cases of detection of illegal *vaccination* during the reporting period and actions taken in response to the detection.
 - ii) Was *vaccination* ever used in the country? If so:
 - Provide the date when the last *vaccination* was carried out;
 - What type of vaccine was used? If DIVA vaccine has been used, describe the type of differential tests and results;
 - Which pigs were vaccinated?
 - How were vaccinated pigs identified?
 - What was the fate of those pigs?
 - iii) In addition, if *vaccination* was applied during the past 24 months, provide a description and justification of the *vaccination* strategy and programme, including the following:
 - the vaccine serotypes;
 - the pigs vaccinated;
 - identification of vaccinated pigs;
 - the way in which the *vaccination* of pigs was certified or reported and the records maintained;
 - evidence that the vaccine used complies with Chapter 2.8.3. of the *Terrestrial Manual*.
- d) Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. CSF diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 2.8.3. of the *Terrestrial Manual* are applied. The following points should be addressed:

- a) Is CSF *laboratory* diagnosis carried out in the country? If so, provide an overview of the CSF-approved *laboratories* in the country. Indicate the *laboratories* where samples originating from the zone are diagnosed. Address the following points:
- i) How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for reporting results;
 - ii) Details of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of CSF tests performed in the past 24 months in national *laboratories* and in *laboratories* in other countries, if relevant;
 - iii) Procedures for quality assurance and for the official accreditation of *laboratories*. Give details of formal internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;
 - iv) Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;
 - v) Provide details of the handling of live pathogenic agent, including a description of the biosecurity and biosafety measures applied;
 - vi) Provide a table identifying the tests carried out by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.
- b) If CSF *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

5. CSF surveillance

Provide documentary evidence that *surveillance* for CSF in the country or *zone* complies with Articles 15.2.26. to 15.2.32. of the *Terrestrial Code*, and Chapter 2.8.3. of the *Terrestrial Manual*. The following information should be included:

- a) What are the criteria for raising a suspicion of CSF? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?
- b) Describe how clinical *surveillance* is conducted, including which sectors of the pig production system are included in clinical *surveillance*, such as *establishments*, markets, fairs, *slaughterhouses/abattoirs*, check points, etc.

Provide a summary table indicating, for the past 24 months, the number of suspected cases, the number of samples tested for CSF, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude CSF. Provide details of follow-up actions taken on all suspicious and positive results.

- c) Serological or virological *surveillance*. Are serological or virological surveys conducted? If so, provide detailed information on the target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 15.2.26. to 15.2.32. of the *Terrestrial Code*. How frequently are they conducted? Are *wild* and *feral* pigs included in *surveillance*? If not, explain the rationale.

For both serological and virological *surveillance* provide a summary table indicating, for the past 24 months, the number of samples tested for CSF, type of sample, testing methods and results (including differential diagnosis). Include in the table the number of false-positive results obtained on screening tests. Provide details of follow-up actions taken on all suspicious and positive results and on how these findings are interpreted and acted upon. Provide criteria for selection of *populations* for targeted surveillance and numbers of pigs examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the *surveillance* programme including indicators.

- d) Provide information on risks in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g. targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.). Provide evidence of how knowledge acquired through these activities assisted in more effective implementation of control measures.
- e) Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in CSF *surveillance* programmes.

6. CSF prevention

Describe the procedures in place to prevent the introduction of CSF into the country, including details of:

- a) Coordination with other countries. Describe any relevant factors in neighbouring countries or *zones* that should be taken into account (e.g. size, distance from the border to affected *herds* or animals). Describe coordination, collaboration and information-sharing activities with other countries and *zones* in the same region or ecosystem.

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

Are *protection zones* in place? If so, indicate whether or not the *protection zones* are included in the proposed free country or *zones*. Provide details of the measures that are applied (e.g. *vaccination*, intensified *surveillance*, density control of pigs), and provide a geo-referenced map of the *zones*.

- b) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the spread of the pathogenic agent within the country or *zone*. Provide evidence that measures to reduce transmission of CSF are in place at markets, such as enhancing awareness of CSF transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity*, hygiene and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).
- c) What measures are taken to limit access of susceptible domestic, *captive wild*, *feral* and *wild* pigs to waste products of animal origin? Is the feeding of swill to pigs regulated? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.
- d) Import control procedures

Provide information on countries, *zones* or *compartments* from which the country authorises the import of pigs or their products into the country or *zone*. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied to entry of such pigs and products, and subsequent internal movement.

Describe the import measures (e.g. quarantine) and test procedures required. Advise whether imported pigs are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and *international veterinary certificates* are required.

Describe any other procedures used for assessing the *risks* posed by import of pigs or their products. Provide summary statistics on imports of pigs and their products for at least the past 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country or *zone*. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

- i) Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border posts*, and between *border posts*.
- ii) Provide a description of the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 24 months, of the quantity disposed of and the disposal locations. What are the biosecurity measures in place at waste disposal sites?
- iii) Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the country or *zone* or their final destination, concerning the import and follow-up of the following:
 - pigs;
 - genetic material (semen, oocytes and embryos);
 - *fresh meat*, pig products and by-products;
 - *veterinary medicinal products*;
 - other materials at risk of being contaminated with CSF virus.

7. Control measures and contingency planning

- a) List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of CSF. The contingency plan should be attached as an annex in one of the OIE official languages. If not available, provide a brief summary of what is covered. Provide information on any simulation exercise for CSF that was conducted in the country in the past five years.
- b) In the event of a suspected or confirmed CSF *outbreak*:
 - i) Are quarantine measures imposed on *establishments* with suspected *cases*, pending final diagnosis? What other procedures are followed with respect to suspected *cases* (e.g. standstills)?
 - ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the pathogenic agent;
 - iii) Describe the actions that would be taken to control the disease situation in and around the *establishments* where the *outbreak* is confirmed;
 - iv) Provide a detailed description of the control or *eradication* procedures (e.g. forward and backward tracing, movement control, *disinfection of establishments*, *vehicles* and equipment, including verification methods, policies on emergency *vaccination*, *stamping-out policy*, partial slaughter, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;
 - v) Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;
 - vi) Give details of any compensation that would be made available to owners, farmers, etc. when pigs are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;
 - vii) Describe how control efforts, including *vaccination* and *biosecurity*, would target critical risk control points.
- c) If DIVA vaccine is used as part of *risk* mitigation, provide details of the vaccine and the differential tests.

8. Control measures and contingency planning

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

NB: FIRST ADOPTED IN 2009; MOST RECENT UPDATE ADOPTED IN 2018.

CHAPTER 1.10.

APPLICATION FOR OFFICIAL RECOGNITION BY THE OIE OF FREE STATUS FOR CONTAGIOUS BOVINE PLEUROPNEUMONIA

Article 1.10.1.

Country free from infection with *Mycoplasma mycoides* subsp. *mycoides* SC (contagious bovine pleuropneumonia)

The following information should be provided by OIE Member Countries to support applications for official recognition of status as a country free from *infection* with *Mycoplasma mycoides* subsp. *mycoides* SC (MMmsSC) in accordance with Chapter 11.5. of the *Terrestrial Code*.

The dossier provided to the OIE should address concisely all the following topics under the headings provided to describe the actual situation in the country and the procedures currently applied, explaining how these comply with the *Terrestrial Code*.

The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

All annexes should be provided in one of the OIE official languages.

The Delegate of the Member Country applying for recognition of CBPP freedom for a country must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Article 11.5.3. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that:

- 1) there has been no case of *infection* with MMmsSC during the past 24 months;
- 2) no evidence of *infection* with MMmsSC has been found during the past 24 months;
- 3) no *vaccination* against CBPP has been carried out during the past 24 months.

In addition, the Delegate of the Member Country applying for recognition of historical freedom must also submit documentary evidence that the provisions of point 1 a) of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.

1. Introduction

- a) Geographical features (rivers, mountain ranges, etc.). Provide a general description of the country and, where relevant, of the region, including physical, geographical and other factors that are relevant to introduction of *infection* and spread of MMmsSC, taking into account the countries sharing common borders and other

epidemiologic pathways for the potential introduction of *infection*. Provide maps identifying the features above. Specify whether the application includes any noncontiguous territories.

- b) Livestock demographics. Describe the composition of the livestock industry in the country. In particular, describe:
- the susceptible animal *population* by species and types of production systems;
 - the number of *herds*, etc. of each susceptible species;
 - their geographical distribution;
 - herd* density;
 - the degree of integration and role of producer organisations in the different production systems;
 - any recent significant changes observed in the production (attach relevant documents if available).
- Provide tables and maps.
- c) *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* 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 susceptible *wildlife* species?
- d) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g. fairs, shows, competitions). What are the major livestock marketing or collection centres? What are the patterns of movement of domestic susceptible species for marketing within the country? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation, regulations and *Veterinary Authority* directives in relation to CBPP and a brief description of the relevance of each. The table should include, but not be limited to, the legislation on disease control measures and compensation systems.
- b) *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, control, enforce and monitor all CBPP-related activities. Provide maps, figures and tables wherever possible.
- c) Provide information on any OIE PVS evaluation conducted in the country and follow-up steps within the PVS Pathway and highlight the results relevant to CBPP and the susceptible species.
- d) Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in CBPP *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, including number of *veterinarians* and their distribution, in CBPP *surveillance* and control. Include a description of continuing education and awareness programmes on CBPP at all relevant levels.
- e) *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the traceability system, including methods of *animal identification* and *establishment* or *herd* registration, applicable to all susceptible species. How are animal movements controlled in the country for all susceptible species? Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months. Provide information on pastoralism, transhumance and related paths of movement.
- Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g. seasonal migration).
- Describe the actions available under national legislation. Provide information on illegal movements detected in the past 24 months and the action taken.

3. CBPP eradication

- a) History. If *infection* has never occurred in the country, or has not occurred within the past 25 years, state explicitly whether or not the country is applying for recognition of historical freedom according to point 1 a) Article 1.4.6. of the *Terrestrial Code*.
- If *infection* has occurred in the country within the past 25 years, provide a description of the CBPP history in the country, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, and the date of last case or *eradication* in the country.

- b) Strategy. Describe how CBPP was controlled and eradicated (e.g. slaughter policy, zoning, *vaccination*, movement control). Provide the time frame for *eradication*. Describe and justify the corrective actions that have been implemented to prevent future *outbreaks* of CBPP in response to any past incursions of *MMmsSC*.
- c) Vaccines and *vaccination*. Briefly answer the following:
- i) Is there any legislation that prohibits *vaccination*? If so:
 - Provide the date when *vaccination* was formally prohibited;
 - Provide information on cases of detection of illegal *vaccination* during the reporting period and actions taken in response to the detection.
 - ii) Was *vaccination* ever used in the country? If so:
 - Provide the date when the last *vaccination* was carried out;
 - What type of vaccine was used?
 - What species were vaccinated?
 - How were vaccinated animals identified?
 - What was the fate of those animals?
 - iii) In addition, if *vaccination* was applied during the past 24 months, provide a description and justification of the *vaccination* strategy and programme, including the following:
 - the vaccine strains;
 - the species vaccinated;
 - identification of vaccinated animals;
 - the way in which the *vaccination* of animals was certified or reported and the records maintained;
 - evidence that the vaccine used complies with Chapter 2.4.8. of the *Terrestrial Manual*.
- d) Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. CBPP diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 2.4.8. of the *Terrestrial Manual* are applied. The following points should be addressed:

- a) Is CBPP *laboratory* diagnosis carried out in the country? If so, provide an overview of the CBPP-approved *laboratories* in the country, including the following:
- i) How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for reporting results;
 - ii) Details of test capability and the types of tests undertaken, including procedures to isolate and identify *M. mycoides* subsp. *mycoides* (*Mmm*), and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of CBPP tests performed in the past 24 months in national *laboratories* and in *laboratories* in other countries, if relevant;
 - iii) Procedures for quality assurance and for the official accreditation of *laboratories*. Give details of formal internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;
 - iv) Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;
 - v) Provide details of the handling of live pathogenic agent, including a description of the biosecurity and biosafety measures applied;
 - vi) Provide a table identifying the tests carried out by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.
- b) If CBPP *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

5. CBPP surveillance

Provide documentary evidence that *surveillance* for CBPP in the country complies with Articles 11.5.13. to 11.5.17. of the *Terrestrial Code* and Chapter 2.4.8. of the *Terrestrial Manual*. The following information should be included :

- a) What are the criteria for raising a suspicion of CBPP? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?

- b) Describe how clinical *surveillance* is conducted, including which sectors of the livestock production system are included in clinical *surveillance*, such as *establishments*, markets, fairs, *slaughterhouses/abattoirs*, check points, etc.
Provide a summary table indicating, for the past 24 months, the number of suspected cases, the number of samples tested for CBPP, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude CBPP. Provide details of follow-up actions taken on all suspicious and positive results.
- c) Serological *surveillance*. Explain whether serological surveys are conducted and, if so, how frequently and for what purpose. Provide detailed information on the target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 11.5.13. to 11.5.17. of the *Terrestrial Code*.
- d) *Slaughterhouses/abattoirs* and slaughter slabs. 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 24 months, the number of suspected cases, the number of samples tested for CBPP agent, species, type of sample, testing methods and results (including differential diagnosis).
- e) For countries where a significant proportion of animals are not slaughtered in controlled *slaughterhouses/abattoirs*, what are the alternative *surveillance* measures applied to detect CBPP (e.g. active clinical *surveillance* programmes, *laboratory* follow-up).
- f) Provide a description of the means employed during the 24 months preceding this application to rule out the presence of CBPP in the susceptible *population*. Provide criteria for selection of *populations* for targeted *surveillance* and numbers of animals examined and samples tested. Provide details of the methods selected and applied for monitoring the performance of the *surveillance* programme including indicators.
- g) Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical and *slaughterhouse/abattoir surveillance*, and the approaches used to increase community involvement in CBPP *surveillance* programmes.

6. CBPP prevention

Describe the procedures in place to prevent the introduction of CBPP into the country, including details of:

- a) Coordination with other countries. Describe any relevant factors in neighbouring countries that should be taken into account (e.g. size, distance from the border to affected *herds* or animals). Describe coordination, collaboration and information-sharing activities with other countries in the same region or ecosystem.
Are *protection zones* in place? If so, provide details of the measures that are applied (e.g. *vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the *zones*.
- b) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the spread of the pathogenic agent within the country. Provide evidence that measures to reduce transmission of CBPP are in place at markets, such as enhancing awareness of CBPP transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity*, hygiene and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).
- c) Import control procedures
Provide information on countries, *zones* or *compartments* from which the country authorises the import of susceptible animals or their products into the country. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied to entry of such animals and products, and subsequent internal movement. Describe the import measures (e.g. quarantine) 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 *international veterinary certificates* are required.
Describe any other procedures used for assessing the *risks* posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country.
Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.
- i) Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import

controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border posts*, and between *border posts*.

- ii) Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the country or their final destination, concerning the import and follow-up of the following:
- animals;
 - genetic material (semen, oocytes and embryos);
 - *Mmm* strains including vaccines;
 - *veterinary medicinal products*;
 - other materials at risk of being contaminated with *Mmm*.

7. Control measures and contingency planning

- a) List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of CBPP. The contingency plan should be attached as an annex in one of the OIE official languages. If not available, provide a brief summary of what is covered. Provide information on any simulation exercise for CBPP that was conducted in the country in the past five years.
- b) In the event of a suspected or confirmed CBPP *outbreak*:
- i) Are quarantine measures imposed on *establishments* with suspected cases, pending final diagnosis? What other procedures are followed with respect to suspected cases (e.g. livestock standstills)?
 - ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the pathogenic agent;
 - iii) Describe the actions that would be taken to control the disease situation in and around the *establishments* where the *outbreak* is confirmed;
 - iv) Provide a detailed description of the control or *eradication* procedures (e.g. forward and backward tracing, *disinfection of establishments, vehicles* and equipment, including verification methods, *vaccination, stamping-out policy*, slaughter policy, movement control, pastured livestock and livestock as pets, control of offal, especially lungs, and carcasses, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;
 - v) Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;
 - vi) Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;
 - vii) Describe how control efforts, including *vaccination* and *biosecurity*, would target critical risk control points.

8. Recovery of free status

Member Countries applying for recognition of recovery of free status for a country should comply with the provisions of Article 11.5.4. of the *Terrestrial Code* and provide detailed information as specified in Sections 3 a), 3 b), 3 c), 5 a), 5 b), 5 c) and 5 d) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Article 1.10.2.

Zone free from infection with *Mycoplasma mycoides* subsp. *mycoides* SC (contagious bovine pleuropneumonia)

The following information should be provided by OIE Member Countries to support applications for official recognition of status as a *zone* free from *infection* with *Mycoplasma mycoides* subsp. *mycoides* SC (*MMmsSC*) in accordance with Chapter 11.5. of the *Terrestrial Code*.

The dossier provided to the OIE should address concisely all the following topics under the headings provided to describe the actual situation in the country and the procedures currently applied, explaining how these comply with the *Terrestrial Code*.

The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

All annexes should be provided in one of the OIE official languages.

The Delegate of the Member Country applying for recognition of CBPP freedom for a *zone* must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Article 11.5.3. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that:

- 1) there has been no case of *infection* with *MMmsSC* during the past 24 months;
- 2) no evidence of *infection* with *MMmsSC* has been found during the past 24 months;
- 3) no *vaccination* against CBPP has been carried out during the past 24 months.

In addition, the Delegate of the Member Country applying for recognition of historical freedom must also submit documentary evidence that the provisions of point 1 a) of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.

1. Introduction

- a) Geographical features (rivers, mountain ranges, etc.). Provide a general description of the country and the *zone*, and where relevant of the region, including physical, geographical and other factors that are relevant to introduction of *infection* and spread of *MMmsSC*, taking into account the countries or *zones* sharing common borders and other epidemiologic pathways for the potential introduction of *infection*.

The boundaries of the *zone* must be clearly defined, including a *protection zone* if applied. Provide maps identifying the features above, including a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zone*.

- b) Livestock demographics. Describe the composition of the livestock industry in the country and the *zone*. In particular, describe:
 - i) the susceptible animal *population* by species and types of production systems in the country and the *zone*;
 - ii) the number of *herds*, etc. of each susceptible species;
 - iii) their geographical distribution;
 - iv) *herd* density;
 - v) the degree of integration and role of producer organisations in the different production systems;
 - vi) any recent significant changes observed in the production (attach relevant documents if available).

Provide tables and maps.

- c) *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* 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 susceptible *wildlife* species?
- d) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of domestic susceptible species for marketing within the country or *zone*, and between *zones* of the same or different status? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation, regulations and *Veterinary Authority* directives in relation to CBPP and a brief description of the relevance of each. The table should include, but not be limited to, the legislation on disease control measures and compensation systems.
- b) *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, control, enforce and monitor all CBPP-related activities. Provide maps, figures and tables wherever possible.
- c) Provide information on any OIE PVS evaluation conducted in the country and follow-up steps within the PVS Pathway and highlight the results relevant to CBPP and the susceptible species.
- d) Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, *veterinary paraprofessionals* including community animal

health workers, and other relevant groups in CBPP *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, including the number of *veterinarians* and their distribution, in CBPP *surveillance* and control. Include a description of continuing education and awareness programmes on CBPP at all relevant levels.

- e) *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the traceability system, including methods of *animal identification* and *establishment* or *herd* registration, applicable to all susceptible species. How are animal movements controlled in and between *zones* of the same or different status for all susceptible species? Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months. Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g. seasonal migration).

Describe the actions available under national legislation. Provide information on illegal movements detected in the past 24 months and the action taken.

3. CBPP eradication

- a) History. If *infection* has never occurred in the *zone*, or has not occurred within the past 25 years, state explicitly whether or not the *zone* is applying for recognition of historical freedom in the *zone* according to point 1 a) of Article 1.4.6. of the *Terrestrial Code*.

If *infection* has occurred in the *zone* within the past 25 years, provide a description of the CBPP history in the country and *zone*, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, and the date of last case or *eradication* in the *zone*.

- b) Strategy. Describe how CBPP was controlled and eradicated in the *zone* (e.g. slaughter policy, zoning, *vaccination*, movement control). Provide the time frame for *eradication*. Describe and justify the corrective actions that have been implemented to prevent future *outbreaks* of CBPP in response to any past incursions of *MMmsSC*.

- c) Vaccines and *vaccination*. Briefly answer the following:

i) Is there any legislation that prohibits *vaccination*? If so:

- Provide the date when *vaccination* was formally prohibited;
- Provide information on cases of detection of illegal *vaccination* during the reporting period and actions taken in response to the detection.

ii) Was *vaccination* ever used in the country? If so:

- Provide the date when the last *vaccination* was carried out;
- What type of vaccine was used in the *zone* and the rest of the country?
- What species were vaccinated?
- How were vaccinated animals identified?
- What was the fate of those animals?

iii) In addition, if *vaccination* was applied during the past 24 months, provide a description and justification of the *vaccination* strategy and programme, including the following:

- the vaccine strains;
- the species vaccinated;
- identification of vaccinated animals;
- the way in which the *vaccination* of animals was certified or reported and the records maintained;
- evidence that the vaccine used complies with Chapter 2.4.8. of the *Terrestrial Manual*.

- d) Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. CBPP diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 2.4.8. of the *Terrestrial Manual* are applied. The following points should be addressed:

- a) Is CBPP *laboratory* diagnosis carried out in the country? If so, provide an overview of the CBPP-approved *laboratories* in the country. Indicate the *laboratories* where samples originating from the *zone* are diagnosed. Address the following points:
 - i) How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for reporting results;
 - ii) Details of test capability and the types of tests undertaken, including procedures to isolate and identify *M. mycoides* subsp. *mycoides* (*Mmm*), and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of CBPP tests performed in the past 24 months in national *laboratories* and in *laboratories* in other countries, if relevant;
 - iii) Procedures for quality assurance and for the official accreditation of *laboratories*. Give details of formal internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;
 - iv) Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;
 - v) Provide details of the handling of live pathogenic agent, including a description of the biosecurity and biosafety measures applied;
 - vi) Provide a table identifying the tests carried out by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.
- b) If CBPP *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

5. CBPP surveillance

Provide documentary evidence that *surveillance* for CBPP in the *zone* complies with Articles 11.5.13. to 11.5.17. of the *Terrestrial Code*, and Chapter 2.4.8. of the *Terrestrial Manual*. The following information should be included:

- a) What are the criteria for raising a suspicion of CBPP? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?
- b) Describe how clinical *surveillance* is conducted, including which sectors of the livestock production system are included in clinical *surveillance*, such as *establishments*, markets, fairs, *slaughterhouses/abattoirs*, check points, etc.
Provide a summary table indicating, for the past 24 months, the number of suspected cases, the number of samples tested for CBPP, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude CBPP. Provide details of follow-up actions taken on all suspicious and positive results.
- c) Serological *surveillance*. Explain whether serological surveys are conducted and, if so, how frequently and for what purpose. Provide detailed information on the target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 11.5.13. to 11.5.17. of the *Terrestrial Code*.
- d) *Slaughterhouses/abattoirs* and slaughter slabs. 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 24 months, the number of suspected cases, the number of samples tested for CBPP agent, species, type of sample, testing methods and results (including differential diagnosis).
- e) For countries where a significant proportion of animals in the *zone* are not slaughtered in controlled *slaughterhouses/abattoirs*, what are the alternative *surveillance* measures applied to detect CBPP (e.g. active clinical *surveillance* programmes, *laboratory* follow-up).
- f) Provide a description of the means employed during the 24 months preceding this application to rule out the presence of CBPP in the susceptible *population* of the *zone*. Provide criteria for selection of *populations* for targeted *surveillance* and numbers of animals examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the *surveillance* programme including indicators.
- g) Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical and *slaughterhouse/abattoir surveillance*, and the approaches used to increase community involvement in CBPP *surveillance* programmes.

6. CBPP prevention

Describe the procedures in place to prevent the introduction of CBPP into the country or *zone*, including details of:

- a) Coordination with other countries. Describe any relevant factors in neighbouring countries and *zones* that should be taken into account (e.g. size, distance from the border to affected *herds* or animals). Describe coordination, collaboration and information-sharing activities with other countries and *zones* in the same region or ecosystem.

If the CBPP free *zone* is established 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 pathogenic agent, taking into consideration existing physical or geographical barriers.

Are *protection zones* in place? If so, indicate whether or not the *protection zones* are included in the proposed free *zones*. Provide details of the measures that are applied (e.g. *vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the *zones*.

- b) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the spread of the pathogenic agent within the country or *zone*. Provide evidence that measures to reduce transmission of CBPP are in place at markets, such as enhancing awareness of CBPP transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity*, hygiene and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).

- c) Import control procedures

Provide information on countries, *zones* or *compartments* 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, *zones* or *compartments*, the controls applied to entry of such animals and products, and subsequent internal movement. Describe the import measures (e.g. quarantine) 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 *international veterinary certificates* are required.

Describe any other procedures used for assessing the *risks* posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country.

Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

- i) Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border posts*, and between *border posts*.
- ii) Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the *zone* or their final destination, concerning the import and follow-up of the following:
- animals;
 - genetic material (semen, oocytes and embryos);
 - *Mmm* strains including vaccines;
 - *veterinary medicinal products*;
 - other materials at risk of being contaminated with *Mmm*.

7. Control measures and contingency planning

- a) List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of CBPP. The contingency plan should be attached as an annex in one of the OIE official languages. If not available, provide a brief summary of what is covered. Provide information on any simulation exercise for CBPP that was conducted in the country in the past five years.

- b) In the event of a suspected or confirmed CBPP *outbreak*:

- i) Are quarantine measures imposed on *establishments* with suspected cases, pending final diagnosis? What other procedures are followed with respect to suspected cases (e.g. livestock standstills)?
- ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the pathogenic agent;
- iii) Describe the actions that would be taken to control the disease situation in and around the *establishments* where the *outbreak* is confirmed;

- iv) Provide a detailed description of the control or *eradication* procedures (e.g. forward and backward tracing, *disinfection of establishments, vehicles* and equipment, including verification methods, *vaccination, stamping-out policy*, slaughter policy, movement control, pastured livestock and livestock as pets, control of offal, especially lungs, and carcasses, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;
- v) Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;
- vi) Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payment;
- vii) Describe how control efforts, including *vaccination* and *biosecurity*, would target critical risk control points.

8. Recovery of free status

Member Countries applying for recognition of recovery of free status for a *zone* should comply with the provisions of Article 11.5.4. of the *Terrestrial Code* and provide detailed information as specified in Sections 3 a), 3 b), 3 c), 5 a), 5 b), 5 c) and 5 d) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Article 1.10.3.

Application for endorsement by the OIE of an official control programme for contagious bovine pleuropneumonia

The following information should be provided by OIE Member Countries to support applications for endorsement by the OIE of an *official control programme* for contagious bovine pleuropneumonia (CBPP) in accordance with Chapter 11.5. of the *Terrestrial Code*.

The dossier provided to the OIE should address concisely all the following topics under the headings provided in Sections 1 to 4 to describe the actual situation in the country and the procedures currently applied, explaining how these comply with the *Terrestrial Code*.

In Sections 3 f) to 3 i) describe concisely the work plan and timelines of the control programme for the next five years.

The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

All annexes should be provided in one of the OIE official languages.

The Delegate of the Member Country applying for endorsement of the *official control programme* should submit documentary evidence that the provisions of Article 11.5.18. have been properly implemented and supervised. In addition, the Delegate of the Member Country must submit the detailed national official control programme for CBPP.

1. Introduction

- a) Geographical features (rivers, mountain ranges, etc.). Provide a general description of the country and *zones*, and where relevant of the region, including physical, geographical and other factors that are relevant to introduction of *infection* and spread of *MMmsSC*, taking into account the countries or *zones* sharing common

borders and other epidemiologic pathways for the potential introduction of *infection*. Provide maps identifying the features above. Specify whether the application includes any noncontiguous territories.

- b) If the endorsed plan is implemented in stages to specific parts of the country, the boundaries of the *zones* should be clearly defined, including the *protection zones* if applied. Provide a digitalised, geo-referenced map with a description of the geographical boundaries of the *zones*.
- c) Livestock demographics. Describe the composition of the livestock industry in the country and any *zones*. In particular, describe:
- i) the susceptible animal *population* by species and types of production systems;
 - ii) the number of *herds*, etc. of each susceptible species;
 - iii) their geographical distribution;
 - iv) *herd* density;
 - v) the degree of integration and role of producer organisations in the different production systems;
 - vi) any recent significant changes observed in the production (attach relevant documents if available).

Provide tables and maps.

- d) *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* species are present in the country and any *zones*? Provide estimates of *population* sizes and geographic distribution. What are the measures in place to prevent contact between domestic and susceptible *wildlife* species?
- e) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic species for marketing within the country? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation, regulations and *Veterinary Authority* directives in relation to the CBPP control programme and a brief description of the relevance of each. The table should include, but not be limited to, the legislation on disease control measures and compensation systems.
- b) *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, control, enforce and monitor all CBPP-related activities. Provide maps, figures and tables wherever possible.
- c) Provide information on any OIE PVS evaluation conducted in the country and follow-up steps within the PVS Pathway and highlight the results relevant to CBPP and the susceptible species.
- d) Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in CBPP *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, including the number of *veterinarians* and their distribution, in CBPP *surveillance* and control.

Include a description of continuing education and awareness programmes on CBPP at all relevant levels of the susceptible species value.

- e) *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the traceability system, including methods of *animal identification* and *establishment* or *herd* registration, applicable to all susceptible species. How are animal movements controlled in the country for all susceptible species? Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months. Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g. seasonal migration).

Describe the actions available under national legislation. Provide information on illegal movements detected in the past 24 months and the action taken.

3. Official control programme for CBPP submitted for OIE endorsement

Submit a concise plan of the measures for the control and eventual *eradication* of CBPP in the country, including:

a) Epidemiology

- i) Describe the CBPP history in the country, with emphasis on recent years. Provide tables and maps showing the date of first detection, the number and location of *outbreaks* per year, the sources and routes of introduction of *infection*, the types and subtypes of *Mmm* present and the date of implementation of the control programme in the country.
- ii) Describe the epidemiological situation of CBPP in the country and the surrounding countries or *zones* highlighting the current knowledge and gaps. Provide maps of:
 - the geography of the country with the relevant information concerning CBPP situation;
 - livestock density and movements and estimated CBPP prevalence.

b) CBPP surveillance

Provide documentary evidence that *surveillance* for CBPP in the country complies with Articles 11.5.14. and 11.5.15. of the *Terrestrial Code*, and Chapter 2.4.8. of the *Terrestrial Manual*. The following information should be included:

- i) What are the criteria for raising a suspicion of CBPP? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?
- ii) Describe how clinical *surveillance* is conducted, including which sectors of the livestock production system are included in clinical *surveillance*, such as *establishments*, markets, fairs, *slaughterhouses/abattoirs*, check points, etc. Provide details of follow-up actions taken on clinical suspicions.
- iii) Serological *surveillance*. Explain whether serological surveys are conducted and, if so, how frequently and for what purpose. Provide detailed information on the target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 11.5.13. and 11.5.14. of the *Terrestrial Code*.
- iv) *Surveillance* at *slaughterhouses/abattoirs*, slaughter slabs. Explain whether *slaughterhouse/abattoir* surveys are conducted and, if so, how frequently and for what purpose. What are the criteria for suspecting a lesion is CBPP? What is the procedure for notify (by whom and to whom)?
- v) Provide a summary table indicating, for at least the past 24 months, the number of suspected cases, the number of samples tested for CBPP, species, type of sample, testing methods and results (including differential diagnosis). Provide procedural details of follow-up actions taken on suspicious and positive results and on how these findings are interpreted and acted upon.

Provide criteria for selection of *populations* for targeted surveillance and numbers of animals examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the *surveillance* programme including indicators.
- vi) In countries where a significant proportion of animals in the country or *zone* are not slaughtered in controlled *slaughterhouses/abattoirs*, what are the alternative *surveillance* measures applied to detect CBPP (e.g. active clinical *surveillance* programme, *laboratory* follow-up).
- vii) Provide information on the level of *risk* in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g. targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.) and that the acquired knowledge assists in more effective implementation of control measures.
- viii) Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical and *slaughterhouse/abattoir surveillance*, and the approaches used to increase community involvement in CBPP *surveillance* programmes.
- ix) Provide evidence that surveys are carried out to assess *vaccination* coverage and population immunity of the target populations, show analysis of *surveillance* data to assess the change in CBPP prevalence over time in the target populations, assess the control measures (cost effectiveness, degree of implementation, impact). Provide information on outcomes of *outbreak* investigations including *outbreaks* that have occurred despite control measures, documented inspections showing compliance with biosecurity and hygiene requirements.

c) CBPP diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.1., 1.1.3. and 2.4.8. of the *Terrestrial Manual* are applied. The following points should be addressed:

- i) Is CBPP *laboratory* diagnosis carried out in the country? If so, provide an overview of the CBPP-approved *laboratories* in the country, including the following:
- How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for reporting results;
 - Details of test capability and the types of tests undertaken including procedures to isolate and identify *M. mycoides* subsp. *mycoides* (*Mmm*) and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of CBPP tests performed in the past 24 months in national *laboratories* and in *laboratories* in other countries, if relevant;
 - Procedures for quality assurance and, if available, for the official accreditation of *laboratories*. Give details of formal internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;
 - Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;
 - Provide details of the handling of live pathogenic agent, including a description of the biosecurity and biosafety measures applied;
 - Provide a table identifying the tests carried out by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.
- ii) If CBPP *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

d) Strategies

- i) Provide a description of the legislation, organisation and implementation of the current CBPP control programme. Outline the legislation applicable to the control programme and how its implementation is organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.
- ii) Describe CBPP control strategies in the country or any *zones*, including in terms of animal movement control, fate of infected and in-contact animals, *vaccination* and possible use of antibiotics. Strategies should be based on the assessment of the CBPP situation in the *zones*, country and region.
- iii) Provide information on what types of vaccines are used and which species are vaccinated. Provide evidence that the vaccine used complies with Chapter 1.1.8. of the *Terrestrial Manual*. Provide information on the licensing process for the vaccines used. Describe the *vaccination* programme in the country and in any *zones*, including records kept, and provide evidence to show its effectiveness, such as *vaccination* coverage, population immunity, etc. Provide details of the studies carried out to determine the *vaccination* coverage and the population immunity, including the study designs and the results.
- iv) Provide a description of the policy on antibiotic treatment within the strategy. If it is banned how is the ban implemented?
- v) Describe how the *stamping-out policy* is implemented in the country or any *zones* and under which circumstances.
- vi) In the event of *outbreaks*, provide evidence of the impact of the control measures already implemented on the reduction in number of *outbreaks* and their distribution. If possible, provide information on primary and secondary *outbreaks*.

e) CBPP prevention

Describe the procedures in place to prevent the introduction of CBPP into the country, including details of:

- i) Coordination with other countries. Describe any relevant factors in neighbouring countries and *zones* that should be taken into account (e.g. size, distance from the border to affected *herds* or animals). Describe coordination, collaboration and information-sharing activities with other countries and *zones* in the same region or ecosystem.

Are *protection zones* in place? If so, provide details of the measures that are applied (e.g. *vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the *zones*.

- ii) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the spread of the pathogenic agent within the country or *zone*. Provide evidence that measures to reduce transmission of CBPP are in place at markets, such as enhancing awareness of CBPP transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity*, hygiene and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).
- iii) Import control procedures
- Provide information on countries, *zones* or *compartments* from which the country authorises the import of susceptible animals or their products into the country or any *zones*. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied to entry of such animals and products and subsequent internal movement. Describe the import measures (e.g. quarantine) 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 *international veterinary certificates* are required.
- Describe any other procedures used for assessing the *risks* posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.
- Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border posts*, and between *border posts*.
 - Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the country or their final destination, concerning the import and follow-up of the following:
 - animals;
 - genetic material (semen, oocytes and embryos);
 - *Mmm* strains including vaccines;
 - *veterinary medicinal products*;
 - other materials at risk of being contaminated with *Mmm*.
- iv) Describe the actions available under national legislation. Provide information on illegal movements detected in the past 24 months and the action taken.
- f) Work plan and timelines of the control programme for the next five years, including cessation of *vaccination*. Describe the progressive objectives including expected status to be achieved in the next five years: for *zones* (if applicable) and for the whole country.
- g) Performance indicators and timeline. The performance indicators should relate to the most important areas and steps where improvements in the programme are needed. These may include, but are not restricted to, strengthening *Veterinary Services*, legislation, clinical and *slaughterhouse/abattoir* reporting, availability and quality of vaccines, *animal identification* systems, *vaccination* coverage, population immunity, movement control, disease awareness, CBPP seroprevalence reduction, cattle owners' participatory perception on the effectiveness of the programme, etc. The progressive reduction of *outbreak* incidence towards elimination of transmission of *Mmm* in all susceptible livestock in at least one *zone* of the country should also be measured and monitored.
- h) Assessment of the evolution of the *official control programme* since the first date of implementation. This should include documented evidence demonstrating that the control programme has been implemented and that the first results are favourable. Measurable evidence of success such as the performance indicators should include, but not be limited to, *vaccination* data, decreased prevalence, successfully implemented import measures, control of animal movements and finally decrease or elimination of CBPP *outbreaks* in the whole country or selected *zones* as described in the programme. This should include documented evidence of the effective implementation of Sections 3 d) and 3 e) above.
- i) Describe the funding for the control programme and annual budgets for its duration.

4. Control measures and emergency response

- a) List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of CBPP. The contingency plan should be attached as an annex in one of the OIE official languages. If not available, provide a brief summary of what is covered. Provide information on any simulation exercise for CBPP that was conducted in the country in the past five years.
- b) In the event of a suspected or confirmed CBPP *outbreak*:
 - i) Are quarantine measures imposed on *establishments* with suspected cases, pending final diagnosis? What other procedures are followed regarding suspected cases (e.g. livestock standstills)?
 - ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the pathogenic agent;
 - iii) Describe the actions that would be taken to control the disease situation in and around the *establishments* where the *outbreak* is confirmed;
 - iv) Describe in detail the control or *eradication* procedures (e.g. forward and backward tracing, *disinfection* of *establishments*, *vehicles* and equipment, including verification methods, *vaccination*, *stamping-out policy*, *slaughter*, movement control, pastured livestock and livestock as pets, control of offal, especially lungs, and carcasses, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;
 - v) Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;
 - vi) Provide details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;
 - vii) Describe how control efforts, including *vaccination* and *biosecurity*, would target critical risk control points.

NB: FIRST ADOPTED IN 2009; MOST RECENT UPDATE ADOPTED IN 2018.

CHAPTER 1.11.

APPLICATION FOR OFFICIAL RECOGNITION BY THE OIE OF FREE STATUS FOR FOOT AND MOUTH DISEASE

Article 1.11.1.

Country free from infection with foot and mouth disease virus where vaccination is not practised

The following information should be provided by OIE Member Countries to support applications for official recognition of status as a country where *vaccination* is not practised that is free from *infection* with foot and mouth disease (FMD) virus in accordance with Chapter 8.8. of the *Terrestrial Code*.

The dossier provided to the OIE should address concisely all the following topics under the headings provided to describe the actual situation in the country and procedures currently applied, explaining how these comply with the *Terrestrial Code*.

The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

All annexes should be provided in one of the OIE official languages.

The Delegate of the Member Country applying for recognition of FMD freedom for a country where *vaccination* is not practised must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Article 8.8.2. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that:

- 1) there has been no case of FMD during the past 12 months;
- 2) no *vaccination* against FMD has been carried out during the past 12 months.

In addition, the Delegate of the Member Country applying for recognition of historical freedom must also submit documentary evidence that the provisions of point 1 a) of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.

1. Introduction

- a) Geographical features (rivers, mountain ranges, etc.). Provide a general description of the country and, where relevant, of the region, including physical, geographical and other factors that are relevant to introduction of *infection* and spread of FMD virus, taking into account the countries or *zones* sharing common borders and

other epidemiologic pathways for the potential introduction of the *infection*. Provide maps identifying the features above. Specify whether the application includes any noncontiguous territories.

- b) Livestock demographics. Describe the composition of the livestock industry in the country. In particular, describe:
- i) the susceptible animal *population* by species and types of production systems;
 - ii) the number of *herds* or *flocks*, etc. of each susceptible species;
 - iii) their geographical distribution;
 - iv) *herd* or *flock* density;
 - v) the degree of integration and role of producer organisations in the different production systems;
 - vi) any recent significant changes observed in the production (attach relevant documents if available).
- Provide tables and maps.
- c) *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* 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 susceptible *wildlife* species?
- d) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic species for marketing within the country? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation, regulations and *Veterinary Authority* directives in relation to FMD and a brief description of the relevance of each. The table should include, but not be limited to, the legislation on disease control measures and compensation systems.
- b) *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, control, enforce and monitor all FMD-related activities. Provide maps, figures and tables wherever possible.
- c) Provide information on any OIE PVS evaluation conducted in the country and follow-up steps within the PVS Pathway and highlight the results relevant to FMD and the susceptible species.
- d) Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in FMD *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, including the number of *veterinarians* and their distribution, in FMD *surveillance* and control. Include a description of continuing education and awareness programmes on FMD at all relevant levels.
- e) *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the traceability system, including methods of *animal identification* and *establishment* or *herd* or *flock* registration, applicable to all susceptible species. How are movements of all susceptible species controlled in the country? Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months. Provide information on pastoralism, transhumance and related paths of movement.
- Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g. seasonal migration).
- Describe the actions available under national legislation. Provide information on illegal movements detected in the past 24 months and the action taken.

3. FMD eradication

- a) History. If *infection* has never occurred in the country, or has not occurred within the past 25 years, state explicitly whether or not the country is applying for recognition of historical freedom according to point 1 a) of Article 1.4.6. of the *Terrestrial Code*.
- If *infection* has occurred in the country within the past 25 years, provide a description of the FMD history in the country, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, the date of last case or *eradication*, and the types and strains in the country.

- b) Strategy. Describe how FMD was controlled and eradicated (e.g. *stamping-out policy*, zoning, *vaccination*, movement control). Provide the time frame for *eradication*. Describe and justify the corrective actions that have been implemented to prevent future *outbreaks* of FMD in response to any past incursions of FMD virus.
- c) Vaccines and *vaccination*. Briefly answer the following:
- i) Is there any legislation that prohibits *vaccination*? If so:
 - Provide the date when *vaccination* was formally prohibited;
 - Provide information on cases of detection of illegal *vaccination* during the reporting period and actions taken in response to the detection.
 - ii) Was *vaccination* ever used in the country? If so:
 - Provide the date when the last *vaccination* was carried out;
 - What type of vaccine was used?
 - What species were vaccinated?
 - How were vaccinated animals identified?
 - What was the fate of those animals?
 - iii) In addition, if *vaccination* was applied during the past 24 months, provide a description and justification of the *vaccination* strategy and programme, including the following:
 - the vaccine strains;
 - potency and formulation, purity, details of any vaccine matching performed;
 - the species vaccinated;
 - identification of vaccinated animals;
 - the way in which the *vaccination* of animals was certified or reported and the records maintained;
 - evidence that the vaccine used complies with Chapter 2.1.8. of the *Terrestrial Manual*.
- d) Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. FMD diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 2.1.8. of the *Terrestrial Manual* are applied. The following points should be addressed:

- a) Is FMD *laboratory* diagnosis carried out in the country? If so, provide an overview of the FMD-approved *laboratories* in the country, including the following:
- i) How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for reporting results;
 - ii) Details of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of FMD tests performed in the last 24 months in national *laboratories* and in *laboratories* in other countries, if relevant;
 - iii) Procedures for quality assurance and for the official accreditation of *laboratories*. Give details of formal internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;
 - iv) Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;
 - v) Provide details of the handling of live pathogenic agent, including a description of the biosecurity and biosafety measures applied;
 - vi) Provide a table identifying the tests carried out by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.
- b) If FMD *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*, and Chapter 2.1.8. of the *Terrestrial Manual*. The following information should be included:

- a) What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?

- b) Describe how clinical *surveillance* is conducted, including which sectors of the livestock production system are included in clinical *surveillance*, such as *establishments*, markets, fairs, *slaughterhouses/abattoirs*, check points, etc.
Provide a summary table indicating, for the past 24 months, the number of suspected cases, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude FMD. Provide details of follow-up actions taken on all suspicious and positive results.
- c) Serological or virological *surveillance*. Are serological or virological surveys conducted? If so, provide detailed information on the target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*. How frequently are surveys conducted? Are susceptible *wildlife* species included in serological or virological surveys? If not, explain the rationale.
Provide a summary table indicating, for the past 24 months, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide details of follow-up actions taken on all suspicious and positive results and on how these findings are acted upon. Provide criteria for selection of *populations* for targeted surveillance based on the risk and numbers of animals examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the *surveillance* programme including indicators.
- d) Provide information on risks in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g. targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.). Provide evidence of how the knowledge acquired through these activities assisted in more effective implementation of control measures.
- e) Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in FMD *surveillance* programmes.

6. FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country, including details of:

- a) Coordination with other countries. Describe any relevant factors in neighbouring countries that should be taken into account (e.g. size, distance from the border to affected *herds*, *flocks* or animals). Describe coordination, collaboration and information-sharing activities with other countries in the same region or ecosystem.
Are *protection zone* in place? If so, provide details of the measures that are applied (e.g. *vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the *zones*.
- b) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the spread of the pathogenic agent within the country or *zone*. Provide evidence that measures to reduce transmission of FMD are in place at markets, such as enhancing awareness of FMD transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity*, hygiene and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).
- c) What measures are taken to limit access of susceptible domestic, *feral* and *wild* animals to waste products of animal origin? Is the feeding of swill to pigs regulated? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.
- d) Import control procedures
Provide information on countries, *zones* or *compartments* from which the country authorises the import of susceptible animals or their products into the country. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied to entry of such animals and products, and subsequent internal movement. Describe the import measures (e.g. quarantine) 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 *international veterinary certificates* are required.
Describe any other procedures used for assessing the *risks* posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.
- i) Provide a map with the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls

and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border posts*, and between *border posts*.

- ii) Provide a description of the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 24 months, of the quantity disposed of and the disposal locations. What are the biosecurity measures in place at waste disposal sites?
- iii) Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the country or their final destination, concerning the import and follow-up of the following:
 - animals;
 - genetic material (semen, oocytes and embryos);
 - animal products;
 - *veterinary medicinal products*;
 - other materials at risk of being contaminated with FMD virus, including bedding, litter and *feed*.

7. Control measures and contingency planning

- a) List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of FMD. The contingency plan should be attached as an annex in one of the OIE official languages. If not available, provide a brief summary of what is covered. Provide information on any simulation exercise for FMD that was conducted in the country in the past five years.
- b) In the event of a suspected or confirmed FMD *outbreak*:
 - i) Are quarantine measures imposed on *establishments* with suspected cases, pending final diagnosis? What other procedures are followed with respect to suspected cases (e.g. livestock standstills)?
 - ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the pathogenic agent;
 - iii) Describe the actions that would be taken to control the disease situation in and around the *establishments* where the *outbreak* is confirmed;
 - iv) Provide a detailed description of the control or *eradication* procedures (e.g. forward and backward tracing, movement control, *disinfection* of *establishments*, *vehicles* and equipment, including verification methods, *vaccination* including vaccine delivery and cold chain, *stamping-out policy*, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;
 - v) Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;
 - vi) Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;
 - vii) Describe how control efforts, including *vaccination* and *biosecurity*, would target critical risk control points.

8. Recovery of free status

Member Countries applying for recognition of recovery of free status for a country should comply with the provisions of Article 8.8.7. and points 1, 3 and 4 of Article 8.8.2. of the *Terrestrial Code* and provide detailed information as specified in Sections 1-7 (inclusive) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Article 1.11.2.

Country free from infection with foot and mouth disease virus where vaccination is practised

The following information should be provided by OIE Member Countries to support applications for official recognition of status as a country where *vaccination* is practised that is free from *infection* with foot and mouth disease (FMD) virus in accordance with Chapter 8.8. of the *Terrestrial Code*.

The dossier provided to the OIE should address concisely all the following topics under the headings provided to describe the actual situation in the country and procedures currently applied, explaining how these comply with the *Terrestrial Code*.

The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

All annexes should be provided in one of the OIE official languages.

The Delegate of the Member Country applying for recognition of FMD freedom for a country where *vaccination* is practised must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Article 8.8.3. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that:

- 1) there has been no case of FMD for the past 24 months;
- 2) no evidence of FMDV transmission for the past 12 months;
- 3) *surveillance* for FMD and FMDV transmission in accordance with Articles 8.8.40. to 8.8.42. and is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;
- 4) routine *vaccination* is carried out for the purposes of the prevention of FMD;
- 5) the vaccine used complies with the standards described in the *Terrestrial Manual*.

In addition, the Delegate of the Member Country applying for recognition of historical freedom must also submit documentary evidence that the provisions of point 1 a) of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.

1. Introduction

- a) Geographical features (rivers, mountain ranges, etc.). Provide a general description of the country and, where relevant, of the region, including physical, geographical and other factors that are relevant to introduction of *infection* and spread of FMD virus, taking into account the countries or *zones* sharing common borders and other epidemiologic pathways for the potential introduction of the *infection*. Provide maps identifying the features above. Specify whether the application includes any noncontiguous territories.
- b) Livestock demographics. Describe the composition of the livestock industry in the country. In particular, describe:
 - i) the susceptible animal *population* by species and types of production systems;
 - ii) the number of *herds* or *flocks*, etc. of each susceptible species;
 - iii) their geographical distribution;
 - iv) *herd* or *flock* density;
 - v) the degree of integration and role of producer organisations in the different production systems;
 - vi) any recent significant changes observed in the production (attach relevant documents if available).Provide tables and maps.
- c) *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* 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 susceptible *wildlife* species?
- d) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic species for marketing within the country? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation, regulations and *Veterinary Authority* directives in relation to FMD and a brief description of the relevance of each. The table should include, but not be limited to, the legislation on disease control measures and compensation systems.
- b) *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, control, enforce and monitor all FMD-related activities. Provide maps, figures and tables wherever possible.
- c) Provide information on any OIE PVS evaluation conducted in the country and follow-up steps within the PVS Pathway and highlight the results relevant to FMD and the susceptible species.

- d) Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in FMD *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, including the number of *veterinarians* and their distribution, in FMD *surveillance* and control. Include a description of continuing education and awareness programmes on FMD at all relevant levels.
- e) *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the traceability system, including methods of *animal identification* and *establishment* or *herd* or *flock* registration, applicable to all susceptible species. How are movements of all susceptible species controlled in the country? Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months. Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g. seasonal migration).

Describe the actions available under national legislation. Provide information on illegal movements detected in the past 24 months and the action taken.

3. FMD eradication

- a) History. Provide a description of the FMD history in the country, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, the date of last *case* or *eradication*, and the types and strains in the country.
- b) Strategy. Describe how FMD was controlled and eradicated (e.g. *stamping-out policy*, modified stamping-out policy, zoning, *vaccination*, movement control). Provide the time frame for *eradication*. Describe and justify the corrective actions that have been implemented to prevent future *outbreaks* of FMD in response to any past incursions of FMD virus.
- c) Vaccines and *vaccination*. Describe any legislation regulating *vaccination*. Provide a description and justification of the *vaccination* strategy and programme, including the following:
- i) the vaccine strains;
 - ii) potency and formulation, purity, details of any vaccine matching performed;
 - iii) the species vaccinated;
 - iv) identification of vaccinated animals;
 - v) the way in which the *vaccination* of animals was certified or reported and the records maintained;
 - vi) the date on which the last *vaccination* was performed;
 - vii) evidence that the vaccine used complies with Chapter 2.1.8. of the *Terrestrial Manual*.
- d) Provide detailed evidence of *vaccination* coverage and population immunity as follows:
- Describe how the number of animals intended for *vaccination* and the number of vaccinated animals are estimated.
- For serological surveys to estimate population immunity, provide detailed information on the sampling frame (target population, age, species and *vaccination* status) and survey design (expected prevalence, acceptable error, confidence level, sample size, stratification, sampling methods and diagnostic tests used). How long after *vaccination* are samples collected? Describe how the threshold for protective immunity has been established.
- Provide the results of the *vaccination* coverage and population immunity by year, serotype, species, as relevant.
- Provide details of any additional methods applied for monitoring the performance of *vaccination*.
- e) Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. FMD diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 2.1.8. of the *Terrestrial Manual* are applied. The following points should be addressed:

- a) Is FMD *laboratory* diagnosis carried out in the country? If so, provide an overview of the FMD-approved *laboratories* in the country, including the following:
 - i) How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for reporting results;
 - ii) Details of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of FMD tests performed in the last 24 months in national *laboratories* and in *laboratories* in other countries, if relevant;
 - iii) Procedures for quality assurance and for the official accreditation of *laboratories*. Give details of formal internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;
 - iv) Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;
 - v) Provide details of the handling of live pathogenic agent, including a description of the biosecurity and biosafety measures applied;
 - vi) Provide a table identifying the tests carried out by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.
- b) If FMD *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*, and Chapter 2.1.8. of the *Terrestrial Manual*. The following information should be included:

- a) What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?
- b) Describe how clinical *surveillance* is conducted, including which sectors of the livestock production system are included in clinical *surveillance*, such as *establishments*, markets, fairs, *slaughterhouses/abattoirs*, check points, etc.

Provide a summary table indicating, for the past 24 months, the number of suspected cases, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude FMD. Provide details of follow-up actions taken on all suspicious and positive results.
- c) Serological or virological *surveillance*. Are serological or virological surveys conducted? If so, provide detailed information on the target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*. How frequently are surveys conducted? Are susceptible *wildlife* species included in serological or virological surveys? If not, explain the rationale.

Provide a summary table indicating, for the past 24 months, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide details of follow-up actions taken on all suspicious and positive results and how these findings are acted upon. Provide criteria for selection of *populations* for targeted surveillance based on the risk and numbers of animals examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the *surveillance* programme including indicators.
- d) Provide information on risks in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g. targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.). Provide evidence of how the knowledge acquired through these activities assisted in more effective implementation of control measures.
- e) Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in FMD *surveillance* programmes.
- f) Provide evidence that surveys are carried out to assess *vaccination* coverage and population immunity of the target populations, show *laboratory* evidence that the vaccine strains used is appropriate.

6. FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country, including details of:

- a) Coordination with other countries. Describe any relevant factors in neighbouring countries that should be taken into account (e.g. size, distance from the border to affected *herds*, *flocks* or animals). Describe coordination, collaboration and information-sharing activities with other countries in the same region or ecosystem.

Are *protection zone* in place? If so, provide details of the measures that are applied (e.g. *vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the *zones*.

- b) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the spread of the pathogenic agent within the country or *zone*. Provide evidence that measures to reduce transmission of FMD are in place at markets, such as enhancing awareness of FMD transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity*, hygiene and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).

- c) What measures are taken to limit access of susceptible domestic, *feral* and *wild* animals to waste products of animal origin? Is the feeding of swill to pigs regulated? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.

- d) Import control procedures

Provide information on countries, *zones* or *compartments* from which the country authorises the import of susceptible animals or their products into the country. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied to entry of such animals and products, and subsequent internal movement. Describe the import measures (e.g. quarantine) 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 *international veterinary certificates* are required.

Describe any other procedures used for assessing the *risks* posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

- i) Provide a map with the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border posts*, and between *border posts*.

- ii) Provide a description of the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 24 months, of the quantity disposed of and the disposal locations. What are the biosecurity measures in place at waste disposal sites?

- iii) Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the country or their final destination, concerning the import and follow-up of the following:

- animals;
- genetic material (semen, oocytes and embryos);
- animal products;
- *veterinary medicinal products*;
- other materials at risk of being contaminated with FMD virus, including bedding, litter and *feed*.

7. Control measures and contingency planning

- a) List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of FMD. The contingency plan should be attached as an annex in one of the OIE official languages. If not available, provide a brief summary of what is covered. Provide information on any simulation exercise for FMD that was conducted in the country in the past five years.

- b) In the event of a suspected or confirmed FMD *outbreak*:

- i) Are quarantine measures imposed on *establishments* with suspected *cases*, pending final diagnosis? What other procedures are followed with respect to suspected *cases* (e.g. livestock standstills)?

- ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the pathogenic agent;

- iii) Describe the actions that would be taken to control the disease situation in and around the *establishments* where the *outbreak* is confirmed;
- iv) Provide a detailed description of the control or *eradication* procedures (e.g. forward and backward tracing, movement control, *disinfection* of *establishments*, *vehicles* and equipment, including verification methods, *vaccination* including vaccine delivery and cold chain, *stamping-out policy*, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;
- v) Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;
- vi) Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;
- vii) Describe how control efforts, including *vaccination* and *biosecurity*, would target critical risk control points.

8. Recovery of free status

Member Countries applying for recognition of recovery of free status for a country should comply with the provisions of Article 8.8.7. and points 1, 3 and 4 of Article 8.8.3. of the *Terrestrial Code* and provide detailed information as specified in Sections 1-7 (inclusive) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Article 1.11.3.

Zone free from infection with foot and mouth disease virus where vaccination is not practised

The following information should be provided by OIE Member Countries to support applications for official recognition of status as a *zone* where *vaccination* is not practised that is free from *infection* with foot and mouth disease (FMD) virus in accordance with Chapter 8.8. of the *Terrestrial Code*.

The dossier provided to the OIE should address concisely all the following topics under the headings provided to describe the actual situation in the country and procedures currently applied, explaining how these comply with the *Terrestrial Code*.

The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

All annexes should be provided in one of the OIE official languages.

The Delegate of the Member Country applying for recognition of FMD zonal freedom must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Article 8.8.2. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that:

- 1) there has been no case of FMD during the past 12 months;
- 2) no *vaccination* against FMD has been carried out during the past 12 months.

In addition, the Delegate of the Member Country applying for recognition of historical freedom must also submit documentary evidence that the provisions of point 1 a) of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.

1. Introduction

- a) Geographical features (rivers, mountain ranges, etc.). Provide a general description of the country and the *zone*, and where relevant of the region, including physical, geographical and other factors that are relevant to introduction of *infection* and spread of FMD virus, taking into account the countries or *zones* sharing common borders and other epidemiologic pathways for the potential introduction of the *infection*.

The boundaries of the *zone* must be clearly defined, including a *protection zone* if applied. Provide maps identifying the features above, including a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zone*.

- b) Livestock demographics. Describe the composition of the livestock industry in the country and the *zone*. In particular, describe:
- i) the susceptible animal *population* by species and types of production systems in the country and the *zone*;
 - ii) the number of *herds* or *flocks*, etc. of each susceptible species;
 - iii) their geographical distribution;
 - iv) *herd* or *flock* density;
 - v) the degree of integration and role of producer organisations in the different production systems;
 - vi) any recent significant changes observed in the production (attach relevant documents if available).

Provide tables and maps.

- c) *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* 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 susceptible *wildlife* species?
- d) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic species for marketing within the country or *zone*, and between *zones* of the same or different status? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation, regulations and *Veterinary Authority* directives in relation to FMD and a brief description of the relevance of each. The table should include, but not be limited to, the legislation on disease control measures and compensation systems.
- b) *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, control, enforce and monitor all FMD-related activities. Provide maps, figures and tables wherever possible.
- c) Provide information on any OIE PVS evaluation conducted in the country and follow-up steps within the PVS Pathway and highlight the results relevant to FMD and the susceptible species.
- d) Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in FMD *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, including the number of *veterinarians* and their distribution, in FMD *surveillance* and control. Include a description of continuing education and awareness programmes on FMD at all relevant levels.
- e) *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the traceability system, including methods of *animal identification* and *establishment* or *herd* or *flock* registration, applicable to all susceptible species. How are movements of all susceptible species controlled in and between *zones* of the same or different status for all production systems? Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months. Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g. seasonal migration).

Describe the actions available under national legislation. Provide information on illegal movements detected in the past 24 months and the action taken.

3. FMD eradication

- a) History. If *infection* has never occurred in the country, or has not occurred within the last 25 years, state explicitly whether or not the *zone* is applying for recognition of historical freedom according to point 1 a) of Article 1.4.6. of the *Terrestrial Code*.

If *infection* has occurred in the *zone* within the past 25 years, provide a description of the FMD history in the country and *zone*, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, the date of last *case* or *eradication* and the types and strains in the country.

- b) Strategy. Describe how FMD was controlled and eradicated in the *zone* (e.g. *stamping-out policy*, modified stamping-out policy, zoning, *vaccination*, movement control). Provide the time frame for *eradication*. Describe and justify the corrective actions that have been implemented to prevent future *outbreaks* of FMD in response to any past incursions of FMD virus.

- c) Vaccines and *vaccination*. Briefly answer the following:

- i) Is there any legislation that prohibits *vaccination*? If so:

- Provide the date when *vaccination* was formally prohibited;
- Provide information on cases of detection of illegal *vaccination* during the reporting period and actions taken in response to the detection.

- ii) Was *vaccination* ever used in the *zone*? If so:

- Provide the date when the last *vaccination* was carried out;
- What type of vaccine was used?
- What species were vaccinated?
- How were vaccinated animals identified?
- What was the fate of those animals?

- iii) In addition, if *vaccination* was applied during the past 24 months, provide a description and justification of the *vaccination* strategy and programme, including the following:

- the vaccine strains;
- potency and formulation, purity, details of any vaccine matching performed;
- the species vaccinated;
- identification of vaccinated animals;
- the way in which the *vaccination* of animals was certified or reported and the records maintained;
- evidence that the vaccine used complies with Chapter 2.1.8. of the *Terrestrial Manual*.

- iv) If *vaccination* continues to be used in the rest of the country, give details of the species vaccinated and on the post-*vaccination* monitoring programme.

- d) Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. FMD diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 2.1.8. of the *Terrestrial Manual* are applied. The following points should be addressed:

- a) Is FMD *laboratory* diagnosis carried out in the country? If so, provide an overview of the FMD-approved *laboratories* in the country. Indicate the *laboratories* where samples originating from the *zone* are diagnosed. Address the following points:
 - i) How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for reporting results;
 - ii) Details of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of FMD tests performed in the last 24 months in national *laboratories* and in *laboratories* in other countries, if relevant;
 - iii) Procedures for quality assurance and for the official accreditation of *laboratories*. Give details of formal internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;
 - iv) Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;
 - v) Provide details of the handling of live pathogenic agent, including a description of the biosecurity and biosafety measures applied;
 - vi) Provide a table identifying the tests carried out by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.
- b) If FMD *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the *zone* complies with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*, and Chapter 2.1.8. of the *Terrestrial Manual*. The following information should be included:

- a) What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?
- b) Describe how clinical *surveillance* is conducted, including which sectors of the livestock production system are included in clinical *surveillance*, such as *establishments*, markets, fairs, *slaughterhouses/abattoirs*, check points, etc.

Provide a summary table indicating, for the past 24 months, the number of suspected cases, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude FMD. Provide details of follow-up actions taken on all suspicious and positive results.

- c) Serological or virological *surveillance*. Are serological or virological surveys conducted? If so, provide detailed information on the target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*. How frequently are surveys conducted? Are susceptible *wildlife* species included in serological or virological surveys? If not, explain the rationale.

Provide a summary table indicating, for the past 24 months, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide details of follow-up actions taken on all suspicious and positive results and how these findings are acted upon. Provide criteria for selection of *populations* for targeted surveillance based on the risk and numbers of animals examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the *surveillance* programme including indicators.

- d) Provide information on risks in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g. targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.). Provide evidence of how the knowledge acquired through these activities assisted in more effective implementation of control measures.
- e) Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in FMD *surveillance* programmes.

6. FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country or *zone*, including details of:

- a) Coordination with other countries. Describe any relevant factors about in neighbouring countries and *zones* that should be taken into account (e.g. size, distance from the border to affected *herds*, *flocks* or animals). Describe coordination, collaboration and information-sharing activities with other countries and *zones* in the same region or ecosystem.

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

Are *protection zone* in place? If so, indicate whether or not the *protection zone* are included in the proposed FMD free *zones*. Provide details of the measures that are applied (e.g. *vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the *zones*.

- b) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the spread of the pathogenic agent within the country or *zone*. Provide evidence that measures to reduce transmission of FMD are in place at markets, such as enhancing awareness of FMD transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity*, hygiene and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).

- c) What measures are taken to limit access of susceptible domestic, *feral* and *wild* animals to waste products of animal origin? Is the feeding of swill to pigs regulated? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.

- d) Import control procedures

Provide information on countries, *zones* or *compartments* from which the country authorises the import of susceptible animals or their products into the *zone*. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied to entry of such animals and products, and subsequent internal movement. Describe the import measures (e.g. quarantine) 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 *international veterinary certificates* are required.

Describe any other procedures used for assessing the *risks* posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

- i) Provide a map with the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border posts*, and between *border posts*.

- ii) Provide a description of the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 24 months, of the quantity disposed of and the disposal locations. What are the biosecurity measures in place at waste disposal sites?

- iii) Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the *zone* or their final destination, concerning the import and follow-up of the following:

- animals;
- genetic material (semen, oocytes and embryos);
- animal products;
- *veterinary medicinal products*;
- other materials at risk of being contaminated with FMD virus, including bedding, litter and *feed*.

7. Control measures and contingency planning

- a) List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of FMD. The contingency plan should be attached as an annex in one of the OIE official languages. If not available, provide a brief summary of what is covered. Provide information on any simulation exercise for FMD that was conducted in the country in the past five years.

- b) In the event of a suspected or confirmed FMD *outbreak*:
- i) Are quarantine measures imposed on *establishments* with suspected *cases*, pending final diagnosis? What other procedures are followed with respect to suspected *cases* (e.g. livestock standstills)?
 - ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the pathogenic agent;
 - iii) Describe the actions that would be taken to control the disease situation in and around the *establishments* where the *outbreak* is confirmed;
 - iv) Provide a detailed description of the control or *eradication* procedures (e.g. forward and backward tracing, movement control, *disinfection of establishments, vehicles* and equipment, including verification methods, *vaccination* including vaccine delivery and cold chain, *stamping-out policy*, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;
 - v) Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;
 - vi) Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;
 - vii) Describe how control efforts, including *vaccination* and *biosecurity*, would target critical risk control points.

8. Recovery of free status

Member Countries applying for recognition of recovery of free status for a *zone* where *vaccination* is not practised should comply with the provisions of Article 8.8.7. and points 1, 3 and 4 of Article 8.8.2. of the *Terrestrial Code* and provide detailed information as specified in Sections 1-7 (inclusive) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Article 1.11.4.

Zone free from infection with foot and mouth disease virus where vaccination is practised

The following information should be provided by OIE Member Countries to support applications for official recognition of status as a *zone* where *vaccination* is practised that is free from *infection* with foot and mouth disease (FMD) virus in accordance with Chapter 8.8. of the *Terrestrial Code*.

The dossier provided to the OIE should address concisely all the following topics under the headings provided to describe the actual situation in the country and procedures currently applied, explaining how these comply with the *Terrestrial Code*.

The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

All annexes should be provided in one of the OIE official languages.

The Delegate of the Member Country applying for recognition of FMD zonal freedom must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Article 8.8.3. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that:

- 1) there has been no case of FMD for the past 24 months;
- 2) no evidence of FMDV transmission for the past 12 months;
- 3) *surveillance* for FMD and FMDV transmission in accordance with Articles 8.8.40. to 8.8.42. and is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;
- 4) routine *vaccination* is carried out for the purposes of the prevention of FMD;
- 5) the vaccine used complies with the standards described in the *Terrestrial Manual*.

In addition, the Delegate of the Member Country applying for recognition of historical zonal freedom must also submit documentary evidence that the provisions of point 1 a) of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.

1. Introduction

- a) Geographical features (rivers, mountain ranges, etc.). Provide a general description of the country and the *zone*, and where relevant of the region, including physical, geographical and other factors that are relevant to introduction of *infection* and spread of FMD virus, taking into account the countries or *zones* sharing common borders and other epidemiologic pathways for the potential introduction of the *infection*.
The boundaries of the *zone* must be clearly defined, including a *protection zone* if applied. Provide maps identifying the features above, including a digitalised, geo-referenced map with a description of the geographical boundaries of the *zone*.
- b) Livestock demographics. Describe the composition of the livestock industry in the country and the *zone*. In particular, describe:
- the susceptible animal *population* by species and types of production systems in the country and the *zone*;
 - the number of *herds* or *flocks*, etc. of each susceptible species;
 - their geographical distribution;
 - herd* or *flock* density;
 - the degree of integration and role of producer organisations in the different production systems;
 - any recent significant changes observed in the production (attach relevant documents if available).
- Provide tables and maps.
- c) *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* 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 susceptible *wildlife* species?
- d) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic species for marketing within the country or *zone*, and between *zones* of the same or different status? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation, regulations and *Veterinary Authority* directives in relation to FMD and a brief description of the relevance of each. The table should include, but not be limited to, the legislation on disease control measures and compensation systems.
- b) *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, control, enforce and monitor all FMD-related activities. Provide maps, figures and tables wherever possible.
- c) Provide information on any OIE PVS evaluation conducted in the country and follow-up steps within the PVS Pathway and highlight the results relevant to FMD and the susceptible species.
- d) Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in FMD *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, including the number of *veterinarians* and their distribution, in FMD *surveillance* and control. Include a description of continuing education and awareness programmes on FMD at all relevant levels.
- e) *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the traceability system, including methods of *animal identification* and *establishment* or *herd* or *flock* registration, applicable to all susceptible species. How are movements of all susceptible species controlled in and between *zones* of the same or different status? Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months. Provide information on pastoralism, transhumance and related paths of movement.
Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g. seasonal migration).
Describe the actions available under national legislation. Provide information on illegal movements detected in the past 24 months and the action taken.

3. FMD eradication

- a) History. Provide a description of the FMD history in the country and *zone*, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, the date of last *case* or *eradication* and the types and strains in the country.
- b) Strategy. Describe how FMD was controlled and eradicated in the *zone* (e.g. *stamping-out policy*, zoning, *vaccination*, movement control). Provide the time frame for *eradication*. Describe and justify the corrective actions that have been implemented to prevent future *outbreaks* of FMD in response to any past incursions of FMD virus.
- c) Vaccines and *vaccination*. Describe any legislation regulating *vaccination*. Provide a description and justification of the *vaccination* strategy and programme, including the following:
- i) the vaccine strains;
 - ii) potency and formulation, purity, details of any vaccine matching performed;
 - iii) the species vaccinated;
 - iv) identification of vaccinated animals;
 - v) the way in which the *vaccination* of animals was certified or reported and the records maintained;
 - vi) the date on which the last *vaccination* was performed;
 - vii) evidence that the vaccine used complies with Chapter 2.1.8. of the *Terrestrial Manual*.
- d) Provide detailed evidence of *vaccination* coverage and population immunity as follows:
Describe how the number of animals intended for *vaccination* and the number of vaccinated animals are estimated.
For serological surveys to estimate population immunity, provide detailed information on the sampling frame (target population, age, species and *vaccination* status) and survey design (expected prevalence, acceptable error, confidence level, sample size, stratification, sampling methods and diagnostic tests used). How long after *vaccination* are samples collected? Describe how the threshold for protective immunity has been established.
Provide the results of the *vaccination* coverage and population immunity by year, serotype, species, as relevant.
Provide details of any additional methods applied for monitoring the performance of *vaccination*.
- e) Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. FMD diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 2.1.8. of the *Terrestrial Manual* are applied. The following points should be addressed:

- a) Is FMD *laboratory* diagnosis carried out in the country? If so, provide an overview of the FMD-approved *laboratories* in the country. Indicate the *laboratories* where samples originating from the *zone* are diagnosed. Address the following points:
- i) How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for reporting results;
 - ii) Details of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of FMD tests performed in the last 24 months in national *laboratories* and in *laboratories* in other countries, if relevant;
 - iii) Procedures for quality assurance and for the official accreditation of *laboratories*. Give details of formal internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;
 - iv) Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;
 - v) Provide details of the handling of live pathogenic agent, including a description of the biosecurity and biosafety measures applied;
 - vi) Provide a table identifying the tests carried out by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.
- b) If FMD *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the *zone* complies with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*, and Chapter 2.1.8. of the *Terrestrial Manual*. The following information should be included:

- a) What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?
- b) Describe how clinical *surveillance* is conducted, including which sectors of the livestock production system are included in clinical *surveillance*, such as *establishments*, markets, fairs, *slaughterhouses/abattoirs*, check points, etc.

Provide a summary table indicating, for the past 24 months, the number of suspected *cases*, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude FMD. Provide details of follow-up actions taken on all suspicious and positive results.

- c) Serological or virological *surveillance*. Are serological or virological surveys conducted? If so, provide detailed information on the target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*. How frequently are surveys conducted? Are susceptible *wildlife* species included in serological or virological surveys? If not, explain the rationale.

Provide a summary table indicating, for the past 24 months, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide details of follow-up actions taken on all suspicious and positive results and how these findings are acted upon. Provide criteria for selection of *populations* for targeted surveillance based on the risk and numbers of animals examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the *surveillance* programme including indicators.

- d) Provide information on risks in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g. targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.). Provide evidence of how the knowledge acquired through these activities assisted in more effective implementation of control measures.
- e) Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in FMD *surveillance* programmes.
- f) Provide evidence that surveys are carried out to assess *vaccination* coverage and population immunity of the target populations, show laboratory evidence that the vaccine strains used is appropriate.

6. FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country, including details of:

- a) Coordination with other countries. Describe any relevant factors in neighbouring countries and *zones* that should be taken into account (e.g. size, distance from the border to affected *herds* or *flocks* or animals). Describe coordination, collaboration and information-sharing activities with other countries and *zones* in the same region or ecosystem.

If the FMD free *zone* with *vaccination* is established in a 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.

Are *protection zone* in place? If so, indicate whether or not the *protection zone* are included in the proposed FMD free *zones*. Provide details of the measures that are applied (e.g. *vaccination*, intensified *surveillance*, density control of susceptible species) and provide a geo-referenced map of the *zones*.

- b) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the spread of the pathogenic agent within the country or *zone*. Provide evidence that measures to reduce transmission of FMD are in place at markets, such as enhancing awareness of FMD transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity*, hygiene and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).
- c) What measures are taken to limit access of susceptible domestic, *feral* and *wild* animals to waste products of animal origin? Is the feeding of swill to pigs regulated? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.

d) Import control procedures

Provide information on countries, *zones* or *compartments* 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, *zones* or *compartments*, the controls applied to entry of such animals and products, and subsequent internal movement. Describe the import measures (e.g. quarantine) 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 *international veterinary certificates* are required.

Describe any other procedures used for assessing the *risks* posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

- i) Provide a map with the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border posts*, and between *border posts*.
- ii) Provide a description of the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 24 months, of the quantity disposed of and the disposal locations. What are the biosecurity measures in place at waste disposal sites?
- iii) Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the *zone* or their final destination, concerning the import and follow-up of the following:
 - animals;
 - genetic material (semen, oocytes and embryos);
 - animal products;
 - *veterinary medicinal products*;
 - other materials at risk of being contaminated with FMD virus, including bedding, litter and *feed*.

7. Control measures and contingency planning

- a) List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of FMD. The contingency plan should be attached as an annex in one of the OIE official languages. If not available, provide a brief summary of what is covered. Provide information on any simulation exercise for FMD that was conducted in the country in the past five years.
- b) In the event of a suspected or confirmed FMD *outbreak*:
 - i) Are quarantine measures imposed on *establishments* with suspected *cases*, pending final diagnosis? What other procedures are followed with respect to suspected *cases* (e.g. livestock standstills)?
 - ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the pathogenic agent;
 - iii) Describe the actions that would be taken to control the disease situation in and around the *establishments* where the *outbreak* is confirmed;
 - iv) Provide a detailed description of the control or *eradication* procedures (e.g. forward and backward tracing, movement control, *disinfection* of *establishments*, *vehicles* and equipment, including verification methods, *vaccination* including vaccine delivery and cold chain, *stamping-out policy*, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;
 - v) Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;
 - vi) Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;
 - vii) Describe how control efforts, including *vaccination* and *biosecurity*, would target critical risk control points.

8. Recovery of free status

Member Countries applying for recognition of recovery of free status for a *zone* where *vaccination* is practised should comply with the provisions of Article 8.8.7. and points 1, 3 and 4 of Article 8.8.3. of the *Terrestrial Code* and provide detailed information as specified in Sections 1-7 (inclusive) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Article 1.11.5.

Application for endorsement by the OIE of an official control programme for foot and mouth disease

The following information should be provided by OIE Member Countries to support applications for endorsement by the OIE of an *official control programme* for foot and mouth disease (FMD) in accordance with Chapter 8.8. of the *Terrestrial Code*.

The dossier provided to the OIE should address concisely all the topics under the headings provided in Sections 1 to 4 to describe the actual situation in the country and the procedures currently applied, explaining how these comply with the *Terrestrial Code*.

In Sections 3 *f*) to 3 *i*) describe concisely the work plan and timelines of the control programme for the next five years.

The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

All annexes should be provided in one of the OIE official languages.

The Delegate of the Member Country applying for endorsement of the *official control programme* should submit documentary evidence that the provisions of Article 8.8.39. have been properly implemented and supervised. In addition, the Delegate of the Member Country must submit the detailed national official control programme for FMD.

1. Introduction

- a) Geographical features (rivers, mountain ranges, etc.). Provide a general description of the country and *zones*, and where relevant of the region, including physical, geographical and other factors that are relevant to introduction of *infection* and spread of FMD virus, taking into account the countries or *zones* sharing common borders and other epidemiologic pathways for the potential introduction of *infection*. Provide maps identifying the features above. Specify whether the application includes any noncontiguous territories.
- b) If the endorsed plan is implemented in stages to specific parts of the country, the boundaries of the *zones* should be clearly defined, including the *protection zone* if applied. Provide a digitalised, geo-referenced map with a description of the geographical boundaries of the *zones*.
- c) Livestock demographics. Describe the composition of the livestock industry in the country and any *zones*. In particular, describe:
 - i) the susceptible animal *population* by species and types of production systems;
 - ii) the number of *herds* or *flocks*, etc. of each susceptible species;
 - iii) their geographical distribution;
 - iv) *herd* or *flock* density;
 - v) the degree of integration and role of producer organisations in the different production systems;
 - vi) any recent significant changes observed in the production (attach relevant documents if available).Provide tables and maps.
- d) *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* species are present in the country and any *zones*? Provide estimates of *population* sizes and geographic distribution. What are the measures in place to prevent contact between domestic and susceptible *wildlife* species?
- e) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic species for marketing within the country? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation, regulations and *Veterinary Authority* directives in relation to FMD and a brief description of the relevance of each. The table should include, but not be limited to, the legislation on disease control measures and compensation systems.
- b) *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, control, enforce and monitor all FMD-related activities. Provide maps, figures and tables wherever possible.
- c) Provide information on any OIE PVS evaluation conducted in the country and follow-up steps within the PVS Pathway and highlight the results relevant to FMD and the susceptible species.
- d) Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in FMD *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, including the number of *veterinarians* and their distribution, in FMD *surveillance* and control. Include a description of continuing education and awareness programmes on FMD at all relevant levels.
- e) *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the traceability system, including methods of *animal identification* and *establishment* or *herd* or *flock* registration, applicable to all susceptible species. How are animal movements controlled in the country for all susceptible species? Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months. Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g. seasonal migration).

Describe the actions available under national legislation. Provide information on illegal movements detected in the past 24 months and the action taken.

3. Official control programme for FMD submitted for OIE endorsement

Submit a concise plan of the measures for the control and eventual *eradication* of FMD in the country, including:

- a) Epidemiology
 - i) Describe the FMD history in the country, with emphasis on recent years. Provide tables and maps showing the date of first detection, the number and location of *outbreaks* per year, the sources and routes of introduction of *infection*, the types and strains present, the susceptible species involved and the date of implementation of the control programme in the country.
 - ii) Describe the epidemiological situation of FMD in the country and the surrounding countries or *zones* highlighting the current knowledge and gaps. Provide maps of:
 - the geography of the country with the relevant information concerning FMD situation;
 - livestock density and movements and estimated FMD prevalence.
- b) FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*, and Chapter 2.1.8. of the *Terrestrial Manual*. The following information should be included:

- i) What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?
- ii) Describe how clinical *surveillance* is conducted, including which sectors of the livestock production system are included in clinical *surveillance*, such as *establishments*, markets, fairs, *slaughterhouses/abattoirs*, check points, etc. Provide details of follow-up actions taken on clinical suspicions.
- iii) Serological or virological *surveillance*. Explain whether or not serological or virological surveys are conducted and, if so, how frequently and for what purpose. Provide detailed information on the target population, design prevalence, confidence level, sample size, stratification, sampling methods and

diagnostic tests used in accordance with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*. Are susceptible *wildlife* species included in serological or virological surveys? If not, explain the rationale.

Provide a summary table indicating, for at least the past 24 months, the number of suspected cases, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide procedural details of follow-up actions taken on suspicious and positive results and on how these findings are interpreted and acted upon.

Provide criteria for selection of *populations* for targeted surveillance and numbers of animals examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the *surveillance* programme including indicators.

- iv) Provide information on circulating strains and the level of *risk* in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g. targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.) and that the acquired knowledge assists in more effective implementation of control measures.
 - v) Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in FMD *surveillance* programmes.
 - vi) Provide evidence that surveys are carried out to assess *vaccination* coverage and population immunity of the target populations, show laboratory evidence that the vaccine used is appropriate for circulating strains of virus, show analysis of *surveillance* data to assess the change in FMD prevalence over time in the target populations, assess the control measures (cost effectiveness, degree of implementation, impact). Provide information on outcomes of *outbreak* investigations including *outbreaks* that have occurred despite control measures, documented inspections showing compliance with biosecurity and hygiene requirements.
- c) FMD diagnosis
- Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 2.1.8. of the *Terrestrial Manual* are applied. The following points should be addressed:
- i) Is FMD *laboratory* diagnosis carried out in the country? If so, provide an overview of the FMD-approved *laboratories* in the country, including the following:
 - How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for reporting results;
 - Details of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of FMD tests performed in the past 24 months in national *laboratories* and in *laboratories* in other countries, if relevant;
 - Procedures for quality assurance and, if available, the official accreditation of *laboratories*. Give details of formal internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;
 - Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;
 - Provide details of the handling of live pathogenic agent, including a description of the biosecurity and biosafety measures applied;
 - Provide a table identifying the tests carried out by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.
 - ii) If FMD *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.
- d) Strategies
- i) Provide a description of the legislation, organisation and implementation of the current FMD control programme. Outline the legislation applicable to the control programme and how its implementation is organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.
 - ii) Describe FMD control strategies in the country or any *zones*, including in terms of animal movement control, fate of infected and in-contact animals and *vaccination*. Strategies should be based on the assessment of the FMD situation in the *zones*, country and region.

- iii) Provide information on what types of vaccines are used and which species are vaccinated. Provide information on the licensing process for the vaccines used. Describe the *vaccination* programme in the country and any *zones*, including records kept, and provide evidence to show its effectiveness, such as *vaccination* coverage, population immunity, etc. Provide details of the studies carried out to determine the *vaccination* coverage and the population immunity, including the study designs and the results.
 - iv) Describe how the *stamping-out policy* is implemented in the country or any *zones* and under which circumstances.
 - v) In the event of *outbreaks*, provide evidence of the impact of the control measures already implemented on the reduction in number of *outbreaks* and their distribution. If possible, provide information on primary and secondary *outbreaks*.
- e) FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country, including details of:

- i) Coordination with other countries. Describe any relevant factors in neighbouring countries and *zones* that should be taken into account (e.g. size, distance from the border to affected *herds* or *flocks* or animals). Describe coordination, collaboration and information-sharing activities with other countries and *zones* in the same region or ecosystem.

Are *protection zone* in place? If so, provide details of the measures that are applied (e.g. *vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the *zones*.

- ii) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the spread of the pathogenic agent within the country or *zone*. Provide evidence that measures to reduce transmission of FMD are in place at markets, such as enhancing awareness of FMD transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity*, hygiene and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).
- iii) What measures are taken to limit access of susceptible domestic, *feral* and *wild* animals to waste products of animal origin? Is the feeding of swill to pigs regulated? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.
- iv) Import control procedures

Provide information on countries, *zones* or *compartments* from which the country authorises the import of susceptible animals or their products into the country or any *zones*. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied to entry of such animals and products and subsequent internal movement. Describe the import measures (e.g. quarantine) 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 *international veterinary certificates* are required.

Describe any other procedures used for assessing the *risks* posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

- Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border posts*, and between *border posts*.
- Provide a description of the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 24 months, of the quantity disposed of and the disposal locations. What *biosecurity* is in place at waste disposal sites?

- Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the country or their final destination, concerning the import and follow-up of the following:
 - animals;
 - genetic material (semen, oocytes and embryos);
 - animal products;
 - *veterinary medicinal products*;
 - other materials at risk of being contaminated with FMD virus, including bedding, litter and *feed*.
 - v) Describe the actions available under legislation when an illegal import is detected. Provide information on illegal imports detected and the action taken.
 - f) Work plan and timelines of the control programme for the next five years, including cessation of *vaccination*. Describe the progressive objectives including expected status to be achieved in the next five years: for *zones* (if applicable) and for the whole country.
 - g) Performance indicators and timeline. The performance indicators should relate to the most important areas and steps where improvements in the programme are needed. These may include, but are not restricted to, strengthening *Veterinary Services*, legislation, reporting, availability and quality of vaccines, *animal identification* systems, *vaccination* coverage, population immunity, movement control, disease awareness, livestock owners' participatory perception on the effectiveness of the programme, etc. The progressive reduction of *outbreak* incidence towards elimination of FMD virus transmission in all susceptible livestock in at least one *zone* of the country should also be measured and monitored.
 - h) Assessment of the evolution of the *official control programme* since the first date of implementation. This should include documented evidence demonstrating that the control programme has been implemented and that the first results are favourable. Measurable evidence of success such as the performance indicators should include, but not be limited to, *vaccination* data, decreased prevalence, successfully implemented import measures, control of animal movements and finally decrease or elimination of FMD *outbreaks* in the whole country or selected *zones* as described in the programme. Where relevant, the transition to the use of vaccines, which are fully compliant with the *Terrestrial Manual* in order to enable demonstration of no evidence of FMD virus transmission, should be included in the timeline. This should include documented evidence of the effective implementation of Sections 3 d) and 3 e) above.
 - i) Describe the funding for the control programme and annual budgets for its duration.
4. Control measures and emergency response
- a) List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of FMD. The contingency plan should be attached as an annex in one of the OIE official languages. If not available, provide a brief summary of what is covered. Provide information on any simulation exercise for FMD that was conducted in the country in the last five years.
 - b) In the event of a suspected or confirmed FMD *outbreak*:
 - i) Are quarantine measures imposed on *establishments* with suspected cases, pending final diagnosis? What other procedures are followed regarding suspected cases (e.g. livestock standstills)?
 - ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the pathogenic agent;
 - iii) Describe the actions that would be taken to control the disease situation in and around the *establishments* where the *outbreak* is confirmed;
 - iv) Describe in detail the control or *eradication* procedures (e.g. forward and backward tracing, *disinfection* of *establishments*, *vehicles* and equipment, including verification methods, *vaccination* including *vaccination* delivery and cold chain, *stamping-out policy*, movement control, control of *wildlife*, pastured livestock and livestock as pets, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;

- v) Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;
- vi) Provide details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;
- vii) Describe how control efforts, including *vaccination* and *biosecurity*, would target critical risk control points.

NB: FIRST ADOPTED IN 2009; MOST RECENT UPDATE ADOPTED IN 2018.

CHAPTER 1.12.

APPLICATION FOR OFFICIAL RECOGNITION BY THE OIE OF FREE STATUS FOR PESTE DES PETITS RUMINANTS

Article 1.12.1.

Country free from infection with peste des petits ruminants virus

The following information should be provided by OIE Member Countries to support applications for official recognition of status as a country free from *infection* with peste des petits ruminants (PPR) virus in accordance with Chapter 14.7. of the *Terrestrial Code*.

The dossier provided to the OIE should address concisely all the following topics under the headings provided to describe the actual situation in the country and the procedures currently applied, explaining how these comply with the *Terrestrial Code*.

The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

All annexes should be provided in one of the OIE official languages.

The Delegate of the Member Country applying for recognition of PPR freedom for a country must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Article 14.7.3. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that:

- 1) there has been no *outbreak* of PPR during the past 24 months;
- 2) no evidence of *infection* with PPR virus has been found during the past 24 months;
- 3) no *vaccination* against PPR has been carried out during the past 24 months;
- 4) importation of domestic ruminants and their semen, oocytes or embryos is carried out in accordance with Articles 14.7.8. to 14.7.26.

In addition, the Delegate of the Member Country applying for recognition of historical freedom must also submit documentary evidence that the provisions of point 1 a) of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.

1. Introduction

- a) Geographical features (rivers, mountain ranges, etc.). Provide a general description of the country and, where relevant, of the region, including physical, geographical and other factors that are relevant to introduction of *infection* and spread of PPR virus, taking into account the countries sharing common borders and other

epidemiologic pathways for the potential introduction of *infection*. Provide maps identifying the features above. Specify whether the application includes any noncontiguous territories.

- b) Livestock demographics. Describe the composition of the livestock industry in the country. In particular, describe:
- the susceptible animal *population* by species and types of production systems;
 - the number of *herds* or *flocks*, etc. of each susceptible species;
 - their geographical distribution;
 - herd* or *flock* density;
 - the degree of integration and role of producer organisations in the different production systems;
 - any recent significant changes observed in the production (attach relevant documents if available).
- Provide tables and maps.
- c) *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* 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 susceptible *wildlife* species?
- d) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic species for marketing within the country? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation, regulations and *Veterinary Authority* directives in relation to PPR and a brief description of the relevance of each. The table should include, but not be limited to, the legislation on disease control measures and compensation systems.
- b) *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, control, enforce and monitor all PPR-related activities. Provide maps, figures and tables wherever possible.
- c) Provide information on any OIE PVS evaluation conducted in the country and follow-up steps within the PVS Pathway and highlight the results relevant to PPR and the susceptible species.
- d) Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in PPR *surveillance* and control. Provide a description of the structure and role of the private veterinary sector, including the number of *veterinarians* and their distribution, in PPR *surveillance* and control. Include a description of continuing education and awareness programmes on PPR at all relevant levels.
- e) *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the traceability system, including methods of *animal identification* and *establishment* or *herd* or *flock* registration, applicable to all susceptible species. How are animal movements controlled in the country for all susceptible species? Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months. Provide information on pastoralism, transhumance and related paths of movement.
- Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g. seasonal migration for pastures and water).
- Describe the actions available under national legislation. Provide information on illegal movements detected in the past 24 months and the action taken.

3. PPR eradication

- a) History. If *infection* has never occurred in the country, or has not occurred within the past 25 years, state explicitly whether or not the country is applying for recognition of historical freedom according to point 1 a) of Article 1.4.6. of the *Terrestrial Code*.
- If *infection* has occurred in the country within the past 25 years, provide a description of the PPR history in the country, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, and the date of last *case* or *eradication* in the country.

- b) Strategy. Describe how PPR was controlled and eradicated (e.g. *stamping-out policy*, modified stamping-out policy, zoning, *vaccination*, movement control). Provide the time frame for *eradication*. Describe and justify the corrective actions that have been implemented to prevent future *outbreaks* of PPR in response to any past incursions of PPR virus.
- c) Vaccines and *vaccination*. Briefly answer the following:
- i) Is there any legislation that prohibits *vaccination*? If so:
 - Provide the date when *vaccination* was formally prohibited;
 - Provide information on cases of detection of illegal *vaccination* during the reporting period and actions taken in response to the detection.
 - ii) Was *vaccination* ever used in the country? If so:
 - Provide the date when the last *vaccination* was carried out;
 - What type of vaccine was used?
 - What species were vaccinated?
 - How were vaccinated animals identified?
 - What was the fate of those animals?
 - iii) In addition, if *vaccination* was applied during the past 24 months, provide a description and justification of the *vaccination* strategy and programme, including the following:
 - the vaccine strains;
 - the species vaccinated;
 - identification of vaccinated animals;
 - the way in which the *vaccination* of animals was certified or reported and the records maintained;
 - evidence that the vaccine used complies with Chapter 2.7.10. of the *Terrestrial Manual*.
- d) Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. PPR diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 2.7.10. of the *Terrestrial Manual* are applied. The following points should be addressed:

- a) Is PPR *laboratory* diagnosis carried out in the country? If so, provide an overview of the PPR-approved *laboratories* in the country, including the following:
- i) How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for reporting results;
 - ii) Details of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of PPR tests performed in the past 24 months in national *laboratories* and in *laboratories* in other countries, if relevant;
 - iii) Procedures for quality assurance and for the official accreditation of *laboratories*. Give details of formal internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;
 - iv) Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;
 - v) Provide details of the handling of live pathogenic agent, including a description of the biosecurity and biosafety measures applied;
 - vi) Provide a table identifying the tests carried out by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.
- b) If PPR *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

5. PPR surveillance

Provide documentary evidence that *surveillance* for PPR in the country complies with Articles 14.7.27. to 14.7.33. of the *Terrestrial Code*, and Chapter 2.7.10. of the *Terrestrial Manual*. The following information should be included:

- a) What are the criteria for raising a suspicion of PPR? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?

- b) Describe how clinical *surveillance* is conducted, including which sectors of the livestock production system are included in clinical *surveillance*, such as *establishments*, markets, fairs, *slaughterhouses/abattoirs*, check points, etc.

Provide a summary table indicating, for the past 24 months, the number of suspected cases, the number of samples tested for PPR, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude PPR. Provide details of follow-up actions taken on all suspicious and positive results.

- c) Serological *surveillance*. Are serological surveys conducted? If so, provide detailed information on the target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 14.7.27. to 14.7.33. of the *Terrestrial Code*. Are susceptible *wildlife* species included in serological surveys? If not, explain the rationale.

Provide a summary table indicating, for the past 24 months, the number of samples tested for PPR, species, type of sample, testing methods and results (including differential diagnosis). Provide details of follow-up actions taken on all suspicious and positive results and on how these findings are acted upon. Provide criteria for selection of *populations* for targeted surveillance and numbers of animals examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the *surveillance* programme including indicators.

- d) Provide information on risks in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g. targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.). Provide evidence of how the knowledge acquired through these activities assisted in more effective implementation of control measures.
- e) Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical and serological *surveillance*, and the approaches used to increase community involvement in PPR *surveillance* programmes.

6. PPR prevention

Describe the procedures in place to prevent the introduction of PPR into the country, including details of:

- a) Coordination with other countries. Describe any relevant factors in neighbouring countries that should be taken into account (e.g. size, distance from the border to affected *herds* or *flocks* or animals). Describe coordination, collaboration and information-sharing activities with other countries in the same region or ecosystem.

Are *protection zones* in place? If so, provide details of the measures that are applied (e.g. *vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the *zones*.

- b) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the spread of the pathogenic agent within the country. Provide evidence that measures to reduce transmission of PPR are in place at markets, such as enhancing awareness of PPR transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity*, hygiene and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).

- c) Import control procedures

Provide information on countries, *zones* or *compartments* from which the country authorises the import of susceptible animals or their products into the country. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied to entry of such animals and products, and subsequent internal movement. Describe the import measures (e.g. quarantine) 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 *international veterinary certificates* are required.

Describe any other procedures used for assessing the *risks* posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country.

- i) Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border posts*, and between *border posts*.

- ii) Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the country or their final destination, concerning the import and follow-up of the following:
 - animals;
 - genetic material (semen, oocytes and embryos);
 - animal products;
 - *veterinary medicinal products*;
 - other materials at risk of being contaminated with PPR virus.

7. Control measures and contingency planning

- a) List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of PPR. The contingency plan should be attached as an annex in one of the OIE official languages. If not available, provide a brief summary of what is covered. Provide information on any simulation exercise for PPR that was conducted in the country in the past five years.
- b) In the event of a suspected or confirmed PPR *outbreak*:
 - i) Are quarantine measures imposed on *establishments* with suspected *cases*, pending final diagnosis? What other procedures are followed with respect to suspected *cases* (e.g. livestock standstills)?
 - ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the pathogenic agent;
 - iii) Describe the actions that would be taken to control the disease situation in and around the *establishments* where the *outbreak* is confirmed;
 - iv) Provide a detailed description of the control or *eradication* procedures (e.g. forward and backward tracing, *disinfection of establishments, vehicles* and equipment, including verification methods, *vaccination, stamping-out policy*, movement control, control of *wildlife*, pastured sheep and goats, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers, etc.) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;
 - v) Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;
 - vi) Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;
 - vii) Describe how control efforts, including *vaccination* and *biosecurity*, would target critical risk control points.

8. Recovery of free status

Member Countries applying for recognition of recovery of free status for a country should comply with the provisions of Article 14.7.7. of the *Terrestrial Code* and provide detailed information as specified in Sections 1 to 7 of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Article 1.12.2.

Zone free from infection with peste des petits ruminants virus

The following information should be provided by OIE Member Countries to support applications for official recognition of status as a *zone* free from *infection* with peste des petits ruminants (PPR) virus in accordance with Chapter 14.7. of the *Terrestrial Code*.

The dossier provided to the OIE should address concisely all the following topics under the headings provided to describe the actual situation in the country and the procedures currently applied, explaining how these comply with the *Terrestrial Code*.

The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

All annexes should be provided in one of the OIE official languages.

The Delegate of the Member Country applying for recognition of PPR freedom for a *zone* must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Article 14.7.3. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that:

- 1) there has been no *outbreak* of PPR during the past 24 months;
- 2) no evidence of *infection* with PPR virus has been found during the past 24 months;
- 3) no *vaccination* against PPR has been carried out during the past 24 months;
- 4) importation of domestic ruminants and their semen, oocytes or embryos is carried out in accordance with Articles 14.7.8. to 14.7.26.

In addition, the Delegate of the Member Country applying for recognition of historical freedom must also submit documentary evidence that the provisions of point 1 a) of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.

1. Introduction

- a) Geographical features (rivers, mountain ranges, etc.). Provide a general description of the country and the *zone*, and where relevant of the region, including physical, geographical and other factors that are relevant to introduction of *infection* and spread of PPR virus, taking into account the countries or *zones* sharing common borders and other epidemiologic pathways for the potential introduction of *infection*.

The boundaries of the *zone* must be clearly defined, including a *protection zone* if applied. Provide maps identifying the features above, including a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zone*.

- b) Livestock demographics. Describe the composition of the livestock industry in the country and the *zone*. In particular, describe:
 - i) the susceptible animal *population* by species and types of production systems in the country and the *zone*;
 - ii) the number of *herds* or *flocks*, etc. of each susceptible species;
 - iii) their geographical distribution;
 - iv) *herd* or *flock* density;
 - v) the degree of integration and role of producer organisations in the different production systems;
 - vi) any recent significant changes observed in the production (attach relevant documents if available).

Provide tables and maps.

- c) *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* 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 susceptible *wildlife* species?
- d) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic species for marketing within the country or *zone*, and between *zones* of the same or different status? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation, regulations and *Veterinary Authority* directives in relation to PPR and a brief description of the relevance of each. The table should include, but not be limited to, the legislation on disease control measures and compensation systems.
- b) *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, control, enforce and monitor all PPR-related activities. Provide maps, figures and tables wherever possible.
- c) Provide information on any OIE PVS evaluation conducted in the country and follow-up steps within the PVS Pathway and highlight the results relevant to PPR and the susceptible species.

- d) Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in PPR *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, including the number of *veterinarians* and their distribution, in PPR *surveillance* and control. Include a description of continuing education and awareness programmes on PPR at all relevant levels.
- e) *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the traceability system, including methods of *animal identification* and *establishment* or *herd* or *flock* registration, applicable to all susceptible species. How are animal movements controlled in and between *zones* of the same or different status for all susceptible species? Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months. Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g. seasonal migration for pastures and water).

Describe the actions available under national legislation. Provide information on illegal movements detected in the past 24 months and the action taken.

3. PPR eradication

- a) History. If *infection* has never occurred in the *zone*, or has not occurred within the past 25 years, state explicitly whether or not the *zone* is applying for recognition of historical freedom according to point 1 a) of Article 1.4.6. of the *Terrestrial Code*.

If *infection* has occurred in the *zone* within the past 25 years, provide a description of the PPR history in the country and *zone*, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, and the date of last *case* or *eradication* in the *zone*.

- b) Strategy. Describe how PPR was controlled and eradicated in the *zone* (e.g. *stamping-out policy*, modified stamping-out policy, zoning, *vaccination*, movement control). Provide the time frame for *eradication*. Describe and justify the corrective actions that have been implemented to prevent future *outbreaks* of PPR in response to any past incursions of PPR virus.

- c) Vaccines and *vaccination*. Briefly answer the following:

- i) Is there any legislation that prohibits *vaccination*? If so:

- Provide the date when *vaccination* was formally prohibited;
- Provide information on cases of detection of illegal *vaccination* during the reporting period and actions taken in response to the detection.

- ii) Was *vaccination* ever used in the country? If so:

- Provide the date when the last *vaccination* was carried out;
- What type of vaccine was used in the *zone* and the rest of the country?
- What species were vaccinated?
- How were vaccinated animals identified?
- What was the fate of those animals?

- iii) In addition, if *vaccination* was applied during the past 24 months, provide a description and justification of the *vaccination* strategy and programme, including the following:

- the vaccine strains;
- the species vaccinated;
- identification of vaccinated animals;
- the way in which the *vaccination* of animals was certified or reported and the records maintained;
- evidence that the vaccine used complies with Chapter 2.7.10. of the *Terrestrial Manual*.

- d) Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. PPR diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 2.7.10. of the *Terrestrial Manual* are applied. The following points should be addressed:

- a) Is PPR *laboratory* diagnosis carried out in the country? If so, provide an overview of the PPR-approved *laboratories* in the country. Indicate the *laboratories* where samples originating from the *zone* are diagnosed. Address the following points:
 - i) How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for reporting results;
 - ii) Details of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of PPR tests performed in the past 24 months in national *laboratories* and in *laboratories* in other countries, if relevant;
 - iii) Procedures for quality assurance and for the official accreditation of *laboratories*. Give details of formal internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;
 - iv) Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;
 - v) Provide details of the handling of live pathogenic agent, including a description of the biosecurity and biosafety measures applied;
 - vi) Provide a table identifying the tests carried out by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.
- b) If PPR *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

5. PPR surveillance

Provide documentary evidence that *surveillance* for PPR in the *zone* complies with Articles 14.7.27. to 14.7.33. of the *Terrestrial Code* and Chapter 2.7.10. of the *Terrestrial Manual*. The following information should be included:

- a) What are the criteria for raising a suspicion of PPR? What is the procedure to notify (by whom and to whom), what incentives are there for reporting and what penalties are involved for failure to report?
- b) Describe how clinical *surveillance* is conducted, including which sectors of the livestock production system are included in clinical *surveillance*, such as *establishments*, markets, fairs, *slaughterhouses/abattoirs*, check points, etc.
Provide a summary table indicating, for the past 24 months, the number of suspected cases, the number of samples tested for PPR, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude PPR. Provide details of follow-up actions taken on all suspicious and positive results.
- c) Serological *surveillance*. Are serological surveys conducted? If so, provide detailed information on the target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 14.7.27. to 14.7.33. of the *Terrestrial Code*. Are susceptible *wildlife* species included in serological surveys? If not, explain the rationale.
Provide a summary table indicating, for the past 24 months, the number of samples tested for PPR, species, type of sample, testing methods and results (including differential diagnosis). Provide details of follow-up actions taken on all suspicious and positive results and on how these findings are acted upon. Provide criteria for selection of *populations* for targeted surveillance and numbers of animals examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the *surveillance* programme including indicators.
- d) Provide information on risks in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g. targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.). Provide evidence of how knowledge acquired through these activities assisted in more effective implementation of control measures.
- e) Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical and serological *surveillance*, and the approaches used to increase community involvement in PPR *surveillance* programmes.

6. PPR prevention

Describe the procedures in place to prevent the introduction of PPR into the country or *zone*, including details of:

- a) Coordination with other countries. Describe any relevant factors in neighbouring countries and *zones* that should be taken into account (e.g. size, distance from the border to affected *herds* or *flocks* or animals).

Describe coordination, collaboration and information-sharing activities with other countries and *zones* in the same region or ecosystem.

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

Are *protection zones* in place? If so, indicate whether or not the *protection zones* are included in the proposed free *zones*. Provide details of the measures that are applied (e.g. *vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the *zones*.

- b) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the spread of the pathogenic agent within the country or *zone*. Provide evidence that measures to reduce transmission of PPR are in place at markets, such as enhancing awareness of PPR transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity*, hygiene and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).

- c) Import control procedures

Provide information on countries, *zones* or *compartments* 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, *zones* or *compartments*, the controls applied to entry of such animals and products, and subsequent internal movement. Describe the import measures (e.g. quarantine) 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 *international veterinary certificates* are required.

Describe any other procedures used for assessing the *risks* posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country or *zone*.

- i) Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border posts*, and between *border posts*.

- ii) Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the *zone* or their final destination, concerning the import and follow-up of the following:

- animals;
- genetic material (semen, oocytes and embryos);
- animal products;
- *veterinary medicinal products*;
- other materials at risk of being contaminated with PPR virus.

7. Control measures and contingency planning

- a) List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of PPR. The contingency plan should be attached as an annex in one of the OIE official languages. If not available, provide a brief summary of what is covered. Provide information on any simulation exercise for PPR that was conducted in the country in the past five years.

- b) In the event of a suspected or confirmed PPR *outbreak*:

- i) Are quarantine measures imposed on *establishments* with suspected *cases*, pending final diagnosis? What other procedures are followed with respect to suspected *cases* (e.g. livestock standstills)?

- ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the pathogenic agent;

- iii) Describe the actions that would be taken to control the disease situation in and around the *establishments* where the *outbreak* is confirmed;

- iv) Provide a detailed description of the control or *eradication* procedures (e.g. forward and backward tracing, *disinfection* of *establishments*, *vehicles* and equipment, including verification methods, *vaccination*, *stamping-out policy*, movement control, control of *wildlife*, pastured sheep and goats, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers, etc.) that would be taken; in the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;
- v) Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;
- vi) Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;
- vii) Describe how control efforts, including *vaccination* and *biosecurity*, would target critical risk control points.

8. Recovery of free status

Member Countries applying for recognition of recovery of free status for a *zone* should comply with the provisions of Article 14.7.7. of the *Terrestrial Code* and provide detailed information as specified in Sections 1 to 7 of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Article 1.12.3.

Application for endorsement by the OIE of an official control programme for peste des petits ruminants

The following information should be provided by OIE Member Countries to support applications for endorsement by the OIE of an *official control programme* for peste des petits ruminants (PPR) in accordance with Chapter 14.7. of the *Terrestrial Code*.

The dossier provided to the OIE should address concisely all the topics under the headings provided in Sections 1 to 4 to describe the actual situation in the country and the procedures currently applied, explaining how these comply with the *Terrestrial Code*.

In Sections 3 f) to 3 i) describe concisely the work plan and timelines of the control programme for the next five years.

The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

All annexes should be provided in one of the OIE official languages.

The Delegate of the Member Country applying for endorsement of the *official control programme* should submit documentary evidence that the provisions of Article 14.7.34. have been properly implemented and supervised. In addition, the Delegate of the Member Country must submit the detailed national official control programme for PPR.

1. Introduction

- a) Geographical features (rivers, mountain ranges, etc.). Provide a general description of the country and *zones*, and where relevant of the region, including physical, geographical and other factors that are relevant to introduction of *infection* and spread of PPR virus, taking into account the countries or *zones* sharing common

borders and other epidemiologic pathways for the potential introduction of *infection*. Provide maps identifying the features above. Specify whether the application includes any noncontiguous territories.

- b) If the endorsed plan is implemented in stages to specific parts of the country, the boundaries of the *zones* should be clearly defined, including the *protection zones* if applied. Provide a digitalised, geo-referenced map with a description of the geographical boundaries of the *zones*.
- c) Livestock demographics. Describe the composition of the livestock industry in the country and any *zones*. In particular, describe:
 - i) the susceptible animal *population* by species and types of production systems;
 - ii) the number of *herds* or *flocks*, etc. of each susceptible species;
 - iii) their geographical distribution;
 - iv) *herd* or *flock* density;
 - v) the degree of integration and role of producer organisations in the different production systems;
 - vi) any recent significant changes observed in the production (attach relevant documents if available).

Provide tables and maps.

- d) *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* species are present in the country and any *zones*? Provide estimates of *population* sizes and geographic distribution. What are the measures in place to prevent contact between domestic and susceptible *wildlife* species?
- e) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic species for marketing within the country? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation, regulations and *Veterinary Authority* directives in relation to the PPR control programme and a brief description of the relevance of each. The table should include, but not be limited to, the legislation on disease control measures and compensation systems.
- b) *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, control, enforce and monitor all PPR-related activities. Provide maps, figures and tables wherever possible.
- c) Provide information on any OIE PVS evaluation conducted in the country and follow-up steps within the PVS Pathway and highlight the results relevant to PPR and the susceptible species.
- d) Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in PPR *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, including the number of *veterinarians* and their distribution, in PPR *surveillance* and control. Include a description of continuing education and awareness programmes on PPR at all relevant levels.
- e) *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the traceability system, including methods of *animal identification* and *establishment* or *herd* or *flock* registration applicable to all susceptible species. How are animal movements controlled in the country for all susceptible species? Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months. Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g. seasonal migration for pastures and water).

Describe the actions available under national legislation. Provide information on illegal movements detected in the past 24 months and the action taken.

3. Official control programme for PPR submitted for OIE endorsement

Submit a concise plan of the measures for the control and eventual *eradication* of PPR in the country, including:

a) Epidemiology

- i) Describe the PPR history in the country, with emphasis on recent years. Provide tables and maps showing the date of first detection, the number and location of *outbreaks* per year, the sources and routes of introduction of *infection*, the types and lineages present, the susceptible species involved and the date of implementation of the control programme in the country.
- ii) Describe the epidemiological situation of PPR in the country and the surrounding countries or *zones* highlighting the current knowledge and gaps. Provide maps of:
 - the geography of the country with the relevant information concerning PPR situation;
 - small ruminant density and movements and estimated PPR prevalence.

b) PPR surveillance

Provide documentary evidence that *surveillance* for PPR in the country complies with Articles 14.7.27. to 14.7.33. of the *Terrestrial Code*, and Chapter 2.7.10. of the *Terrestrial Manual*. The following information should be included :

- i) What are the criteria for raising a suspicion of PPR? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?
- ii) Describe how clinical *surveillance* is conducted, including which sectors of the livestock production system are included in clinical *surveillance*, such as *establishments*, markets, fairs, *slaughterhouses/abattoirs*, check points, etc. Provide details of follow-up actions taken on clinical suspicions.
- iii) Serological or virological *surveillance*. Explain whether or not serological or virological surveys are conducted and, if so, how frequently and for what purpose. Provide detailed information on the target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 14.7.27. to 14.7.33. of the *Terrestrial Code*. Are susceptible *wildlife* species included in serological or virological surveys? If not, explain the rationale.

Provide a summary table indicating, for at least the past 24 months, the number of suspected *cases*, the number of samples tested for PPR, species, type of sample, testing methods and results (including differential diagnosis). Provide procedural details of follow-up actions taken on suspicious and positive results and on how these findings are interpreted and acted upon.

Provide criteria for selection of *populations* for targeted surveillance and numbers of animals examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the *surveillance* programme including indicators.

- iv) Provide information on the level of *risk* in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g. targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.) and that the acquired knowledge assists in more effective implementation of control measures.
- v) Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in PPR *surveillance* programmes.
- vi) Provide evidence that surveys are carried out to assess *vaccination* coverage and population immunity of the target populations, show analysis of *surveillance* data to assess the change in PPR prevalence over time in the target populations, assess the control measures (cost effectiveness, degree of implementation, impact). Provide information on outcomes of *outbreak* investigations including *outbreaks* that have occurred despite control measures, documented inspections showing compliance with biosecurity and hygiene requirements.

c) PPR diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 2.7.10. of the *Terrestrial Manual* are applied. The following points should be addressed:

- i) Is PPR *laboratory* diagnosis carried out in the country? If so, provide an overview of the PPR-approved *laboratories* in the country, including the following:
 - How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for reporting results;
 - Details of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of PPR tests performed in the past 24 months in national *laboratories* and in *laboratories* in other countries, if relevant;
 - Procedures for quality assurance and, if available, the official accreditation of *laboratories*. Give details of formal internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;
 - Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;
 - Provide details of the handling of live pathogenic agent, including a description of the biosecurity and biosafety measures applied;
 - Provide a table identifying the tests carried out by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.
- ii) If PPR *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

d) Strategies

- i) Provide a description of the legislation, organisation and implementation of the current PPR control programme. Outline the legislation applicable to the control programme and how its implementation is organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.
- ii) Describe PPR control strategies in the country or any *zones*, including in terms of animal movement control, fate of infected and in-contact animals and *vaccination*. Strategies should be based on the assessment of the PPR situation in the *zones*, country and region.
- iii) Provide information on what types of vaccines are used and which species are vaccinated. Provide evidence that the vaccine used complies with Chapter 1.1.8. of the *Terrestrial Manual*. Provide information on the licensing process for the vaccines used. Describe the *vaccination* programme in the country and any *zones*, including records kept, and provide evidence to show its effectiveness, such as *vaccination* coverage, population immunity, etc. Provide details of the studies carried out to determine the *vaccination* coverage and the population immunity, including the study designs and the results.
- iv) Describe how the *stamping-out policy* is implemented in the country or any *zones* and under which circumstances.
- v) In the event of *outbreaks*, provide evidence of the impact of the control measures already implemented on the reduction in number of *outbreaks* and their distribution. If possible, provide information on primary and secondary *outbreaks*.

e) PPR prevention

Describe the procedures in place to prevent the introduction of PPR into the country, including details of:

- i) Coordination with other countries. Describe any relevant factors in neighbouring countries and *zones* that should be taken into account (e.g. size, distance from the border to affected *herds* or *flocks* or animals). Describe coordination, collaboration and information-sharing activities with other countries and *zones* in the same region or ecosystem.

Are *protection zones* in place? If so, provide details of the measures that are applied (e.g. *vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the *zones*.

- ii) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the spread of the pathogenic agent within the country or *zone*. Provide evidence that measures to reduce transmission of PPR are in place at markets, such as enhancing awareness of PPR transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity*, hygiene and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).
- iii) Import control procedures
- Provide information on countries, *zones* or *compartments* from which the country authorises the import of susceptible animals or their products into the country or any *zones*. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied to entry of such animals and products and subsequent internal movement. Describe the import measures (e.g. quarantine) 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 *international veterinary certificates* are required.
- Describe any other procedures used for assessing the *risks* posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.
- Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border posts*, and between *border posts*.
 - Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the country or their final destination, concerning the import and follow-up of the following:
 - animals;
 - genetic material (semen, oocytes and embryos);
 - animal products;
 - *veterinary medicinal products*;
 - other materials at risk of being contaminated with PPR virus.
- iv) Describe the actions available under national legislation. Provide information on illegal movements detected in the past 24 months and the action taken.
- f) Work plan and timelines of the control programme for the next five years, including cessation of *vaccination*. Describe the progressive objectives including expected status to be achieved in the next five years: for *zones* (if applicable) and for the whole country.
- g) Performance indicators and timeline. The performance indicators should relate to the most important areas and steps where improvements in the programme are needed. These may include, but are not restricted to, strengthening *Veterinary Services*, legislation, reporting, availability and quality of vaccines, *animal identification* systems, *vaccination* coverage, population immunity, movement control, disease awareness, livestock owners' participatory perception on the effectiveness of the programme, etc. The progressive reduction of *outbreak* incidence towards elimination of PPR virus transmission in all susceptible livestock in at least one *zone* of the country should also be measured and monitored.
- h) Assessment of the evolution of the *official control programme* since the first date of implementation. This should include documented evidence demonstrating that the control programme has been implemented and that the first results are favourable. Measurable evidence of success such as the performance indicators should include, but not be limited to, *vaccination* data, decreased prevalence, successfully implemented import measures, control of animal movements and finally decrease or elimination of PPR *outbreaks* in the whole country or selected *zones* as described in the programme. This should include documented evidence of the effective implementation of Sections 3 d) to 3 e) above.
- i) Describe the funding for the control programme and annual budgets for its duration.

4. Control measures and emergency response

- a) List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of PPR. The contingency plan should be attached as an annex in one of the OIE official languages. If not available, provide a brief summary of what is covered. Provide information on any simulation exercise for PPR that was conducted in the country in the past five years.
- b) In the event of a suspected or confirmed PPR *outbreak*:
 - i) Are quarantine measures imposed on *establishments* with suspected cases, pending final diagnosis? What other procedures are followed regarding suspected cases (e.g. livestock standstills)?
 - ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the pathogenic agent;
 - iii) Describe the actions that would be taken to control the disease situation in and around the *establishments* where the *outbreak* is confirmed;
 - iv) Describe in detail the control or *eradication* procedures (e.g. forward and backward tracing, *disinfection* of *establishments*, *vehicles* and equipment, including verification methods, *vaccination*, *stamping-out policy*, movement control, control of *wildlife*, pastured sheep and goats, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;
 - v) Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;
 - vi) Provide details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;
 - vii) Describe how control efforts, including *vaccination* and *biosecurity*, would target critical risk control points.

NB: FIRST ADOPTED IN 2009; MOST RECENT UPDATE ADOPTED IN 2018.

SECTION 2.

RISK ANALYSIS

CHAPTER 2.1.

IMPORT RISK ANALYSIS

Article 2.1.1.

Introduction

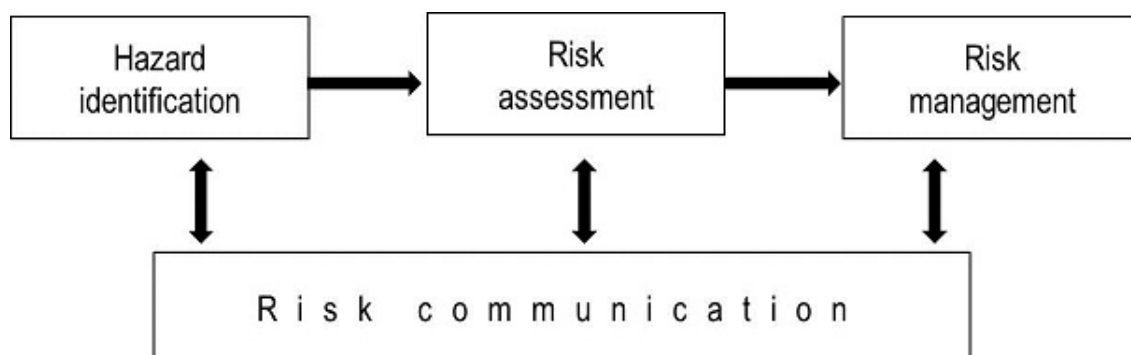
The importation of *animals* and animal products involves a certain level of disease *risk* to the *importing country*. This *risk* may be represented by one or several diseases, *infections* or *infestations*.

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. Transparency means the comprehensive documentation and communication of all data, information, assumptions, methods, results, discussion and conclusions used in the *risk analysis*. This is necessary so that the *exporting country* and all interested parties are 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 provides recommendations and principles for conducting transparent, objective and defensible *risk analyses* for *international trade*. The components of *risk analysis* 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 *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 *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 *hazards* or not. The *risk assessment* may be concluded if *hazard* identification fails to identify *hazards* associated with the importation.

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

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

Article 2.1.3.

Principles of risk assessment

- 1) *Risk assessment* should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. *Risk assessment* should be able to accommodate the variety of animal *commodities*, the multiple *hazards* that may be identified with an importation and the specificity of each disease, detection and *surveillance* systems, exposure scenarios and types and amounts of data and information.
- 2) Both *qualitative risk assessment* and *quantitative risk assessment* methods are valid.
- 3) The *risk assessment* should be based on the best available information that is in accord with current scientific thinking. The assessment should be well-documented and supported with references to the scientific literature and other sources, including expert opinion.
- 4) Consistency in *risk assessment* methods should be encouraged and transparency is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding by all the interested parties.
- 5) *Risk assessments* should document the uncertainties, the assumptions made, and the effect of these on the final *risk* estimate.
- 6) *Risk* increases with increasing volume of *commodity* imported.
- 7) The *risk assessment* should be amenable to updating when additional information becomes available.

Article 2.1.4.

Risk assessment steps

1. Entry assessment

Entry assessment consists of describing the biological pathways necessary for an importation activity to introduce pathogenic agents into a particular environment, and estimating the probability of that complete process occurring, either qualitatively (in words) or quantitatively (as a numerical estimate). The entry assessment describes the probability of the 'entry' of each of the *hazards* (the pathogenic agents) under each specified set of conditions with

respect to amounts and timing, and how these might change as a result of various actions, events or measures. Examples of the kind of inputs that may be required in the entry assessment are:

- a) Biological factors
 - species, age and breed of *animals*
 - agent predilection sites
 - *vaccination*, testing, treatment and quarantine.
- b) Country factors
 - incidence or prevalence
 - evaluation of *Veterinary Services*, *surveillance* and control programmes and zoning and compartmentalisation systems of the *exporting country*.
- c) Commodity factors
 - quantity of *commodity* to be imported
 - ease of contamination
 - effect of processing
 - effect of storage and transport.

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

2. Exposure assessment

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

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

- a) Biological factors
 - properties of the agent.
- b) Country factors
 - presence of potential *vectors*
 - human and animal demographics
 - customs and cultural practices
 - geographical and environmental characteristics.
- c) Commodity factors
 - quantity of *commodity* to be imported
 - intended use of the imported *animals* or products
 - disposal practices.

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

3. Consequence assessment

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

- a) Direct consequences
 - animal *infection*, disease and production losses
 - public health consequences.
- b) Indirect consequences
 - *surveillance* and control costs
 - compensation costs

- potential trade losses
- adverse consequences to the environment.

4. Risk estimation

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

For a quantitative assessment, the final outputs may include:

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

Article 2.1.5.

Principles of risk management

- 1) *Risk management* is the process of deciding upon and implementing measures to address the *risks* identified in the *risk assessment*, whilst at the same time ensuring that negative effects on trade are minimised. The objective is to manage *risk* appropriately to ensure that a balance is achieved between a country's desire to minimise the likelihood or frequency of disease incursions and their consequences and its desire to import *commodities* and fulfil its obligations under *international trade* agreements.
- 2) The international standards of the OIE are the preferred choice of *sanitary measures* for *risk management*. The application of these *sanitary measures* should be in accordance with the intentions in the standards.

Article 2.1.6.

Risk management components

- 1) Risk evaluation - the process of comparing the *risk* estimated in the *risk assessment* with the reduction in *risk* expected from the proposed *risk management* measures.
- 2) Option evaluation - the process of identifying, evaluating the efficacy and feasibility of, and selecting measures to reduce the *risk* associated with an importation. The efficacy is the degree to which an option reduces the likelihood or magnitude of adverse health and economic consequences. Evaluating the efficacy of the options selected is an iterative process that involves their incorporation into the *risk assessment* and then comparing the resulting level of *risk* with that considered acceptable. The evaluation for feasibility normally focuses on technical, operational and economic factors affecting the implementation of the *risk management* options.
- 3) Implementation - the process of following through with the *risk management* decision and ensuring that the *risk management* measures are in place.
- 4) Monitoring and review - the ongoing process by which the *risk management* measures are continuously audited to ensure that they are achieving the results intended.

Article 2.1.7.

Principles of risk communication

- 1) *Risk communication* is the process by which information and opinions regarding *hazards* and *risks* are gathered from potentially affected and interested parties during a *risk analysis*, and by which the results of the *risk assessment* and proposed *risk management* measures are communicated to the decision-makers and interested parties in the *importing* and *exporting countries*. It is a multidimensional and iterative process and should ideally begin at the start of the *risk analysis* process and continue throughout.
- 2) A *risk communication* strategy should be put in place at the start of each *risk analysis*.
- 3) The *communication of the risk* should be an open, interactive, iterative and transparent exchange of information that may continue after the decision on importation.

- 4) The principal participants in *risk communication* include the authorities in the *exporting country* and other stakeholders such as domestic and foreign industry groups, domestic livestock producers and consumer groups.
- 5) The assumptions and uncertainty in the model, model inputs and the *risk* estimates of the *risk assessment* should be communicated.
- 6) Peer review is a component of *risk communication* in order to obtain scientific critique and to ensure that the data, information, methods and assumptions are the best available.

NB: FIRST ADOPTED IN 1998; MOST RECENT UPDATE ADOPTED IN 2018.

CHAPTER 2.2.

CRITERIA APPLIED BY THE OIE FOR ASSESSING THE SAFETY OF COMMODITIES

Article 2.2.1.

General provisions

For the purposes of this chapter the word 'safety' is applied only to animal and human health considerations for *listed diseases*.

In many disease-specific chapters, the second article lists *commodities* that can be traded from a country or *zone* regardless of its status with respect to the specific *listed disease*. The criteria for their inclusion in the list of *safe commodities* are based on the absence of the pathogenic agent in the traded *commodity*, either due to its absence in the tissues from which the *commodity* is derived or to its inactivation by the processing or treatment that the *animal* products have undergone.

The assessment of the safety of the *commodities* using the criteria relating to processing or treatment can only be undertaken when processing or treatments are well defined. It may not be necessary to take into account the entire process or treatment, so long as the steps critical for the inactivation of the pathogenic agent of concern are considered.

For the criteria in Article 2.2.2. to be applied, it is expected that processing or treatment (i) uses standardised protocols, which include the steps considered critical in the inactivation of the pathogenic agent of concern; (ii) is conducted in accordance with Good Manufacturing Practices; and (iii) that any other steps in the treatment, processing and subsequent handling of the *animal* product do not jeopardise its safety.

Article 2.2.2.

Criteria

For an *animal* product to be considered a *safe commodity* for *international trade* as described in the User's guide and Article 2.2.1., it should comply with the following criteria:

- 1) There is strong evidence that the pathogenic agent is not present in the tissues from which the *animal* product is derived in an amount able to cause *infection* in a human or *animal* by a natural exposure route. This evidence is based on the known distribution of the pathogenic agent in an infected *animal*, whether or not it shows clinical signs of disease.

OR

- 2) If the pathogenic agent may be present in, or may contaminate, the tissues from which the *animal* product is derived, the standard processing or treatment applied to produce the *commodity* to be traded, while not being specifically directed at this pathogenic agent, inactivates it to the extent that possible *infection* of a human or *animal* is prevented through its action, which is:
 - a) physical (e.g. temperature, drying, irradiation);OR
 - b) chemical (e.g. iodine, pH, salt, smoke);OR
 - c) biological (e.g. fermentation);OR
 - d) a combination of a) to c) above.

NB: FIRST ADOPTED IN 2017; MOST RECENT UPDATE ADOPTED IN 2018.

SECTION 3.

QUALITY OF VETERINARY SERVICES

CHAPTER 3.1.

VETERINARY SERVICES

Article 3.1.1.

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

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

The same fundamental principles should apply in countries where the responsibility for establishing or applying certain animal health or *animal 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 able to anticipate the requirements for, and 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 *Terrestrial Code*. Adequate coverage of animal populations should also be demonstrated. They should at all times endeavour to improve their performance in terms of animal health information systems and animal disease control.

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

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

8. Quality policy

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

9. Procedures and standards

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

- a) programming and management of activities, including international veterinary certification activities;
- b) prevention, control and notification of disease *outbreaks*;
- c) *risk analysis*, epidemiological *surveillance* and zoning;
- d) emergency preparedness for disasters which could have impact on animal health and *animal welfare*;
- e) inspection and sampling techniques;
- f) diagnostic tests for animal diseases;
- g) preparation, production, registration and control of biological products for use in the diagnosis or prevention of diseases;
- h) border controls and import regulations;
- i) *disinfection* and *disinfestation*;

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

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

10. Information, complaints and appeals

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

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

11. Documentation

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

12. Self-evaluation

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

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

13. Communication

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

14. Human and financial resources

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

Article 3.1.3.

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

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

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

Article 3.1.4.

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

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

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

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

In the event of a dispute between two Member Countries over the conduct or the conclusions of the evaluation of the *Veterinary Services*, the matter should be dealt with having regard to the procedures set out in Article 5.3.8.

Article 3.1.5.

Evaluation facilitated by OIE experts under the auspices of the OIE

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

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

Under these procedures, the Director General of the OIE recommends experts from that list.

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

The experts produce a report in consultation with the *Veterinary Services* of the Member Country.

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

NB: FIRST ADOPTED IN 1998; MOST RECENT UPDATE ADOPTED IN 2014.

CHAPTER 3.2.

**EVALUATION OF
VETERINARY SERVICES**

Article 3.2.1.

General considerations

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

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

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

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

- 3) The purpose of evaluation may be either to assist a national authority in the decision-making process regarding priorities to be given to its own *Veterinary Services* (self-evaluation) or to assist the process of *risk analysis in international trade in animals* and animal-derived products to which official sanitary or zoonosanitary controls apply.
- 4) In both situations, the evaluation should demonstrate that the *Veterinary Services* have the capability for effective control of the sanitary and zoonosanitary status of *animals* and animal products. Key elements to be covered in this process include adequacy of resources, management capability, legislative and administrative infrastructures, independence in the exercise of official functions and history of performance, including disease reporting.
- 5) Good governance is the key to competence, integrity and confidence in organisations. Mutual confidence between relevant official *Veterinary Services* of trading partner countries contributes fundamentally to stability in *international trade in animals* and animal-related products. In this situation, scrutiny is directed more at the *exporting country* than at the *importing country*.
- 6) Although quantitative data can be provided on *Veterinary Services*, the ultimate evaluation will be essentially qualitative. While it is appropriate to evaluate resources and infrastructure (organisational, administrative and legislative), it is also appropriate to place emphasis on the evaluation of the quality of outputs and performance of *Veterinary Services*. Evaluation should take into consideration any quality systems used by *Veterinary Services*.
- 7) An *importing country* has a right of assurance that information on sanitary or zoonosanitary situations provided by the *Veterinary Services* of an *exporting country* is objective, meaningful and correct. Furthermore, the *Veterinary Services* of the *importing country* are entitled to expect validity in the veterinary certification of export.
- 8) An *exporting country* is entitled to expect that its *animals* and animal products will receive reasonable and valid treatment when they are subjected to import inspection in the country of destination. The country should also be able to expect that any evaluation of its standards and performance will be conducted on a non-discriminatory basis. The *importing country* should be prepared and able to defend any position which it takes as a consequence of the evaluation.
- 9) As the *veterinary statutory body* is not a part of the *Veterinary Services*, an evaluation of that body should be carried out to ensure that the registration or licensing of *veterinarians* and authorisation of *veterinary paraprofessionals* 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 Member Countries' obligations.
- 2) To complement the evaluation of *Veterinary Services*, the legislative and regulatory framework, the organisational structure and functioning of the *veterinary statutory body* should also be considered.
- 3) Article 3.2.14. outlines appropriate information requirements for:
 - self-evaluation by the *Veterinary Authority* which perceives a need to prepare information for national or international purposes;
 - evaluation by a prospective or actual *importing country* of the *Veterinary Services* of a prospective or actual *exporting country*;
 - verification or re-verification of an evaluation in the course of a visit to the *exporting country* by the *importing country*;
 - evaluation by third parties such as OIE PVS experts or regional organisations.

Article 3.2.3.

Evaluation criteria for the organisational structure of the Veterinary Services

- 1) A key element in the evaluation is the study of the organisation and structure of the official *Veterinary Services*. The *Veterinary Services* should define and set out their policy, objectives and commitment to quality systems and standards. These organisational and policy statements should be described in detail. Organisational charts and details of functional responsibilities of staff should be available for evaluation. The role and responsibility of the Chief Veterinary Officer/Veterinary Director should be clearly defined. Lines of command should also be described.
- 2) The organisational structure should also clearly set out the interface relationships of government Ministers and departmental Authorities with the Chief Veterinary Officer/Veterinary Director and the *Veterinary Services*. Formal relationships with statutory authorities and with industry organisations and associations should also be described. It is recognised that Services may be subject to changes in structure from time to time. Major changes should be notified to trading partners so that the effects of re-structuring may be assessed.
- 3) Organisational components of *Veterinary Services* which have responsibility for key functional capabilities should be identified. These capabilities include epidemiological *surveillance*, disease control, import controls, animal disease reporting systems, *animal identification systems*, traceability systems, animal movement control systems, communication of epidemiological information, training, inspection and certification. Laboratory and field systems and their organisational relationships should be described.
- 4) To reinforce the reliability and credibility of their services, the *Veterinary Services* may have set up quality systems that correspond with their fields of activity and to the nature and scale of activities that they carry out. Evaluation of such systems should be as objective as possible.
- 5) The *Veterinary Authority* alone speaks for the country as far as official international dialogue is concerned. This is also particularly important to cases where zoning and compartmentalisation are being applied. The responsibilities of the *Veterinary Authority* should be made clear in the process of evaluation of *Veterinary Services*.
- 6) The *Veterinary Authority* is defined in the Glossary. 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 paraprofessionals*. The human resources may also include part-time and private sector *veterinarians* and *veterinary paraprofessionals*. 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 paraprofessionals* 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 paraprofessionals* 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 paraprofessionals*) need fixed, mobile and budgetary resources for animal health activities in the livestock farming territory of the country. If deficiencies are evident, there would be reason to challenge the validity of epizootiological information.

Article 3.2.6.

Evaluation criteria for material resources

1. Financial

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

2. Administrative

a) Accommodation

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

b) Communications

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

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

c) Transport systems

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

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

3. Technical

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

a) Cold chain for laboratory samples and veterinary medicines

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

b) Diagnostic laboratories

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

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

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

c) Research

The scope of animal health, *animal welfare* 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. This information should be accessible for evaluation purposes.

Article 3.2.7.

Legislation and functional capabilities1. 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 anticipate and exercise control over all animal health and *animal welfare* matters. These controls should include, where appropriate, compulsory notification of prescribed animal diseases, inspection, movement controls through systems which provide adequate traceability, registration of facilities, quarantine of infected premises or areas, testing, treatment, humane *killing* of infected *animals*, disposal of carcasses, or destruction of contaminated materials, controls over the use of veterinary medicines, etc. The scope of the legislative controls should include domestic *animals* and their reproductive material, animal products, *wildlife* as it relates to the transmission of diseases to humans and domestic *animals*, and other products subject to veterinary inspection. Arrangements should exist for co-operation with the *Veterinary Authorities* of the neighbouring countries for the control of animal diseases in border areas and for establishing linkages to recognise and regulate transboundary activities. Within the structure of *Veterinary Services*, there should be appropriately qualified personnel whose responsibilities include *animal welfare*. Information on the veterinary public health legislation covering the production of products of animal origin for national consumption may be also considered in the evaluation.

2. Export and import inspection

The *Veterinary Authority* should have appropriate legislation and adequate capabilities to prescribe the methods for control and to exercise systematic control over the import and export processes of *animals* 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* pre-export period.

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

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

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

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

Article 3.2.8.

Animal health controls1. 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 a Member Country, failure to provide the necessary animal health reports consistent with OIE requirements will detract from the overall outcome of the evaluation of the country.

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

2. Animal health control

Details of current animal disease control programmes should be considered in the evaluation. These programmes would include epidemiological *surveillance*, official government-administered or officially-endorsed, industry-administered control or eradication programmes for specific diseases or disease complexes, and animal disease emergency preparedness. Details should include enabling legislation, programme plans for epidemiological *surveillance* and animal disease emergency responses, quarantine arrangements for infected and exposed *animals, herds or flocks*, 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 programmes1. Strategic plans

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

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

2. Performance assessment

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

3. Compliance

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

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

e) Publications

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

f) Formal linkages with sources of independent scientific expertise

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

g) Trade performance history

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

Article 3.2.11.

Participation in OIE activities

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

Article 3.2.12.

Evaluation of the veterinary statutory body1. Scope

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

- a) objectives and functions;
- b) legislative basis for the *veterinary statutory body*, including autonomy and functional capacity;
- c) the composition of the *veterinary statutory body*, including the organisation represented in it;
- d) accountability and transparency of decision-making;
- e) sources and management of funding;
- f) administration of training programmes and continuing professional development for *veterinarians* and *veterinary paraprofessionals*.

2. Evaluation of objectives and functions

The policy and the objectives of the *veterinary statutory body*, including details of its power and functions, should be defined, notably with regard to:

- a) the licensing or registration of *veterinarians* and *veterinary paraprofessionals* to perform the activities of veterinary medicine/science;
- b) the minimum standards of education (initial and continuing) required for degrees, diplomas and certificates entitling the holders thereof to be registered or licensed as *veterinarians* and *veterinary paraprofessionals*;
- c) the standards of professional conduct and competence of *veterinarians* and *veterinary paraprofessionals* and ensuring that these standards are met.

3. Evaluation of legislative basis, autonomy and functional capacity

The *veterinary statutory body* should be able to demonstrate that it has the capacity, supported by appropriate legislation, to exercise and enforce control over all *veterinarians* and *veterinary paraprofessionals* subject to its authority. These controls should include, where appropriate, compulsory licensing or registration, participation in the definition of minimum standards of education (initial and continuing) for the recognition of degrees, diplomas and certificates by the *Competent Authority*, setting standards of professional conduct and competence, investigating complaints and the application of disciplinary procedures.

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

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

4. Evaluation of the composition of the veterinary statutory body

Detailed descriptions of the composition, rules and conditions for membership, including duration of appointment and representation of interested third parties, public and private, should be available.

5. Evaluation of accountability and transparency of decision-making

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

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

6. Evaluation of financial sources and financial management

Information regarding income and expenditure, including fee structures for the licensing or registration of persons should be available.

7. Evaluation of training programmes and programmes for continuing professional development, for veterinarians and veterinary paraprofessionals

Documentary evidence should be available to demonstrate compliance with initial and continuing education requirements, including with OIE recommendations.

8. Evaluation of mechanisms for coordination between Veterinary Authority and veterinary statutory body

The exact mechanisms will vary in accordance with the national governance systems.

Article 3.2.13.

- 1) The *Veterinary Services* of a country may undertake self-evaluation against the above criteria for such purposes as national interest, improvement of internal efficiency or export trade facilitation. The way in which the results of self-evaluation are used or distributed is a matter for the country concerned.
- 2) A prospective *importing country* may undertake an evaluation of the *Veterinary Services* of an *exporting country* as part of a *risk analysis* process, which is necessary to determine the *sanitary* or *zoosanitary measures* which the country will use to protect human or animal life or health from disease or pest threats posed by imports. Periodic evaluation reviews are also valid following the commencement of trade.
- 3) In the case of evaluation for the purposes of *international trade*, the authorities of an *importing country* should use the principles elaborated above as the basis for the evaluation and should attempt to acquire information in accordance with 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 in accordance with case-by-case circumstances. This ranking should be established in an objective and justifiable way. Analysis of the information obtained in the course of an evaluation study should be performed in as objective a manner as possible. The validity of the information should be established and reasonableness should be employed in its application. The assessing country should be willing to defend any position taken on the basis of this type of information, if challenged by the other party.

Article 3.2.14.

This article outlines appropriate information requirements for the self-evaluation or evaluation of the *Veterinary Services* of a country.

1. Organisation and structure of Veterinary Services

a) National Veterinary Authority

Organisational chart including numbers, positions and numbers of vacancies.

b) Sub-national components of the Veterinary Authority

Organisational charts including numbers, positions and number of vacancies.

c) Other providers of veterinary services

Description of any linkage with other providers of veterinary services.

2. National information on human resources

a) Veterinarians

- i) Total numbers of *veterinarians* registered or licensed by the *veterinary statutory body* of the country.
- ii) Numbers of:
 - full time government *veterinarians*: national and sub-national;
 - part time government *veterinarians*: national and sub-national;
 - private *veterinarians* authorised by the *Veterinary Services* to perform official veterinary functions [Describe accreditation standards, responsibilities and limitations applying to these private *veterinarians*.];
 - other *veterinarians*.
- iii) Animal health and welfare:

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

 - full time government *veterinarians*: national and sub-national;
 - part time government *veterinarians*: national and sub-national;
 - other *veterinarians*.
- iv) Veterinary public health:

Numbers employed in food inspection on a majority time basis, by commodity [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 and the post-graduate and continuing education topics to assure the delivery of quality veterinary services, as described in the relevant chapters 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 paraprofessionals employed by the Veterinary Services

- i) Animal health and welfare:
 - Categories and numbers involved with farm livestock on a majority time basis:
 - by geographical area;
 - proportional to numbers of field Veterinary Officers in the *Veterinary Services*, by geographical area.
 - Education or training details.
- ii) Veterinary public health:
 - Categories and numbers involved in food inspection on a majority time basis:
 - *meat* inspection: export *meat* establishments with an export function and domestic *meat* establishments (no export function);
 - dairy inspection;
 - other foods.

- Numbers in import and export inspection.
 - Education or training details.
 - d) Support personnel
Numbers directly available to *Veterinary Services* per sector (administration, communication, transport).
 - e) Descriptive summary of the functions of the various categories of staff mentioned above
 - f) *Veterinary, veterinary paraprofessionals*, livestock owner, farmer and other relevant associations
 - g) Additional information or comments.
3. Financial management information
- a) Total budgetary allocations to the *Veterinary Authority* for the current and past two fiscal years:
 - i) for the national *Veterinary Authority*;
 - ii) for each of any sub-national components of the *Veterinary Authority*;
 - iii) for other relevant government-funded institutions.
 - b) Sources of the budgetary allocations and amount:
 - i) government budget;
 - ii) sub-national authorities;
 - iii) taxes and fines;
 - iv) grants;
 - v) private services.
 - c) Proportional allocations of the amounts in a) above for operational activities and for the programme components of *Veterinary Services*.
 - d) Total allocation proportionate of national public sector budget. [*This data may be necessary for comparative assessment with other countries which should take into account the contexts of the importance of the livestock sector to the national economy and of the animal health status of the country.*]
 - e) Actual and proportional contribution of animal production to gross domestic product.
4. Administration details
- a) Accommodation
Summary of the numbers and distribution of official administrative centres of the *Veterinary Services* (national and sub-national) in the country.
 - b) Communications
Summary of the forms of communication systems available to the *Veterinary Services* on a nation-wide and local area bases.
 - c) Transport
 - i) Itemised numbers of types of functional transport available on a full-time basis for the *Veterinary Services*. In addition provide details of transport means available part-time.
 - ii) Details of annual funds available for maintenance and replacement of motor vehicles.
5. Laboratories engaged in diagnosis
- a) Descriptive summary of the organisational structure and role of the government veterinary laboratory service in particular its relevance to the field *Veterinary Services*.
 - b) Numbers of veterinary diagnostic laboratories operating in the country:
 - i) government operated laboratories;
 - ii) private laboratories authorised by veterinary authority for the purposes of supporting official or officially-endorsed animal health control or public health testing and monitoring programmes and import and export testing.
 - c) Descriptive summary of accreditation procedures and standards for private laboratories.
 - d) Human and financial resources allocated to the government veterinary laboratories, including staff numbers, graduate and post-graduate qualifications and opportunities for further training.
 - e) List of diagnostic methodologies available against major diseases of farm livestock (including *poultry*).
 - f) List of related National Reference Laboratories, if any.
 - g) Details of collaboration with external laboratories including international reference laboratories and details on numbers of samples submitted.

- h) Details of quality control and assessment (or validation) programmes operating within the veterinary laboratory service.
 - i) Recent published reports of the official veterinary laboratory service which should include details of specimens received and foreign animal disease investigations made.
 - j) Details of procedures for storage and retrieval of information on specimen submission and results.
 - k) Reports of independent reviews of the laboratory service conducted by government or private organisations (if available).
 - l) Strategic and operational plans for the official veterinary laboratory service (if available).
6. Institutes engaged in research
- a) Numbers of veterinary research institutes operating in the country:
 - i) government operated institutes;
 - ii) private institutes involved in full time research directly related to animal health and welfare, and veterinary public health matters involving production animal species.
 - b) Summary of human and financial resources allocated by government to veterinary research.
 - c) Published programmes of future government sponsored veterinary research.
 - d) Annual reports of the government research institutes.
7. Veterinary legislation, regulations and functional capabilities
- a) Animal health and animal welfare 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 management of disasters which could have impact on animal health and *animal welfare*, and control of exotic disease *outbreaks*, including zoonoses;
 - inspection and registration of facilities;
 - animal feeding;
 - veterinary public health controls of the production, processing, storage and marketing of *meat* for domestic consumption;
 - veterinary public health controls of the production, processing, storage and marketing of fish, dairy products and other food of animal origin for domestic consumption;
 - registration and use of veterinary pharmaceutical products including vaccines;
 - *animal welfare*.
 - ii) Assessment of ability of *Veterinary Services* to enforce legislation.
 - b) Export and import inspection
 - i) Assessment of the adequacy and implementation of relevant national legislation concerning:
 - veterinary public health controls of the production, processing, storage and transportation of *meat* for export;
 - veterinary public health controls of production, processing, storage and marketing of fish, dairy products and other food of animal origin for export;
 - animal health and veterinary public health controls of the export and import of *animals*, animal genetic material, animal products, animal feedstuffs and other products subject to veterinary inspection;
 - animal health controls at export and importation of *animals*;
 - animal health controls of the importation, use and biocontainment of organisms which are pathogenic 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.

8. Animal health, animal welfare 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) Animal welfare

- i) Description of major animal welfare issues.
- ii) Description of specific official programmes initiated by the *Veterinary Services* to address animal welfare problems.

c) Veterinary public health

i) Food hygiene

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

ii) Zoonoses

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

- Descriptive summary of the role and relationships of other official organisations involved in monitoring and control of zoonoses to be provided if the *Veterinary Authority* does not have these responsibilities.
 - iii) Chemical residue testing programmes
 - Descriptive summary of national surveillance and monitoring programmes for environmental and chemical residues and contaminants applied to animal-derived foodstuffs, *animals* and animal feedstuffs.
 - Role and function in these programmes of the *Veterinary Authority* and other *Veterinary Services* to be described in summary form.
 - Descriptive summary of the analytical methodologies used and their consistency with internationally recognised standards.
 - iv) Veterinary medicines
 - Descriptive summary of the administrative and technical controls involving registration, supply and use of veterinary pharmaceutical products especially including biological products. This summary should include a focus on veterinary public health considerations relating to the use of these products in food-producing animals.
 - Role and function in these programmes of the *Veterinary Authority* and other *Veterinary Services* to be described in summary form.
9. 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.
10. 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.

11. Membership of the OIE

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

NB: FIRST ADOPTED IN 2002; MOST RECENT UPDATE ADOPTED IN 2016.

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 in accordance with situations, objectives and target audiences.

The recognition of communication as a discipline of the *Veterinary Services* and its incorporation within it is critical for their operations. The integration of veterinary and communication expertise is essential for effective communication.

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

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

Article 3.3.2.

Principles of communication

- 1) *Veterinary Services* should have the authority and capability to communicate on matters within their mandate.
- 2) Veterinary and communication expertise should be combined, and have established linkages with relevant agencies, particularly for management of disasters which could have impact on animal health and *animal welfare*, and for exotic disease control.
- 3) Communication should be targeted and follow the fundamental criteria of transparency, consistency, timeliness, balance, accuracy, honesty and empathy and respect the fundamental principles of quality of *Veterinary Services* (Article 3.1.2.).
- 4) Communication should be a continuous process.
- 5) *Veterinary Services* should have oversight of planning, implementing, monitoring, evaluating and revising their strategic and operational communication plans.

Article 3.3.3.

Definitions

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

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

'**Crisis communication**': means the process of communicating information as accurately as possible, albeit potentially incomplete, within time constraints in the event of a crisis.

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

Article 3.3.4.

Communication system

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

1. Organisational chart indicating a direct link between the communication personnel and the Veterinary Authority, through the chain of command, such as dedicated communication unit or communication officer

2. Human resources
 - a) Identified and accessible official communication focal point
 - b) Job descriptions of communication personnel identifying roles and responsibilities
 - c) Sufficient number of qualified personnel with knowledge, skills, attitude and abilities relevant to communication
 - d) Continuous training and education on communication provided to communication personnel.

3. Financial and physical resources
 - a) Clearly identified budget for communication that provides adequate funding
 - b) Provision or access to appropriate material resources in order to carry out roles and responsibilities: suitable premises or accommodation that is adequately equipped with sufficient office and technical equipment, including information technology and access to the Internet.

4. Management of the communication system
 - a) Roles and responsibilities of the communication personnel
 - i) Report to the *Veterinary Authority*
 - ii) Engage in decision-making process by providing guidance and expertise on communication issues to the *Veterinary Services*
 - iii) Be responsible for the planning, implementation and evaluation of the strategic and operational plans for communication and relevant standard operating procedures
 - iv) Function as contact point on communication issues for the *Veterinary Services* with established linkages to relevant *Competent Authorities* with which *Veterinary Services* collaborate
 - v) Provide and coordinate continuous education on communication for the *Veterinary Services*.
 - b) Strategic plan for communication

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

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

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

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

c) Operational plans for communication

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

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

NB: FIRST ADOPTED IN 2011; MOST RECENT UPDATE ADOPTED IN 2014.

CHAPTER 3.4.

VETERINARY LEGISLATION

Article 3.4.1.

Introduction and objective

Good governance is a recognised global public good and is of critical importance to Member Countries. Legislation is a key element in achieving good governance.

Veterinary legislation should, at a minimum, provide a basis for *Competent Authorities* to meet their obligations as defined in the *Terrestrial Code* and the relevant recommendations of the Codex Alimentarius Commission. In addition, there is an obligation for World Trade Organization (WTO) Members under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) to notify the WTO of changes in *sanitary measures*, including changes in legislation that affect trade, and provide relevant information.

For the purposes of the *Terrestrial Code*, *veterinary legislation* comprises all legal instruments necessary for the governance of the veterinary domain.

The objective of this chapter is to provide advice and assistance to Member Countries when formulating or modernising *veterinary legislation* so as to comply with OIE standards, thus ensuring good governance of the entire veterinary domain.

Article 3.4.2.

Definitions

For the purposes of this chapter the following definitions apply:

'Hierarchy of legislation': means the ranking of the legal instruments as prescribed under the fundamental law (e.g. the constitution) of a country. Respect for the hierarchy means that each legal instrument must comply with higher order legal instruments.

'Legal instrument': means the legally binding rule that is issued by a body with the required legal authority to issue the instrument.

'Primary legislation': means the legal instruments issued by the legislative body of a Member Country.

'Secondary legislation': means the legal instruments issued by the executive body of a Member Country under the authority of primary legislation.

'Stakeholder': means a person, group, or organisation that can affect or be affected by the impacts of *veterinary legislation*.

'Veterinary domain': means all the activities that are directly or indirectly related to *animals*, their products and by-products, which help to protect, maintain and improve the health and welfare of humans, including by means of the protection of animal health and *animal welfare*, and food safety.

Article 3.4.3.

General principles

1. Respect for the hierarchy of legislation

Veterinary legislation should scrupulously respect the hierarchy between primary legislation and secondary legislation.

2. Legal basis

Competent Authorities should have available the primary legislation and secondary legislation necessary to carry out their activities at all administrative and geographic levels.

Veterinary legislation should be consistent with national and international law, as appropriate, including civil, penal and administrative laws.

3. Transparency

Veterinary legislation should be inventoried and be readily accessible and intelligible for use, updating and modification, as appropriate.

Competent Authorities should ensure communication of *veterinary legislation* and related documentation to stakeholders.

4. Consultation

The drafting of new and revised legislation relevant to the veterinary domain should be a consultative process involving *Competent Authorities* and legal experts to ensure that the resulting legislation is scientifically, technically and legally sound.

To facilitate implementation of the *veterinary legislation*, *Competent Authorities* should establish relationships with stakeholders, including taking steps to ensure that they participate in the development of significant legislation and required follow-up.

5. Quality of legislation and legal certainty

Veterinary legislation should be clear, coherent, stable and transparent and protect citizens against unintended adverse side effects of legal instruments. It should be technically relevant, acceptable to society, able to be effectively implemented and sustainable in technical, financial and administrative terms. A high quality of legislation is essential for achieving legal certainty.

Article 3.4.4.

The drafting of veterinary legislation

Veterinary legislation should:

- 1) be drafted in a manner that establishes clear rights, responsibilities and obligations (i.e. 'normative');
- 2) be unambiguous, with clear and consistent syntax and vocabulary;
- 3) be precise, accurate and consistent in the repeated use of the terminology;
- 4) contain no definitions that create any conflict or ambiguity;
- 5) include a clear statement of scope and objectives;
- 6) provide for the application of penalties and sanctions, either criminal or administrative, as appropriate to the situation; and
- 7) make provision for the financing needed for the execution of all activities of *Competent Authorities*; the financing should be ensured in accordance with the national funding system.

Article 3.4.5.

Competent Authorities

Competent Authorities should be legally mandated, capacitated and organised to ensure that all necessary actions are taken quickly and coherently to address animal health, public health and *animal welfare* emergencies effectively.

Veterinary legislation should provide for a chain of command that is as effective as possible (i.e. short, with all responsibilities clearly defined). For this purpose, the responsibilities and powers of *Competent Authorities*, from the central level to those responsible for the implementation of legislation in the field, should be clearly defined. Where more than one *Competent Authority* is involved such as in relation to environmental, food safety or other public health matters a reliable system of coordination and cooperation should be in place.

Competent Authorities should appoint technically qualified officials to take any actions needed for implementation or verification of compliance with the *veterinary legislation*, respecting the principles of independence and impartiality prescribed in Article 3.1.2.

1. Necessary powers of the Competent Authority

The *veterinary legislation* should also ensure that:

- a) officials have the legal authority to intervene in accordance with the legislation and the penal procedures in force;
- b) while executing their legal mandate, officials are protected against legal action and physical harm for actions carried out in good faith;
- c) the powers and functions of officials are explicitly and thoroughly listed to protect the rights of stakeholders and the general public against any abuse of authority. This includes respecting confidentiality, as appropriate; and
- d) at least the following powers are available through the primary legislation:
 - i) access to premises and vehicles for carrying out inspections;
 - ii) access to documents;
 - iii) taking samples;
 - iv) retention (setting aside) of *animals* and goods, pending a decision on final disposition;
 - v) seizure of *animals*, products and food of animal origin;
 - vi) suspension of one or more activities of an inspected establishment;
 - vii) temporary, partial or complete closure of inspected establishments; and
 - viii) suspension or withdrawal of authorisations or approvals.

These essential powers must be identified as they can result in actions that may conflict with individual rights ascribed in fundamental laws.

2. Delegation of powers by the Competent Authority

The *veterinary legislation* should provide the possibility for *Competent Authorities* to delegate specific tasks related to official activities. The specific tasks delegated, the bodies to which the tasks are delegated and the conditions of supervision by the *Competent Authority* should be defined.

For this purpose, the *veterinary legislation* should:

- a) define the field of activities and the specific tasks covered by the delegation;
- b) provide for the control, supervision and, when appropriate, financing of the delegation;
- c) define the procedures for making delegation;
- d) define the competencies to be held by persons receiving delegation; and
- e) define the conditions of withdrawals of delegations.

Article 3.4.6.

Veterinarians and veterinary paraprofessionals

1. Veterinary medicine/science

In order to ensure quality in the conduct of veterinary medicine/science, the *veterinary legislation* should:

- a) define the prerogatives of *veterinarians* and of the various categories of *veterinary paraprofessionals* that are recognised by the Member Country;
- b) define the minimum initial and continuous educational requirements and competencies for *veterinarians* and *veterinary paraprofessionals*;
- c) prescribe the conditions for recognition of the qualifications for *veterinarians* and *veterinary paraprofessionals*;
- d) define the conditions to perform the activities of veterinary medicine/science; and
- e) identify the exceptional situations, such as epizootics, under which persons other than *veterinarians* can undertake activities that are normally carried out by *veterinarians*.

2. The control of veterinarians and veterinary paraprofessionals

Veterinary legislation should provide a basis for regulation of *veterinarians* and *veterinary paraprofessionals* in the public interest. To that end, the legislation should:

- a) describe the general system of control in terms of the political, administrative and geographic configuration of the country;

- b) describe the various categories of *veterinary paraprofessionals* recognised by the Member Country in accordance with its needs, notably in animal health and food safety, and for each category, prescribe its training, qualifications, tasks and extent of supervision;
- c) prescribe the powers to deal with conduct and competence issues, including licensing requirements, that apply to *veterinarians* and *veterinary paraprofessionals*;
- d) provide for the possibility of delegation of powers to a professional organisation such as a *veterinary statutory body*; and
- e) where powers have been so delegated, describe the prerogatives, the functioning and responsibilities of the mandated professional organisation.

Article 3.4.7.

Laboratories in the veterinary domain1. Facilities

Veterinary legislation should define the role, responsibilities, obligations and quality requirements for:

- a) reference *laboratories*, which are responsible for controlling the veterinary diagnostic and analytical network, including the maintenance of reference methods;
- b) *laboratories* designated by the *Competent Authority* for carrying out the analysis of official samples; and
- c) *laboratories* recognised by the *Competent Authority* to conduct analyses required under the legislation e.g. for the purposes of quality control.

Veterinary legislation should define the conditions for the classification, approval, operations and supervision of *laboratories* at each level.

2. Reagents

Veterinary legislation should provide a basis for actions to address the elements listed below:

- a) procedures for authorising reagents that are used to perform official analyses;
- b) quality assurance by manufacturers of reagents used in official analyses; and
- c) surveillance of marketing of reagents, where these can affect the quality of analyses required by the *veterinary legislation*.

Article 3.4.8.

Health provisions relating to animal production1. Identification and traceability

Veterinary legislation should provide a basis for actions to address all the elements in point 6) of Article 4.2.3.

2. Animal markets and other gatherings

Veterinary legislation should address, for animal markets and other commercially or epidemiologically significant animal gatherings, the following elements:

- a) registration of animal markets and other animal gatherings;
- b) health measures to prevent disease transmission, including procedures for cleaning and *disinfection*, and *animal welfare* measures; and
- c) provision for veterinary checks.

3. Animal reproduction

Veterinary legislation should provide a basis for actions to address the health regulation of animal reproduction as appropriate. Health regulations may be implemented at the level of *animals*, genetic material, establishments or operators.

4. Animal feed

Veterinary legislation should provide a basis for actions to address the elements listed below:

- a) standards for the production, composition and quality control of animal feed;

- b) registration and, if necessary, approval of establishments and the provision of health requirements for relevant operations; and
- c) recall from the market of any product likely to present a hazard to human health or animal health.

5. Animal by-products

Veterinary legislation should provide a basis for actions to address the elements listed below:

- a) definition of the animal by-products subject to the legislation;
- b) rules for collection, processing, use and disposal of animal by-products;
- c) registration and, if necessary, approval of establishments and the provision of health requirements for relevant operations; and
- d) rules to be followed by animal owners.

6. Disinfection

Veterinary legislation should provide a basis for actions to address the regulation and use of products and methods of *disinfection* relating to the prevention and control of animal diseases.

Article 3.4.9.

Animal diseases

Veterinary legislation should provide a basis for the *Competent Authority* to manage diseases of importance to the country and to list those diseases, guided by the recommendations in Chapters 1.1.and 1.2.

1. Surveillance

Veterinary legislation should provide a basis for the collection, transmission and utilisation of epidemiological data relevant to diseases listed by the *Competent Authority*.

2. Disease prevention and control

- a) *Veterinary legislation* should include general animal health measures applicable to all diseases and, if necessary, additional or specific measures such as *surveillance*, establishment of a regulatory programme or emergency response for particular diseases listed in the country.
- b) The legislation should also provide a basis for contingency plans to include the following for use in disease responses:
 - i) administrative and logistic organisation;
 - ii) exceptional powers of the *Competent Authority*; and
 - iii) special and temporary measures to address all identified *risks* to human or animal health.
- c) *Veterinary legislation* should provide for the financing of animal disease control measures, such as operational expenses and, as appropriate, owners' compensation in the event of *killing* or *slaughtering* of *animals* and seizure or destruction of carcasses, *meat*, animal feed or other things.

3. Emerging diseases

Veterinary legislation should provide for measures to investigate and respond to *emerging diseases*.

Article 3.4.10.

Animal welfare

1. General provisions

Veterinary legislation should provide a basis for actions to address the *animal welfare* related requirements in Section 7.

To this end, the legislation should contain, as a minimum, a legal definition of cruelty as an offence, and provisions for direct intervention of the *Competent Authority* in the case of neglect by animal keepers.

2. Stray dogs and other free-roaming animals

Veterinary legislation should provide a basis for actions to address the requirements in Chapter 7.7. and, as appropriate, prohibition of the abandonment of *animals*, and management of abandoned *animals*, including transfer of ownership, veterinary interventions and *euthanasia*.

Article 3.4.11.

Veterinary medicines and biologicals

Veterinary legislation should provide a basis for assuring the quality of veterinary medicines and biologicals and minimising the *risk* to human, animal and environmental health associated with their use.

1. General measures

Veterinary legislation should provide a basis for actions to address the elements listed below:

- a) definition of veterinary medicines and biologicals, including any specific exclusions; and
- b) regulation of the importation, manufacture, distribution and usage of, and commerce in, veterinary medicines and biologicals.

2. Raw materials for use in veterinary medicines and biologicals

Veterinary legislation should provide a basis for actions to address the elements listed below:

- a) quality standards for raw materials used in the manufacture or composition of veterinary medicines and biologicals and arrangements for checking quality;
- b) establishment of the withdrawal periods and maximum residue limits for veterinary medicines and biologicals, as appropriate; and
- c) requirements for substances in veterinary medicines and biologicals that may, through their effects, interfere with the conduct of veterinary checks.

3. Authorisation of veterinary medicines and biologicals

- a) *Veterinary legislation* should ensure that only authorised veterinary medicines and biologicals may be placed on the market.
- b) Special provisions should be made for:
 - i) medicated feed;
 - ii) products prepared by authorised *veterinarians* or authorised pharmacists; and
 - iii) emergencies and temporary situations.
- c) *Veterinary legislation* should address the technical, administrative and financial conditions associated with the granting, renewal, refusal and withdrawal of authorisations.
- d) In defining the procedures for seeking and granting authorisations, the legislation should:
 - i) describe the role of the relevant *Competent Authorities*; and
 - ii) establish rules providing for the transparency in decision making.
- e) *Veterinary legislation* may provide for the possibility of recognition of the equivalence of authorisations made by other countries.

4. Quality of veterinary medicines and biologicals

Veterinary legislation should address the following elements:

- a) the conduct of clinical and non-clinical trials to verify all claims made by the manufacturer;
- b) conditions for the conduct of trials;
- c) qualifications of experts involved in trials; and
- d) surveillance for adverse effects arising from the use of veterinary medicines and biologicals.

5. Establishments producing, storing and wholesaling veterinary medicines and biologicals

Veterinary legislation should provide a basis for actions to address the following elements:

- a) registration or authorisation of all operators manufacturing importing, storing, processing, wholesaling or otherwise distributing veterinary medicines and biologicals or raw materials for use in making veterinary medicines and biologicals;

- b) definition of the responsibilities of operators;
 - c) good manufacturing practices appropriate;
 - d) reporting on adverse effects to the *Competent Authority*; and
 - e) mechanisms for traceability and recall.
6. Retailing, use and traceability of veterinary medicines and biologicals
Veterinary legislation should provide a basis for actions to address the following elements:
- a) control over the distribution of veterinary medicines and biologicals and arrangements for traceability, recall and conditions of use;
 - b) establishment of rules for the prescription and provision of veterinary medicines and biologicals to end users;
 - c) restriction to authorised professionals and, as appropriate, authorised *veterinary paraprofessionals* of commerce in veterinary medicines and biologicals that are subject to prescription;
 - d) the supervision by an authorised professional of organisations approved for holding and use of veterinary medicines and biologicals;
 - e) the regulation of advertising claims and other marketing and promotional activities; and
 - f) reporting on adverse effects to the *Competent Authority*.

Article 3.4.12.

Human food production chain

Veterinary legislation should provide a basis for actions to safeguard the human food production chain through controls at all critical steps, consistent with national food safety standards. The role of the *Veterinary Services* in food safety is described in Chapter 6.1.

1. General provisions

Veterinary legislation should provide a basis for actions to address the following elements:

- a) controls over all stages of the production, processing and distribution of food of animal origin;
- b) recording all significant animal and public health events that occur during primary production;
- c) giving operators of food production premises the primary responsibility for compliance with food safety requirements, including traceability established by the *Competent Authority*;
- d) inspection for compliance with food standards, where this is relevant to health or safety;
- e) inspection of premises;
- f) prohibition of the marketing of products not fit for human consumption; and
- g) provisions for recall from the marketplace of all products likely to be hazardous for human or animal health.

2. Products of animal origin intended for human consumption

Veterinary legislation should provide a basis for actions to address the following elements:

- a) arrangements for inspection and audit;
- b) the conduct of inspection and audit;
- c) health standards; and
- d) the application of health identification marks that are visible to the intermediary or final user.

The *Competent Authority* should have the necessary powers and means to rapidly withdraw any products deemed to be hazardous from the food chain or to prescribe uses or treatments that ensure the safety of such products for human or animal health.

3. Operators responsible for premises and establishments pertaining to the food chain

Veterinary legislation should provide a basis for actions to address the following elements as appropriate:

- a) registration of premises and establishments by the *Competent Authority*;
- b) the use of *risk*-based management procedures; and
- c) prior authorisation of operations that are likely to constitute a significant *risk* to human or animal health.

Article 3.4.13.

Import and export procedures and veterinary certification

Veterinary legislation should provide a basis for actions to address the elements relating to import and export procedures and veterinary certification referred to in Section 5.

NB: FIRST ADOPTED IN 2012; MOST RECENT UPDATE ADOPTED IN 2013.

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* or *flock* husbandry, zoning or 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 objectives 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 or 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* or 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*.

NB: FIRST ADOPTED IN 2006; MOST RECENT UPDATE ADOPTED IN 2007.

CHAPTER 4.2.

DESIGN AND IMPLEMENTATION OF IDENTIFICATION SYSTEMS TO ACHIEVE ANIMAL TRACEABILITY

Article 4.2.1.

Introduction and objectives

These recommendations are based on the general principles presented in Article 4.1.1. The recommendations outline for Member Countries the basic elements that need to be taken into account in the design and implementation of an *animal identification system* to achieve *animal traceability*. Whatever *animal identification system* the country adopts, it should comply with relevant OIE standards, including Chapters 5.10. to 5.12. for *animals* and animal products intended for export. Each country should design a programme in accordance with the scope and relevant performance criteria to ensure that the desired *animal traceability* outcomes can be achieved.

Article 4.2.2.

Definitions

For the purpose of this chapter:

'**Desired outcomes**': describe the overall goals of a programme and are usually expressed in qualitative terms, e.g. 'to help ensure that *animals* 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 or production or trade sector within a defined area (country, *zone*) or *compartment* that is the subject of the *identification* and *traceability* programme.

'**Transhumance**': means periodic or 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 in accordance with 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 in accordance with 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 systems*,
- 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 or reuse of identifiers;
- v) penalties for the tampering 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* 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 or 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*, *slaughterhouses/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 or owner. Other relevant information about the *animals* at each establishment or 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, in accordance with 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 in accordance with 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;
- minimise 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) Slaughterhouses/abattoirs, rendering plants, dead stock collection points, markets and assembly centres
Slaughterhouses/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 *slaughterhouses/abattoirs* should complement and be compatible with arrangements for tracking animal products throughout the food chain. At a *slaughterhouse/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 *slaughterhouse/abattoir*, rendering plant and dead stock collection points.

Slaughterhouses/abattoirs, rendering plants and dead stock collection points should ensure that identifiers are collected and disposed of in accordance with the procedures established and regulated within the legal framework. These procedures should minimise the risk of unauthorised reuse and, if appropriate, should establish arrangements and rules for the reuse of identifiers.

Reporting of movement by *slaughterhouses/abattoirs*, rendering plants and dead stock collection points should occur in accordance with the scope, performance criteria and desired outcomes and the legal framework.

- i) Penalties

Different levels and types of penalties should be defined in the programme and supported by the legal framework.

6. Legal framework

The *Veterinary Authority*, with other relevant governmental agencies and in consultation with stakeholders, should establish a legal framework for the implementation and enforcement of *animal identification system* and *animal traceability* in the country. The structure of this framework will vary from country to country.

Animal identification, *animal traceability* and animal movement should be under the responsibility of the *Veterinary Authority*.

This legal framework should address:

- a) desired outcomes and scope;
- b) obligations of the *Veterinary Authority* and other parties;
- c) organisational arrangements, including the choice of technologies and methods used for the *animal identification system* and *animal traceability*;
- d) management of animal movement;
- e) confidentiality of data;
- f) data access or accessibility;
- g) checking, verification, inspection and penalties;
- h) where relevant, funding mechanisms;
- i) where relevant, arrangements to support a pilot project.

7. Implementation

- a) Action plan

For implementing the *animal identification system*, an action plan should be prepared specifying the timetable and including the milestones and performance indicators, the human and financial resources, and checking, enforcement and verification arrangements.

The following activities should be addressed in the action plan:

- i) Communication

The scope, performance criteria, desired outcomes, responsibilities, movement and registration requirements and sanctions need to be communicated to all parties.

Communication strategies need to be targeted to the audience, taking into account elements such as the level of literacy (including technology literacy) and spoken languages.

- ii) Training programmes

It is desirable to implement training programmes to assist the *Veterinary Services* and other parties.

- iii) Technical support

Technical support should be provided to address practical problems.

b) Checking and verification

Checking activities should start at the beginning of the implementation to detect, prevent and correct errors and to provide feedback on programme design.

Verification should begin after a preliminary period as determined by the *Veterinary Authority* in order to determine compliance with the legal framework and operational requirements.

c) Auditing

Auditing should be carried out under the authority of the *Veterinary Authority* to detect any problems with the *animal identification system* and *animal traceability* and to identify possible improvements.

d) Review

The programme should be subject to periodic review, taking into account the results of checking, verification and auditing activities.

NB: FIRST ADOPTED IN 2002; MOST RECENT UPDATE ADOPTED IN 2011.

CHAPTER 4.3.

ZONING AND COMPARTMENTALISATION

Article 4.3.1.

Introduction

The purpose of this chapter is to provide recommendations on the principles of zoning and compartmentalisation to Member Countries wishing to establish and maintain different *subpopulations* with specific health status within their territory. These principles should be applied in accordance with the relevant chapters of the *Terrestrial Code*. This chapter also outlines a process by which trading partners may recognise such *subpopulations*.

Establishing and maintaining a disease-free status throughout the country should be the final goal for Member Countries. However, given the difficulty of achieving this goal, there may be benefits to a Member Country in establishing and maintaining a *subpopulation* with a specific health status within its territory for the purposes of *international trade* or disease prevention or control. *Subpopulations* may be separated by natural or artificial geographical barriers or by the application of appropriate *biosecurity* management.

While zoning applies to an animal *subpopulation* defined primarily on a geographical basis, compartmentalisation applies to an animal *subpopulation* defined primarily by management and husbandry practices related to *biosecurity*. In practice, spatial considerations and appropriate management, including *biosecurity plans*, play important roles in the application of both concepts.

Zoning may encourage the more efficient use of resources within certain parts of a country. Compartmentalisation may allow the functional separation of a *subpopulation* from other domestic or *wild animals* through *biosecurity*, which would not be achieved through geographical separation. In a country where a disease is endemic, establishment of *free zones* may assist in the progressive control and eradication of the disease. To facilitate disease control and the continuation of trade following a disease *outbreak* in a previously free country or *zone*, zoning may allow a Member Country to limit the extension of the disease to a defined restricted area, while preserving the status of the remaining territory. For the same reasons, the use of compartmentalisation may allow a Member Country to take advantage of epidemiological links among *subpopulations* or common practices relating to *biosecurity*, despite diverse geographical locations.

A Member Country may thus have more than one *zone* or *compartment* within its territory.

Article 4.3.2.

General considerations

The *Veterinary Services* of a Member Country that is establishing a *zone* or *compartment* within its territory should clearly define the *subpopulation* in accordance with the recommendations in the relevant chapters of the *Terrestrial Code*, including those on *surveillance*, on *animal identification* and *animal traceability* and on *official control programmes*.

The procedures used to establish and maintain the specific *animal health status* of a *zone* or *compartment* depend on the epidemiology of the disease, including the presence and role of *vectors* and susceptible *wildlife* and environmental factors, on the animal production systems as well as on the application of *biosecurity* and *sanitary measures*, including movement control.

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

The *Veterinary Services*, including *laboratories*, should be established and should operate in accordance with Chapters 3.1. and 3.2., to provide confidence in the integrity of the *zone* or *compartment*. The final authority over the *zone* or *compartment*, for the purposes of domestic and *international trade*, lies with the *Veterinary Authority*. The *Veterinary Authority* should conduct an assessment of the resources needed and available to establish and maintain a *zone* or *compartment*. These include the human and financial resources and the technical capability of the *Veterinary Services* and of the relevant industry and production system (especially in the case of a *compartment*), including for *surveillance*, diagnosis and, when appropriate, *vaccination*, treatment and protection against *vectors*.

In the context of maintaining the *animal health status* of a *population* or *subpopulation* of a country, *zone* or *compartment*, importations into the country as well as movements of *animals* and their products, and fomites, into the *zones* or *compartments* should be the subject of appropriate *sanitary measures* and *biosecurity*.

The *Veterinary Services* should provide movement certification, when necessary, and carry out documented periodic inspections of facilities, *biosecurity*, records and *surveillance* procedures. *Veterinary Services* should conduct or audit *surveillance*, reporting, *laboratory* diagnostic examinations and, when relevant, *vaccination*.

The production sector's responsibilities include, in consultation with the *Veterinary Services* if appropriate, the application of *biosecurity*, documenting and recording movements of *commodities* and personnel, managing quality assurance schemes, documenting the implementation of corrective actions, conducting *surveillance*, rapid reporting and maintenance of records in a readily accessible form.

Article 4.3.3.

Principles for defining and establishing a zone or compartment

The following principles apply when Member Countries define a *zone* or a *compartment*.

- 1) The extent of a *zone* and its geographical limits should be established by the *Veterinary Authority* on the basis of natural, artificial or legal boundaries, and made public through official channels.
- 2) The factors defining a *compartment* should be established by the *Veterinary Authority* on the basis of relevant criteria such as management and husbandry practices related to *biosecurity*, and communicated to the relevant operators through official channels.
- 3) *Animals* and *herds* or *flocks* belonging to *subpopulations* of *zones* or *compartments* should be recognisable as such through a clear epidemiological separation from other *animals* and all factors presenting a *risk*. The measures taken to ensure the identification of the *subpopulation* and to establish and maintain its health status through a *biosecurity plan* should be documented in detail. These measures should be appropriate to the particular circumstances, and depend on the epidemiology of the disease, environmental factors, the health status of *animals* in adjacent areas, applicable *biosecurity* (including movement controls, use of natural, artificial or legal boundaries, spatial separation of *animals*, control of fomites, and commercial management and husbandry practices), and *surveillance*.
- 4) Relevant *commodities* 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* or *flock* or individual animal level. Relevant movements of *commodities* into and out of the *zone* or *compartment* should be well documented and controlled. The existence of an *animal identification system* is a prerequisite to assess the integrity of the *zone* or *compartment*.
- 5) For a *compartment*, the *biosecurity plan* should describe the partnership between the relevant industry and the *Veterinary Authority*, and their respective responsibilities. It should also describe the standard operating procedures to provide clear evidence that the *surveillance* conducted, the *animal identification* and *traceability* system, and the management and husbandry practices are adequate to meet the definition of the *compartment*. In addition to information on controls of movements of relevant *commodities*, the plan should include *herd* or *flock* production records, *feed*, water and bedding sources, *surveillance* results, birth and *death* records, visitor logbook, morbidity and mortality history and investigations, medications, *vaccinations*, documentation of training of relevant personnel and any other criteria necessary for evaluation of *risk management*. The information required may vary in accordance with the species and diseases under consideration. The *biosecurity plan* should also describe how the measures will be audited to ensure that the *risks* are being managed and regularly reassessed, and the measures adjusted accordingly.

Articles 4.3.4. to 4.3.7. describe different types of *zones* that can be established by Member Countries. However, other types of *zones* may be established for the purposes of disease control or trade.

Article 4.3.4.

Free zone

A *free zone* is one in which the absence of a specific *infection* or *infestation* in an *animal population* has been demonstrated in accordance with the relevant requirements of the *Terrestrial Code*.

In conjunction with Articles 4.3.2. and 4.3.3., and depending on the prevailing epidemiological situation, the attainment or maintenance of free status may require past or ongoing specific *surveillance* and *vector surveillance*, as well as appropriate *biosecurity* and *sanitary measures*, within the *zone* and at its borders. The *surveillance* should be conducted in accordance with Chapter 1.4. and the relevant chapters of the *Terrestrial Code*.

The free status can apply to one or more susceptible animal species populations, domestic or *wild*.

So long as an ongoing *surveillance* demonstrates there is no occurrence of the specific *infection* or *infestation*, and principles determined for its definition and establishment are respected, the *zone* maintains its free status.

Article 4.3.5.

Infected zone

An *infected zone* is one either in which an *infection* or *infestation* has been confirmed, or that is defined as such in the relevant chapters of the *Terrestrial Code*.

An *infected zone* in which an *infection* or *infestation* has been confirmed may be:

- 1) a *zone* of a country where the *infection* or *infestation* is present and has not yet been eradicated, while other *zones* of the country may be free; or
- 2) a *zone* of a previously free country or *zone*, in which the *infection* or *infestation* has been introduced or reintroduced, while the rest of the country or *zone* remains unaffected.

To gain free status in an *infected zone*, or regain free status following an *outbreak* in a previously *free zone*, Member Countries should follow the recommendations in the relevant chapters of the *Terrestrial Code*.

Article 4.3.6.

Protection zone

A *protection zone* may be established to preserve the *animal health status* of an *animal population* in a free country or a *free zone* by preventing the introduction of a pathogenic agent of a specific *infection* or *infestation* from neighbouring countries or *zones* of different *animal health status* to that *animal population*. A *protection zone* can be established within or outside the *free zone* or within the free country.

Biosecurity and *sanitary measures* should be implemented in the *protection zone* based on the animal management systems, the epidemiology of the disease under consideration and the epidemiological situation prevailing in the neighbouring infected countries or *zones*.

These measures should include intensified movement control and *surveillance* and specific *animal identification* and *animal traceability* to ensure that *animals* in the *protection zone* are clearly distinguishable from other populations, and may also include:

- 1) *vaccination* of all or at risk susceptible *animals*;
- 2) testing or *vaccination* of *animals* moved;
- 3) specific procedures for sample handling, dispatching and testing;
- 4) enhanced *biosecurity* including *disinfection* and disinsection procedures for *vehicles/vessels* and vehicles used for transportation of animal products, *feed* or fodder, and possible compulsory routes for their movements within, to or from the *zone*;
- 5) specific *surveillance* of susceptible *wildlife* and relevant *vectors*;
- 6) awareness campaigns aimed at the public or targeted at breeders, traders, hunters or *veterinarians*.

Anytime the status of the *protection zone* changes, the status of the country or *zone* in which it was established should be redetermined in accordance with the relevant *listed disease*-specific chapters.

Article 4.3.7.

Containment zone

In the event of *outbreaks* in a country or *zone* previously free from a disease, a *containment zone*, which includes all epidemiologically linked *outbreaks* may be established to minimise the impact on the rest of the country or *zone*.

A *containment zone* is an *infected zone* that should be managed in such a way that *commodities* for *international trade* can be shown to have originated either from inside or outside the *containment zone*.

Establishment of a *containment zone* should be based on a rapid response, prepared in a contingency plan, and that includes:

- 1) appropriate control of movement of *animals* and other *commodities* upon declaration of suspicion of the specified disease;
- 2) epidemiological investigation (trace-back, trace-forward) after confirmation of *infection* or *infestation*, demonstrating that the *outbreaks* are epidemiologically related and all contained within the defined boundaries of the *containment zone*;
- 3) a *stamping-out policy* or another effective emergency control strategy aimed at eradicating the disease;
- 4) *animal identification* of the susceptible population within the *containment zone* enabling its recognition as belonging to the *containment zone*;
- 5) increased passive and targeted surveillance in accordance with Chapter 1.4. in the rest of the country or *zone* demonstrating no occurrence of *infection* or *infestation*;
- 6) *biosecurity* and *sanitary measures*, including ongoing *surveillance* and control of the movement of *animals*, other *commodities* and fomites within and from the *containment zone*, consistent with the *listed disease*-specific chapter, when there is one, to prevent spread of the *infection* or *infestation* from the *containment zone* to the rest of the country or *zone*.

A *containment zone* is considered as effectively established when the following is demonstrated:

EITHER

- there have been no new *cases* in the *containment zone* within a minimum of two *incubation periods* from the disposal of the last detected case;

OR

- the *containment zone* comprises an *infected zone* where *cases* may continue to occur and a *protection zone*, where no *outbreaks* have occurred for at least two *incubation periods* after the control measures above are in place, and that separates the *infected zone* from the rest of the country or *zone*.

The free status of the areas outside the *containment zone* is suspended pending the effective establishment of the *containment zone*. Once the *containment zone* has been established, the areas outside the *containment zone* regain free status.

The free status of the *containment zone* should be regained in accordance with the relevant *listed disease*-specific chapters or, if there are none, with Article 1.4.6.

In the event of an occurrence of a *case* of the *infection* or *infestation* for which the *containment zone* was established, either in the *containment zone* defined in point a) or in the *protection zone* defined in point b), the rest of the country or *zone* is considered infected.

Article 4.3.8.

Bilateral recognition of country or zone status by trading countries

While the OIE has procedures for official recognition of status for a number of *infections* (refer to Chapter 1.6.), for other *infections* or *infestations*, countries may recognise each other's status through a bilateral process. Trading partners should exchange information allowing the recognition of different *subpopulations* within their respective territories. This recognition process is best implemented through establishing parameters and gaining agreement on the necessary measures prior to *outbreaks* of disease.

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 specific *animal health status* for a given *zone* or *compartment* under consideration.

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*.

In accordance with Chapter 5.3., 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* is able to demonstrate that this is the case.

NB: FIRST ADOPTED IN 1998; MOST RECENT UPDATE ADOPTED IN 2018.

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 Chapter 4.3. with the objective to facilitate trade in *animals* and products of animal origin and as a tool for disease management.

Establishing and maintaining a disease free status throughout the country should be the final goal for Member Countries. However, establishing and maintaining a disease free status for an entire country may be difficult, especially in the case of diseases that can easily cross international boundaries. For many diseases, Member Countries have traditionally applied the concept of zoning to establish and maintain an animal *subpopulation* with a different animal health status within national boundaries.

The essential difference between zoning and compartmentalisation is that the recognition of *zones* is based on geographical boundaries whereas the recognition of *compartments* is based on management practices and *biosecurity*. However, spatial considerations and good management practices play a role in the application of both concepts.

Compartmentalisation is not a new concept for *Veterinary Services*; in fact, it has been applied for a long time in many disease control programmes that are based on the concept of disease free *herds* or *flocks*.

The fundamental requirement for compartmentalisation is the implementation and documentation of management and biosecurity measures to create a functional separation of *subpopulations*.

For example, an animal production operation in an infected country or *zone* might have biosecurity measures and management practices that result in negligible *risk* from diseases or agents. The concept of a *compartment* extends the application of a 'risk boundary' beyond that of a geographical interface and considers all epidemiological factors that can help to create an effective disease-specific separation between *subpopulations*.

In disease free countries or *zones*, *compartments* preferably should be defined prior to the occurrence of a disease *outbreak*. In the event of an *outbreak* or in infected countries or *zones*, compartmentalisation may be used to facilitate trade.

For the purpose of *international trade*, *compartments* should be under the responsibility of the *Veterinary Authority* in the country. For the purposes of this chapter, compliance by Member Countries with Chapters 1.1. and 3.1. is an essential prerequisite.

Article 4.4.2.

Principles for defining a compartment

A *compartment* may be established with respect of a specific disease or diseases. A *compartment* should be clearly defined, indicating the location of all its components including *establishments*, as well as related functional units (such as feed mills, *slaughterhouses/abattoirs*, 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/abattoirs*, 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 or source.

More detailed recommendations for certain *establishments* can be found in Sections 4 and 6.

3. Biosecurity plan

The integrity of the *compartment* relies on effective *biosecurity*. The management of the *compartment* should develop, implement and monitor a comprehensive *biosecurity plan*.

The *biosecurity plan* should describe in detail:

- a) potential pathways for introduction and spread into the *compartment* of the agents for which the *compartment* was defined, including animal movements, rodents, fauna, aerosols, arthropods, *vehicles*, people, biological products, equipment, fomites, feed, waterways, drainage or other means. Consideration should also be given to the survivability of the agent in the environment;
- b) the critical control points for each pathway;
- c) measures to mitigate exposure for each critical control point;
- d) standard operating procedures including:
 - i) implementation, maintenance, monitoring of the measures,
 - ii) application of corrective actions,
 - iii) verification of the process,
 - iv) record keeping;
- e) contingency plan addressing any potential future changes in the *risk* factors;
- f) reporting procedures to the *Veterinary Authority*;
- g) the programme for educating and training workers to ensure that all persons involved are knowledgeable and informed on *biosecurity* principles and practices;

h) the *surveillance* programme in place.

In any case, sufficient evidence should be submitted to assess the efficacy of the *biosecurity plan* in accordance with the level of *risk* for each identified pathway. This evidence should be structured in line with the principles of Hazard Analysis and Critical Control Point (HACCP). The *biosecurity* risk of all operations of the *compartment* should be regularly re-assessed and documented at least on a yearly basis. Based on the outcome of the assessment, concrete and documented mitigation steps should be taken to reduce the likelihood of introduction of the pathogenic 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 diseases for which it was defined should be documented and demonstrate compliance with the requirements for freedom in the relevant *Terrestrial Code* chapter.

In addition, a *compartment* seeking recognition should submit to the *Veterinary Authority* a baseline animal health report indicating the presence or absence of *listed diseases* for the animal species of interest to the *compartment* in accordance with Chapter 1.3. This report should be regularly updated to reflect the current animal health situation of the *compartment*.

Vaccination records including the type of vaccine and frequency of administration should be available to enable interpretation of *surveillance* data.

The time period for which all records should be kept may vary in accordance with the species and diseases 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. and the specific recommendations for *surveillance* for the diseases 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 or *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 diseases 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 minimise 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 in accordance with the baseline animal health report of the *compartment* referred to in Article 4.4.4., the management of the *compartment* should notify the *Veterinary Authority*, and initiate a review to determine whether there has been a breach in the biosecurity measures. If a significant breach in *biosecurity*, even in the absence of *outbreak*, is detected, export certification as a free *compartment* should be suspended. Disease free status of the *compartment* may only be reinstated after the *compartment* has adopted the necessary measures to re-establish the original *biosecurity* level and the *Veterinary Authority* re-approves the status of the *compartment*.

In the event of a *compartment* being at risk from a change, in the surrounding area, in the disease situation for which the *compartment* was defined, the *Veterinary Authority* should re-evaluate without delay the status of the *compartment* and consider whether any additional biosecurity measures are needed to ensure that the integrity of the *compartment* is maintained.

Article 4.4.8.

Supervision and control of a compartment

The authority, organisation, and infrastructure of the *Veterinary Services*, including *laboratories*, should be clearly documented in accordance with Chapter 3.2., to provide confidence in the integrity of the *compartment*.

The *Veterinary Authority* has the final authority in granting, suspending and revoking the status of a *compartment*. The *Veterinary Authority* should continuously supervise compliance with all the requirements critical to the maintenance of the *compartment* status described in this chapter and ensure that all the information is readily accessible to the *importing countries*. Any significant change should be notified to the *importing country*.

NB: FIRST ADOPTED IN 2008; MOST RECENT UPDATE ADOPTED IN 2012.

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 agents. 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 agents. 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 agents 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.

NB: FIRST ADOPTED IN 1986; MOST RECENT UPDATE ADOPTED IN 2010.

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 pathogenic agents 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) Brucellosis – Chapter 8.4.

b) Bovine tuberculosis – Point 3) or 4) of Article 8.11.5.

c) Bovine viral diarrhoea (BVD)

The animals should be subjected to:

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

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

d) Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis

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

i) come from an IBR/IPV free *herd* as defined in Article 11.8.3.; 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 antibody serological testing (see point 2 b) i) below).

a) Brucellosis

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

- b) BVD
- i) The animals should be subjected to a virus isolation test or a test for virus antigen, with negative results. Only when all the animals in pre-entry isolation have had negative results, may the animals enter the semen collection facilities.
 - ii) All animals should be subjected to a serological test to determine the presence or absence of BVD antibodies.
 - iii) Only if no seroconversion occurs in the animals which tested seronegative before entry into the pre-entry isolation facility, may any animal (seronegative or seropositive) be allowed entry into the semen collection facilities.
 - iv) If seroconversion occurs, all the animals that remain seronegative should be kept in pre-entry isolation until there is no more seroconversion in the group for a period of three weeks. Serologically positive animals may be allowed entry into the semen collection facilities.
- c) *Campylobacter fetus* subsp. *venerealis*
- i) Animals less than six months old or kept since that age only in a single sex group prior to pre-entry isolation should be tested once on a preputial specimen, with a negative result.
 - ii) Animals aged six months or older that could have had contact with females prior to pre-entry isolation should be tested three times at weekly intervals on a preputial specimen, with a negative result in each case.
- d) *Tritrichomonas foetus*
- i) Animals less than six months old or kept since that age only in a single sex group prior to pre-entry isolation, should be tested once on a preputial specimen, with a negative result.
 - ii) Animals aged six months or older that could have had contact with females prior to pre-entry isolation should be tested three times at weekly intervals on a preputial specimen, with a negative result in each case.
- e) IBR/IPV
- If the *artificial insemination centre* is to be considered as IBR/IPV free, the animals should be subjected, with negative results, to a diagnostic test for IBR/IPV on a blood sample. If any animal tests positive, the animal should be removed immediately from the pre-entry isolation facility and the other animals of the same group should remain in pre-entry isolation and be retested, with negative results, not less than 21 days after removal of the positive animal.
- f) Bluetongue
- The animals should comply with the provisions referred to in Articles 8.3.6., 8.3.7. or 8.3.8., depending on the bluetongue status of the country or *zone* where the pre-entry isolation facility is located.

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

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

- a) Brucellosis
 - b) Bovine tuberculosis
 - c) BVD
- Animals negative to previous serological tests should be retested to confirm absence of antibodies. Should an animal become serologically positive, every ejaculate of that animal collected since the last negative test should be either discarded or tested for virus with negative results.
- d) *Campylobacter fetus* subsp. *venerealis*
- i) A preputial specimen should be tested.
 - ii) Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a lay-off of more than six months should be tested not more than 30 days prior to resuming production.
- e) Bluetongue
- The animals should comply with the provisions referred to in Article 8.3.9. or Article 8.3.10.
- 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 11.8.3.

4. Testing for BVD prior to the initial dispatch of semen from each serologically positive bull

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

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

Each aliquot of frozen semen should be tested as per Article 11.8.7.

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) Brucellosis – Chapter 8.4.

b) Ovine epididymitis – Article 14.6.3.

c) Contagious agalactia – Points 1) and 2) of Article 14.2.1.

d) Peste des petits ruminants – Points 1), 2 a) or 3) of Article 14.7.10.

e) Contagious caprine pleuropneumonia – Article 14.3.7., 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 14.8.8. if the animals do not originate from a scrapie free country or *zone* as defined in Article 14.8.3.

h) Maedi-visna – Article 14.5.2.

i) Caprine arthritis/encephalitis – Article 14.1.2. 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) Brucellosis – Chapter 8.4.

b) Ovine epididymitis – Point 1 d) of Article 14.6.4.

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

d) Bluetongue

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

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

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

a) 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 8.3.9. or Article 8.3.10.

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) Brucellosis – Chapter 8.4.
- b) Foot and mouth disease – Articles 8.8.10., 8.8.11. or 8.8.12.
- c) Aujeszky's disease – Article 8.2.9. or Article 8.2.10.
- d) Transmissible gastroenteritis – Article 15.5.2.
- e) African swine fever – Article 15.1.5. or Article 15.1.6.
- f) Classical swine fever – Article 15.2.7. or Article 15.2.8.
- g) 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) Brucellosis – Chapter 8.4.
- b) Foot and mouth disease – Articles 8.8.13., 8.8.14., 8.8.15. or 8.8.16.
- c) Aujeszky's disease – Articles 8.2.13., 8.2.14. or 8.2.15.
- d) Transmissible gastroenteritis – Article 15.5.4.
- e) African swine fever – Article 15.1.8. or Article 15.1.9.
- f) Classical swine fever – Article 15.2.10. or Article 15.2.11.
- g) 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) Brucellosis – Chapter 8.4.
- b) Foot and mouth disease – Articles 8.8.13., 8.8.14., 8.8.15. or 8.8.16.
- c) Aujeszky's disease – Articles 8.2.13., 8.2.14. or 8.2.15.
- d) Transmissible gastroenteritis – Article 15.5.4.
- e) African swine fever – Article 15.1.8. or Article 15.1.9.
- f) Classical swine fever – Article 15.2.10. or Article 15.2.11.
- g) 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 sterilised 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, sterilised (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 from pathogenic agents 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 sterilised 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), divexacin (25 µg).

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

2. Procedure for dilution and packing

- a) The tube containing freshly collected semen should be sealed as soon as possible after collection, and kept sealed until processed.
- b) After dilution and during refrigeration, the semen should also be kept in a stoppered container.
- c) During the course of filling receptacles for dispatch (such as insemination straws), the receptacles and other disposable items should be used immediately after being unpacked. Materials for repeated use should be disinfected with alcohol, ethylene oxide, steam or other approved *disinfection* techniques.
- d) If sealing powder is used, care should be taken to avoid its being contaminated.

3. Conditions applicable to the storage and identification of frozen semen

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

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

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

4. Sperm sorting

Equipment used for sex-sorting sperm should be clean and disinfected between animals in accordance with the recommendations of the licencer of the system. Where seminal plasma, or components thereof, is added to sorted semen prior to cryopreservation and storage, it should be derived from animals of same or better health status.

Semen straws containing sex-sorted sperm should be permanently identified as such.

NB: FIRST ADOPTED IN 1986; MOST RECENT UPDATE ADOPTED IN 2013.

CHAPTER 4.7.

COLLECTION AND PROCESSING OF IN VIVO DERIVED EMBRYOS FROM LIVESTOCK AND EQUIDS

Article 4.7.1.

Aims of control

The purpose of official sanitary control of *in vivo* derived embryos intended for movement internationally is to ensure that specific pathogenic agents, 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* or *flock* from which the donor animals have been sourced.
- b) The donor animals should not be situated in a *herd* or *flock* subject to veterinary restrictions for OIE *listed disease* or pathogenic agents for relevant species (see Chapter 1.2.), other than those that are in International Embryo Transfer Society (IETS) Category 1 for the species of embryos being collected (see Article 4.7.14.).
- c) At the time of collection, the donor animals should be clinically inspected by the team *veterinarian*, or by a *veterinarian* responsible to the team *veterinarian* and certified to be free of clinical signs of diseases.

2. Semen donors

- a) Semen used to inseminate donor animals artificially should have been produced and processed in accordance with 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 (Article 4.7.14.), comprises the risk potential for embryo contamination and depends on:
 - a) the disease situation in the *exporting country* or *zone*;
 - b) the health status of the *herds* or *flocks* and the donors from which the embryos are collected;
 - c) the characteristics of the specified pathogenic agents that are of concern to the *Veterinary Authority* of the *importing country*.
- 2) The second phase covers risk mitigation by use of internationally accepted procedures for processing of embryos which are set out in the IETS Manual. These include the following:
 - a) The embryos should be washed at least ten times with at least 100-fold dilutions between each wash, and a fresh pipette should be used for transferring the embryos through each wash.
 - b) Only embryos from the same donor should be washed together, and no more than ten embryos should be washed at any one time.
 - c) Sometimes, for example when inactivation or removal of certain viruses, such as bovine herpesvirus-1 and Aujeszky's disease virus, is required, the standard washing procedure should be modified to include additional washes with the enzyme trypsin, as described in the IETS Manual.
 - d) The zona pellucida of each embryo, after washing, should be examined over its entire surface area at not less than 50X magnification to ensure that it is intact and free of adherent material.

- e) All shipments of embryos should be accompanied by a statement signed by the team veterinarian certifying that these embryo processing procedures have been completed.
- 3) The third phase, which is applicable to diseases not included in Category 1 of the IETS categorisation (Article 4.7.14.) and which are of concern to the *Veterinary Authority* of the *importing country*, encompasses the risk reductions resulting from:
 - a) post-collection *surveillance* of the donors and donor *herd or flock* based on the recognised *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 pathogenic 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 from pathogenic agents. Media and solutions used in the collection and storage of embryos should be sterilised by approved methods in accordance with the IETS Manual and handled in such a manner as to ensure that sterility is maintained. Antibiotics should be added to collection, processing, washing and storage media as recommended in the IETS Manual.

2. Equipment

- a) All equipment used to collect, handle, wash, freeze and store embryos should ideally be new or at least sterilised prior to use as recommended in the IETS Manual.
- b) Used equipment should not be transferred between countries for re-use by the embryo collection team.

Article 4.7.7.

Optional tests and treatments

- 1) The testing of samples can be requested by an *importing country* to confirm the absence of pathogenic agents that may be transmitted via *in vivo* derived embryos, or to help assess whether the degree of quality control of the collection team (with regard to adherence to procedures as described in the IETS Manual) is at an acceptable level. Samples may include:
 - a) Non-viable embryos and oocytes
Where the viable, zona pellucida intact embryos from a donor are intended for export, all non-fertilized oocytes and degenerated or zona pellucida compromised embryos collected from that donor should be washed in accordance with the IETS Manual and pooled for testing if requested by the *importing country*. Non-viable embryos and oocytes from the donor should be processed and stored together.
 - b) Embryo collection (flushing) fluids
The collection fluid should be placed in a sterile, closed container and, if there is a large amount, it should be allowed to stand undisturbed for one hour. The supernatant fluid should then be removed and the bottom 10–20 ml, along with accumulated debris, decanted into a sterile bottle. If a filter is used in the collection of embryos and oocytes then any debris that is retained on the filter should be rinsed off into the retained fluid.
 - c) Washing fluids
The last four washes of the embryos and oocytes should be pooled in accordance with the IETS Manual.
 - d) Samples
The samples referred to above should be stored at 4°C and tested within 24 hours. If this is not possible, then samples should be stored frozen at -70°C or lower.
- 2) When treatment of the viable embryos is modified to include additional washings with the enzyme trypsin (see point 2 c) in Article 4.7.5.), the procedure should be carried out in accordance with the IETS Manual. Enzyme treatment is necessary only when pathogenic agents for which the IETS recommends this additional treatment (such as with trypsin) may be present. It should be noted that such a 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 sterilised 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 in accordance with the standardised system recommended in the IETS Manual.
- 5) Liquid nitrogen containers should be sealed under the supervision of the *Official Veterinarian* prior to shipment from the *exporting country*.
- 6) Embryos should not be exported until the appropriate veterinary certificates are completed.

Article 4.7.9.

Procedure for micromanipulation

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

Article 4.7.10.

Specific conditions applicable to porcine embryos

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

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

Article 4.7.11.

Specific conditions applicable to equine embryos

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

Article 4.7.12.

Specific conditions applicable to camelid embryos

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

Article 4.7.13.

Specific conditions applicable to cervid embryos

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

Article 4.7.14.

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

Based on the conclusions of the IETS, the following 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 in accordance with the IETS Manual.
- b) The following diseases or pathogenic agents are in category 1:
 - Bluetongue (cattle)
 - Bovine spongiform encephalopathy (cattle)
 - *Brucella abortus* (cattle)
 - Enzootic bovine leukosis
 - Foot and mouth disease (cattle)
 - Infection with Aujeszky's disease virus (pigs): trypsin treatment required
 - Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis: 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 in accordance with the IETS Manual, but for which additional transfers are required to verify existing data.
- b) The following diseases are in category 2:
 - Bluetongue (sheep)
 - Caprine arthritis/encephalitis
 - Infection with classical swine fever virus.

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 in accordance with the IETS Manual, but for which additional *in vitro* and *in vivo* experimental data are required to substantiate the preliminary findings.
- b) The following diseases or pathogenic agents are in category 3:
 - Atypical scrapie (not a *listed disease*)
 - Bovine immunodeficiency virus (not a *listed disease*)
 - Bovine spongiform encephalopathy (goats) (not a *listed disease* of goats)
 - Bovine viral diarrhoea virus (cattle)
 - *Campylobacter fetus* (sheep) (not a *listed disease* of sheep)
 - Foot and mouth disease (pigs, sheep and goats)
 - *Haemophilus somnus* (cattle) (not a *listed disease*)
 - Infection with rinderpest virus (cattle)

- Maedi-visna (sheep)
- *Mycobacterium paratuberculosis* (cattle)
- *Neospora caninum* (cattle) (not a listed disease)
- Ovine pulmonary adenomatosis (not a listed disease)
- Porcine circovirus (type 2) (pigs) (not a listed disease)
- Porcine reproductive and respiratory disease syndrome (PRRS)
- Swine vesicular disease (not a listed 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 in accordance with the IETS Manual between collection and transfer.
- b) The following diseases or pathogenic agents are in category 4:
- African swine fever
 - Akabane (cattle) (not a listed disease)
 - Bovine anaplasmosis
 - Bluetongue (goats)
 - Border disease (sheep) (not a listed disease)
 - Bovine herpesvirus-4 (not a listed disease)
 - *Chlamydia psittaci* (cattle, sheep)
 - Contagious equine metritis
 - Enterovirus (cattle, pigs) (not a listed disease)
 - *Escherichia coli* 09:K99 (cattle) (not a listed disease)
 - Infection with equid herpesvirus 1 (Equine rhinopneumonitis)
 - Infection with equine arteritis virus
 - *Leptospira borgpetersenii* serovar *hardjobovis* (cattle) (not a listed disease)
 - *Leptospira* sp. (pigs) (not a listed disease)
 - Lumpy skin disease
 - *Mycobacterium bovis* (cattle)
 - *Mycoplasma* spp. (pigs)
 - Ovine epididymitis (*Brucella ovis*)
 - Parainfluenza-3 virus (cattle) (not a listed disease)
 - Parvovirus (pigs) (not a listed disease)
 - Q fever (*Coxiella burnetii*)
 - Scrapie (goats)
 - *Tritrichomonas foetus* (cattle)
 - *Ureaplasma* and *Mycoplasma* spp. (cattle, goats) (not a listed disease)
 - Vesicular stomatitis (cattle, pigs) (not a listed disease).

NB: FIRST ADOPTED IN 1986; MOST RECENT UPDATE ADOPTED IN 2015.

CHAPTER 4.8.

COLLECTION AND PROCESSING OF OOCYTES AND IN VITRO PRODUCED EMBRYOS 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 fertilisation of the oocytes, then *in vitro* culture to the morula or blastocyst stage. At this stage, 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 agents, 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 and 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 or oocytes;
 - b) processing of oocytes and production of embryos at a permanent or mobile laboratory;
 - c) storing oocytes 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 Services* 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 where oocytes 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 no 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.
- 5) The processing laboratory should have and use appropriate facilities to handle and process embryos for export, in accordance with the recommendations in the Manual of the International Embryo Technology Society (IETS).

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 IETS.

Batch collection involves the removal of ovaries from batches of donors slaughtered at a *slaughterhouse/abattoir*; these ovaries are then transported to the processing laboratory where the oocytes are recovered from the ovarian follicles by aspiration or slicing techniques. Batch collection has the disadvantage that it is usually impractical to trace the ovaries transported to the laboratory back to the donors slaughtered at the *slaughterhouse/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 Services* should have knowledge of the *herds* or *flocks* from which the donor animals were sourced.
- 2) The donor animals should not originate from *herds* or *flocks* that are subject to veterinary restrictions for foot and mouth disease or 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 *herds* or *flocks* should be conducted based on the recognised *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 a *slaughterhouse/abattoir*, the *slaughterhouse/abattoir* should be officially approved and under the supervision of a *veterinarian* responsible for ensuring that ante- and post-mortem inspections of potential donor animals are carried out, and for certifying them free from clinical or pathological signs of the diseases listed in point 2).
- 5) Donor animals slaughtered at a *slaughterhouse/abattoir* should not be animals designated for compulsory *slaughter* for a *notifiable disease* or be slaughtered at the same time as such animals.
- 6) Batches of ovaries and other tissues collected from a *slaughterhouse/abattoir* should not be transported to the processing laboratory before confirmation has been obtained that ante-mortem and post-mortem inspections of donors have been carried out with favourable results.
- 7) Equipment for the removal and transport of ovaries and other tissues should be cleaned and sterilised before use and used exclusively for these purposes.
- 8) Records of the identities and origins of all donors should be maintained for inspection by the *Veterinary Services* 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* or *flocks* from which the donors originated will be maintained.

Article 4.8.5.

Tests and treatments

A supplementary approach for ensuring that *in vitro* produced embryos do not transmit disease is testing various materials to confirm the absence of pathogenic agents listed in point 2) of Article 4.8.4.

Tests may also be used to assess whether quality control procedures being applied in the processing laboratory are of an acceptable standard.

Tests may be carried out on the following materials:

- 1) non-viable oocytes or embryos from any stage of the *in vitro* production line from batches intended for export;
- 2) samples of *in vitro* maturation medium taken prior to mixing the oocytes with semen for the fertilisation process;
- 3) samples of embryo culture medium taken immediately prior to embryo storage;
- 4) a pool of the last three washes from the 10 washes performed on the embryos.

These samples should be stored at 4°C and tested within 24 hours. If this is not possible, then the samples should be stored frozen at minus 70°C or lower.

Additionally:

- 1) Semen used to fertilise oocytes *in vitro* should have been collected and processed in accordance with Chapter 4.5. and meet the health requirements in Chapter 4.6. as appropriate to the species and in relevant *listed disease*-specific chapters.

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 from pathogenic agents. Media should be sterilised prior to use by approved methods in accordance with the Manual of the IETS and handled appropriately to ensure that sterility is maintained. Antibiotics should be added to all fluids and media as recommended in the Manual of the IETS.
- 3) All equipment used to recover, handle, culture, wash, freeze and store oocytes or embryos should be new or cleaned and sterilised prior to use as recommended in the Manual of the IETS.

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 and pathogenic agents by the IETS, as described for *in vivo* derived embryos in Article 4.7.14., does not apply in the case of *in vitro* produced embryos. Irrespective of the animal species, there are three phases in the embryo production and transfer process that determine the final level of risk. These are as follows:

- 1) the first phase comprises the risk potential for ovary, oocyte or embryo contamination and depends on:
 - a) the disease situation in the exporting country or zone;
 - b) the health status of the *herds or flocks* and the donors from which the ovaries, oocytes, embryos or semen for fertilisation of oocytes are collected;
 - c) the characteristics of the pathogenic 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 Manual of the IETS. These include the following:
 - a) oocytes and embryos should be washed between each stage of production;
 - b) after the *in vitro* culture period is finished the embryos should be washed at least 10 times with at least 100-fold dilutions between each wash, and a fresh pipette should be used for transferring the embryos through each wash;
 - c) 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;

- d) 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 Manual of the IETS;
 - e) 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 from 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* or *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 a *slaughterhouse/abattoir*, although surveillance of the *herds* or *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 pathogenic agents.

Article 4.8.7.

Conditions applicable to the storage, transport and export of oocytes and embryos

Oocytes and *in vitro* produced embryos can be stored and transported fresh, chilled or frozen.

Fresh embryos may undergo culture in portable incubators during transportation and should arrive at the recipient animal within five days, in time for transfer of the mature blastocysts. Chilled embryos should be transferred within ten days of chilling.

The *Veterinary Services* should have knowledge of the variety of oocyte and embryo storage systems available and should have procedures in place for the safe and timely inspection and certification of these oocytes and embryos to ensure their viability.

- 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) For frozen oocytes and embryos:
 - a) sterile ampoules, vials or straws should be sealed prior to freezing or after vitrification and should be labelled according to the Manual of the IETS;
 - b) the frozen oocytes and embryos should be frozen in liquid nitrogen that has not been used previously then stored in liquid phase nitrogen that has not been used previously or in the vapour phase of liquid nitrogen disinfected containers under strict hygienic conditions at a storage place;
 - c) liquid nitrogen containers should be sealed prior to shipment from the *exporting country*.
- 3) For fresh or chilled oocytes and embryos:
 - a) sterile ampoules, vials or straws should be sealed prior to storing in portable incubators and should be labelled in accordance with the Manual of the IETS;
 - b) the fresh or chilled oocytes and embryos should be stored under strict hygienic conditions in portable incubators disinfected in accordance with the Manual of the IETS and manufacturer's instructions;
 - c) portable incubators should be sealed prior to shipment from the *exporting country*.
- 4) Oocytes and 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.

NB: FIRST ADOPTED IN 1992; MOST RECENT UPDATE ADOPTED IN 2018.

CHAPTER 4.9.

COLLECTION AND PROCESSING OF MICROMANIPULATED OOCYTES OR EMBRYOS 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 or *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 oocytes or embryos 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 oocytes or embryos 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 oocytes or embryos should be collected and processed in accordance with the sanitary conditions laid down in Chapter 4.7. (*in vivo* derived embryos), or produced in accordance with the sanitary conditions laid down in Chapter 4.8. (*in vitro* produced oocytes or embryos).
- 2) Responsibility for the oocytes or embryos 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 from pathogenic agents 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 in accordance with the protocols laid down in the IETS Manual¹ and they should be observed to have an intact zona pellucida before and after washing. Only embryos from the same donor, or, in the case of some *in vitro* produced embryos, embryos originating from the same batch of ovaries from a *slaughterhouse/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 oocytes or embryos 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 oocytes, embryos or other cells, and in their micromanipulation, culture, washing and storage should be free from pathogenic agents (including transmissible spongiform encephalopathy agents, sometimes called prions). All media and solutions should be sterilised by approved methods in accordance with the IETS Manual¹ 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 Manual¹.

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 oocytes or embryos batch) or should be effectively sterilised between oocytes or embryos batch in accordance with recommendations in the IETS Manual¹.

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, foetal and adult cells, including spermatozoa or spermatids for ICSI) are to be transplanted, the parent embryo, foetus 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 in accordance with 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 agents are absent.

1. Samples

Samples to be tested may include those referred to in Article 4.7.7. and in Article 4.8.5. Where cells other than 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 agents may be requested when pathogenic agents that are not removed by washing may be present. If used, such treatments should also be applied prior to any micromanipulation, and in accordance with the IETS Manual¹.

Article 4.9.5.

Conditions applicable to storage, quarantine and transport

Micromanipulated embryos should be stored, quarantined and transported in accordance with 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.

NB: FIRST ADOPTED IN 1992; MOST RECENT UPDATE ADOPTED IN 2009.

1 Manual of the International Embryo Transfer Society.

CHAPTER 4.10.

COLLECTION AND PROCESSING OF LABORATORY RODENT AND RABBIT OOCYTES OR EMBRYOS

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 agents (i.e. gnotobiotic), although sometimes a cocktail of known, non-pathogenic agents 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') pathogenic agents as well as non-pathogenic agents 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 Report¹.

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 agents, 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 oocytes or embryos.

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 or 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 pathogenic agents 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 Manual² 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* 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 characteristics of the specified pathogenic 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 Manual². 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 Manual².
 - d) The zona pellucida of each embryo, after washing, should be examined over its entire surface area at not less than 50X magnification to ensure that it is intact and (apart from the mucin layer in the case of rabbit embryos) free of adherent material.
- 3) The third phase, which is applicable to diseases of concern to the *Veterinary Authority* of the *importing country*, encompasses risk mitigation resulting from:
- a) post-collection surveillance of the microbial status of the donor colony based on the recognised 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 donors 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 or 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 in accordance with 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 pathogenic agents depends on the animal species and may be influenced by geographical location. Recommendations regarding specific pathogenic agents to be tested for in different laboratory animal species have been published elsewhere¹.

1. Defined microbial status

- a) Microbiologically defined colonies (Article 4.10.1.) represent the cleanest sources of gametes, and the embryos recovered from these animals can be regarded as pathogen free.
- b) Since the male and female donors are pathogen free, dissection of the female reproductive tract and embryo collection procedures should be performed under aseptic laboratory conditions, using a biological safety cabinet if appropriate.
- c) Embryo washed as described in point 2) of Article 4.10.4. is not necessary but it is recommended that embryos are washed two or three times. In each wash, embryos should be gently agitated in the medium.
- d) The embryos should be recorded as coming from a germfree or microbiologically defined, barrier maintained colony, thus indicating that special risk management procedures (Article 4.10.4.) for the removal of pathogenic agents 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 pathogenic agents, resulting in *infection*, with positive antibody titres or even active clinical disease, but the pathogenic agents of concern in each individual colony should be well known.
- b) Reproductive tracts (uteri, oviducts 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 pathogenic agents 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, pathogenic agents are known to occur in the colony, embryos should be processed in accordance with the risk management procedures, including washing, as described in Article 4.10.4., and in the IETS Manual².
- d) Embryos derived from animals that have positive antibody titres or other evidence of specific pathogenic agents 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 pathogenic agents of concern, and introduction of offspring into the colony should only take place if the test results are satisfactory.

3. Undefined microbial conditions

- a) Embryos from free ranging animals or from colonies of unknown health status require the full range of risk management procedures that are described in Article 4.10.4. and in the IETS Manual². The procedures resemble those used for embryos of livestock as recommended in Chapters 4.7. and 4.8. of this *Terrestrial Code*. Ideally, the breeder males and donor females should be separated from other animals and tested 15 days before and on the day of breeding (for males) or at embryo collection (for females). Alternatively, the animals could be incorporated into a conventional colony, where, over time, a health history can be documented to reduce the strict monitoring and embryo handling requirements.
- b) Biological safety cabinet should be used for handling donors and reproductive tissues, and for processing embryos.
- c) Post-mortem testing of the donor females for diseases or pathogenic agents of concern to the *importing country* may be appropriate after the oocytes or embryos 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 pathogenic agents of concern.
- d) Embryos should be washed at least ten times in accordance with the protocols in the IETS Manual² and trypsin treatment should be used if presence of certain pathogenic herpesviruses is of concern.
- e) Cryopreserved embryos should be stored in the exporting laboratory until such time as the necessary disease screening of colonies, tissues or fluids is completed and the supporting documents for certification completed and signed by the institute *veterinarian*.
- f) On arrival in the *importing country* the embryos should be transferred into recipients in a quarantine system. Recipients should be tested at intervals appropriate to recognised 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 in accordance with or similar to the system recommended in the IETS Manual². Identification should include details of the species or genotype of the donors, microbial status (e.g. defined, conventional or undefined), collection or cryopreservation date, number and developmental stage of the embryos, container number and details of any specialised procedure such as *in vitro* fertilisation, 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* fertilisation and micromanipulation

If embryos are to be produced by *in vitro* fertilisation of oocytes, it is advised that the washed sperm should be used so as to minimise the risk of possible exposure to pathogenic agents. 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.

NB: FIRST ADOPTED IN 1998; MOST RECENT UPDATE ADOPTED IN 2010.

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 in accordance with 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 results 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 *risk assessments* can be qualitative or quantitative (see Chapter 2.1.). In disease scenarios it is more likely that a *qualitative risk assessment*, in which 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', is all that is required. *Qualitative assessments* do not require mathematical modelling to carry out routine decision-making. *Quantitative risk assessments* assign magnitudes to the *risks* in numerical terms (e.g. 1/1,000,000).
- 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 *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:

- 1) Oocytes (obtained from the slaughterhouse/abattoir, recovered from trans-vaginal ultrasound-guided procedures or by laparotomy procedures)

Ovaries which are collected at an *slaughterhouse/abattoir* should be collected, transported and processed in accordance with the recommendations laid down in Chapter 4.8.

The primary *risks* are associated with the health status of the animal from which the ovaries are harvested and the quality of the oocytes.
- 2) Donor cells (cells obtained from animals chosen to be cloned – by biopsy, harvesting at slaughter or after death)

Currently there are no specific new *risks* identified with SCNT cloning. There is a proposed *risk* related to activation of endogenous retroviruses during cell transfer procedures, however, this may be more theoretical than practical. In some current experimental procedures, the donor cell may be treated with chemicals to modify its composition, for example cell cycle inhibitors or chromatin modifiers.
- 3) *In vitro* culture of reconstructed embryos (procedure used to fuse the donor and recipient material and to culture the reconstructed embryo)
- 4) *Risks* associated with the method of fusing donor cells with enucleated recipient oocytes and with culture conditions.

In addition, the practitioner should ensure that the clone pregnancy is compatible to the surrogate dam's breed, anatomy and physiology.

1. Oocytes

The laboratory or the producer should establish a detailed record of ovaries – their origin, health of the animal from which the ovaries are obtained, details of any systemic lesion on the animal and proper *herd* or *flock* 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 or 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 or 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% in a *herd* or *flock*. 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, umbilical hernia, flexor muscle contractions, respiratory or cardiac insufficiency, and failure to suckle. This will allow proper treatment and care of the newborn and increase the survival of the young one.
- To consolidate current understanding of the health status of animal clones, a comprehensive veterinary examination should be performed to monitor the progress of the clone, as unexplained fatalities or fatalities arising from systemic complications have been reported. It is encouraged to follow the health profile of the animals to at least the reproductive maturity stage, and to record the ability to reproduce (fertility index).
- *Animal welfare* concerns ranging from LOS to serious abnormalities are notable in the debates pertaining to cloning technology. Proper research and peer-reviewed data should be generated. The animal clones should undergo species-specific basic *welfare* assessments. If *welfare* concerns are detected at initial screening, a more extensive characterisation of that phenotype should be performed to document the *animal welfare* concerns.
- Proper monitoring of the animal population during different stages of life from birth to puberty should be documented to address and validate the genomic potential of the animal clones.

4. Managing animal health risks related to sexually reproduced progeny of clones

Presently there is no evidence of an increased health *risk* if sexual reproduction is used for obtaining progeny. Some data indicate that the reprogramming errors during the cloning process may actually be corrected during the natural mating and reproduction process:

- a) Characterisation of the health profile, including health status and data on *animal welfare*, would consolidate the knowledge of sexually reproduced progeny.
- b) Monitoring the reproductive performance of sexually reproduced progeny of clones would be useful to assess their reproductive capacity in comparison with their conventional counterparts.

5. Managing animal health risks associated with re-cloning or clones of clones

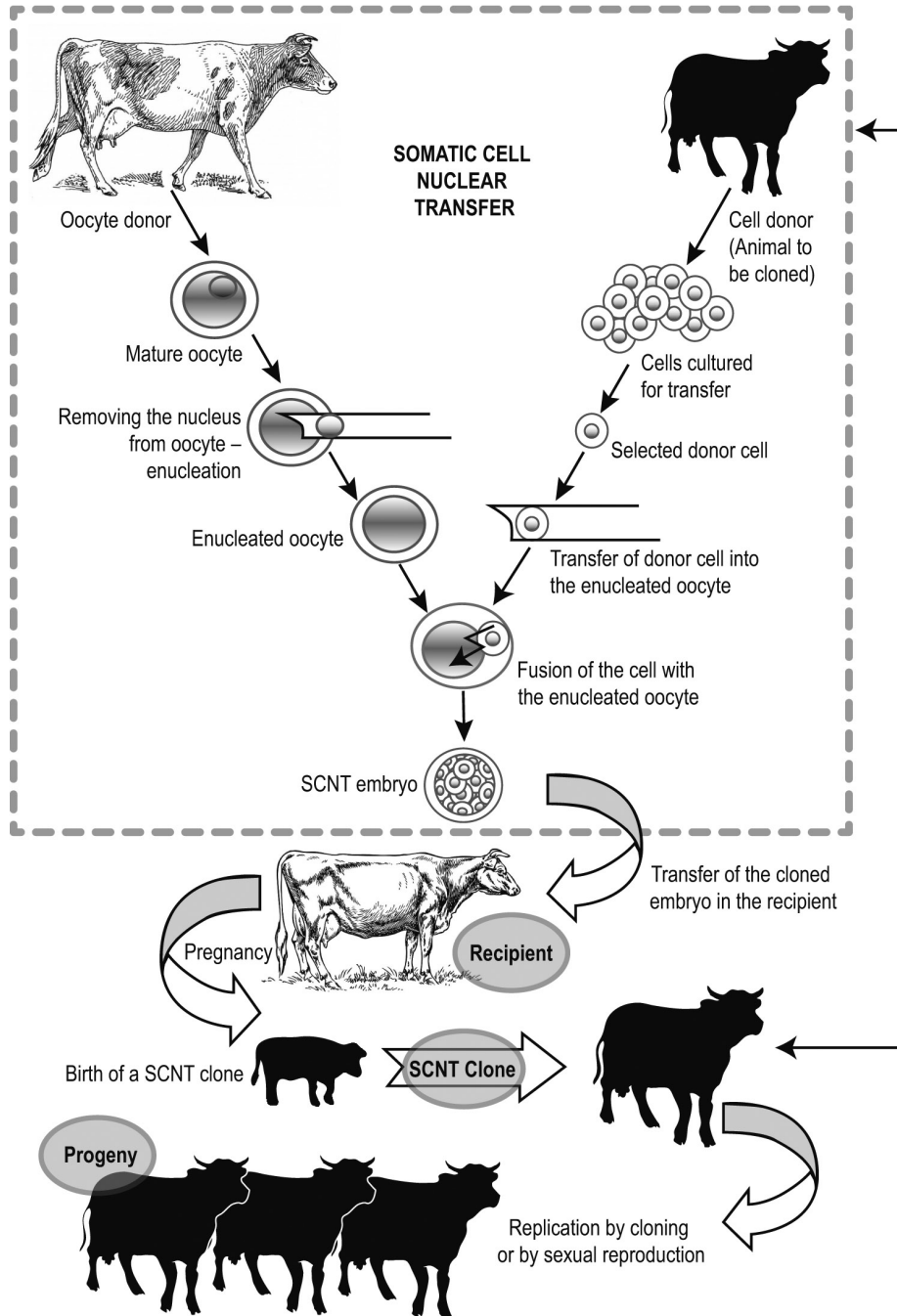
Information on re-cloning is only beginning to appear. It is therefore necessary to follow the approach below:

- 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.



NB: FIRST ADOPTED IN 2008; MOST RECENT UPDATE ADOPTED IN 2017.

CHAPTER 4.12.

DISPOSAL OF DEAD ANIMALS

Article 4.12.1.

Introduction

The mass disposal of dead *animals* associated with an animal disease *outbreak* is often subject to intense public and media scrutiny thereby obligating the *Veterinary Authority* of a Member Country to not only conduct disposal operations within acceptable scientific principles to destroy the pathogenic agent 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 organisations, 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 pathogenic agent are important. Spread of the pathogenic agent 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 pathogenic agent.

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 the pathogenic agent.

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 *slaughterhouses/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 methods 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 pathogenic 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, sterilised products, e.g. animal fat and dried animal protein. The technology exists in dedicated facilities. It produces an effective inactivation of all pathogenic agents 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 pathogenic agents, 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 pathogenic agents.

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 inactivation of pathogenic agents, 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 pathogenic agents 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 pathogenic agents. 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 pathogenic agents.

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 by-products are the mineral constituents of bones and teeth. This residue (2% of the original weight of the animal) is sterile and easily crushed into a powder. The temperature and alkali conditions of the process destroy the protein coats of viruses and the peptide bonds of prions. Both lipids and nucleic acids are degraded. The process is carried out in an insulated steam-jacketed, stainless steel pressure vessel.

10. Bio-refining

Bio-refining is a process of high pressure, high temperature, thermal hydrolysis conducted in a sealed pressurised chamber. The waste material is treated with high-pressure saturated steam at 180°C under a minimum of 10 bar pressure and continuous disruption by mechanical stirring for a period of 40 minutes. The whole procedure, from the loading of the chamber until the discharge from the chamber, occupies approximately 120 minutes. All microbiological agents are inactivated and the infectivity of the infectious agents causing transmissible spongiform encephalopathies is destroyed.

11. Dead animal disposal at sea

International Conventions define the conditions to be met for the disposal of dead *animals* at sea.

Article 4.12.7.

Recommendations for decision-making for the disposal of dead animals

The disposal of large numbers of dead *animals* will be expensive. As well, fixed and variable costs will vary with the choice of the disposal method. Each method used will result in indirect costs on the environment, local economies, producers, and the livestock industry. In addition to *biosecurity* considerations, decision makers need to understand the economic, social, environmental protection and aesthetic impact of various disposal technologies.

A disposal option hierarchy may be incapable of fully capturing and systematizing the relevant dimensions at stake, and decision makers may be forced to consider the least preferred means. It therefore requires a comprehensive understanding of any array of dead animal disposal technologies and should reflect a balance between the scientific, economic, and social issues at stake. Timely *slaughter*, maintenance of security and prevention of further spread of disease, are the essential considerations in terms of disease control.

The following is an example of a possible process for aiding decision-making by comparing the suitability of various disposal options against factors that are considered important for the specific disposal event in question:

- 1) Step 1 - Define the factors to be considered. Include all relevant factors and allow enough flexibility to permit modifications for different situations and locations. Examples of possible factors include operator safety, community concerns, international acceptance, transport availability, industry standards, cost effectiveness and speed of resolution. These factors can be modified or changed, as is shown in the following example, to best fit the situation of event involved.
- 2) Step 2 - Assess the relative importance of the factors by weighting each on their considered importance to addressing the event in question. The sum of all the weightings, regardless of the number of factors, should total 100.
- 3) Step 3 - Identify and list all disposal options under consideration. Rate each disposal option against each factor and assign a Utility Rating of between 1 to 10 to each comparison. The Utility Rating (U) is a number between 1 and 10 which is allocated in accordance with how well the option achieves the ideal with respect to each factor (e.g. 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), (e.g. $V = F \times U$).
- 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	

NB: FIRST ADOPTED IN 2006; MOST RECENT UPDATE ADOPTED IN 2010.

CHAPTER 4.13.

GENERAL RECOMMENDATIONS ON DISINFECTION AND DISINSECTION

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% 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% formaldehyde (approximately 30% formalin), or
 - 4% 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% aqueous solution of formaldehyde) with stirring for one hour daily is recommended:
- i) for slurry up to 5% dry matter, 50 kg formalin per m³ for 4 days;
 - ii) for slurry >5% and <10% 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% formaldehyde (approximately 30% formalin); or
 - 4% 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% formaldehyde (approximately 30% formalin), repeated after one hour; or
 - 4% glutaraldehyde (pH 8.0–8.5), repeated after one hour; or
 - 3% hydrogen peroxide; or
 - 1% peracetic acid, repeated after one hour; or
 - 5–10% 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% w/v formaldehyde) in an electric kettle (with a timing switch to turn it off) should be boiled away and the room left overnight. Room temperature should be >15°C.

[Note: Formaldehyde fumigation is hazardous and proper respirators should be on hand for operator safety. The effectiveness of the fumigation process should be verified by exposing dried discs of filter paper which have been dipped in a suspension of spores of *B. subtilis* var. *globigii* or *B. cereus* or Sterne vaccine strain of *B. anthracis* and placed in the room before fumigation is started. At the end of fumigation, the discs should be placed on nutrient agar plates containing 0.1% histidine and incubated overnight at 37°C. If fumigation has been effective, there will be no bacterial growth.]

NB: FIRST ADOPTED IN 1976; MOST RECENT UPDATE ADOPTED IN 2014.

CHAPTER 4.14.

OFFICIAL HEALTH CONTROL OF BEE DISEASES

Article 4.14.1.

Purpose

This chapter is intended to set out guidelines for *official health control* of bee diseases. These are needed for the control of endemic bee diseases at the country level and to detect incursions of exotic diseases, thereby ensuring safe *international trade* of bees, bee products and used apicultural equipment. The guidelines are designed to be general in nature and more specific recommendations or requirements are made in chapters on bee diseases.

Article 4.14.2.

Overview

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

- 1) official *registration* of the *apiaries* by the *Veterinary Authority* or other *Competent Authority* in the whole country or region;
- 2) an organisation for permanent health *surveillance*;
- 3) approval of breeding *apiaries* for export trade;
- 4) measures for cleaning, *disinfection* and *disinfestation* of apicultural equipment;
- 5) rules precisely stating the requirements for issuing an *international veterinary certificate*.

Article 4.14.3.

Official registration of the apiaries by the Veterinary Authority or other Competent Authority in the whole country or region

The *registration* of *apiaries* is the first step in developing a regional management plan for bee disease *surveillance* and control. With knowledge of bee density and location it is possible to design valid sampling schemes, to predict the spread of disease and to design inspection programmes to target areas of high risk.

The official *registration* of *apiary* sites should be annual and may provide information such as the presumptive locations of the *apiary* sites in the next 12 months, the average number of colonies in each *apiary* site, and the name and address of the principal owner of the bees in the *apiary*.

The main *apiary* locations (places where the *bee hives* are located the longest time in the year) should be registered first, followed as far as possible by the seasonal *apiary* locations.

Article 4.14.4.

Organisation for permanent official sanitary surveillance of apiaries

Veterinary Authorities or other *Competent Authorities* of countries are requested to regulate the organisation for permanent official sanitary *surveillance* of *apiaries*.

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

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

- 1) visit *apiaries*:
 - a) annual visits to an appropriate sample of *apiaries*, based on the estimated risk in the whole country or region, during the most appropriate periods for the detection of diseases;
 - b) additional visits to *apiaries* may be carried out for specific purposes including trade or transfer to other regions, or any other purpose whereby diseases could be spread;
- 2) collect samples required for the diagnosis of diseases and despatch them to a *laboratory*; the results of *laboratory* examinations should be communicated within the shortest delay to the *Veterinary Authority* or other *Competent Authority*;
- 3) apply hygiene measures, comprising, in particular, treatment of colonies of bees, as well as *disinfection* of the equipment and possibly the destruction of affected or suspect colonies and of the contaminated equipment so as to ensure rapid eradication of any *outbreak* of a disease.

Article 4.14.5.

Conditions for approval of breeding apiaries for export trade

Veterinary Authorities or other *Competent Authorities* of *exporting countries* are requested to regulate the conditions for approval of breeding *apiaries* for export trade.

The *apiaries* should:

- 1) have received, for at least the past two years, visits by a health inspector and adviser, carried out at least once a year using a *risk*-based approach during the most appropriate periods for detection of *listed diseases* of bees. During these visits, there should be a systematic examination of at least 10% of the hives containing bees and of the used apicultural equipment (especially stored combs), and the collection of samples to be sent to a *laboratory* and, depending on the situation of the *importing* and *exporting countries*, no positive results were reported to the *Veterinary Authorities* or other *Competent Authorities* for the relevant *listed disease* of bees;
- 2) be regularly sampled, depending on the epidemiological situation of the *importing* and *exporting countries*, and found free from the relevant *listed diseases* of bees. To achieve this, a statistically valid number of bee colonies should be examined by any method complying with the relevant chapters of the *Terrestrial Manual*.

Bee-keepers should:

- 3) immediately notify the *Veterinary Authority* or other *Competent Authority* of any suspicion of a *listed disease* of bees in the breeding *apiary* and in other epidemiologically linked *apiaries*;
- 4) not introduce into the *apiary* any bee (including pre-imago stages) or used apicultural equipment or product originating from another *apiary* unless that *apiary* is recognised by the *Veterinary Authority* or other *Competent Authority* to be of equivalent or higher health status or the used apicultural equipment or product has been treated in agreement with a procedure described in the relevant chapters of the *Terrestrial Code*;
- 5) apply special breeding and despatch techniques to ensure protection against any outside contamination, especially for the breeding and sending of queen-bees and accompanying bees and to enable retesting in the *importing country*;
- 6) collect at least every 30 days, during the breeding and despatch period, appropriate samples to be sent to a *laboratory* and all the positive results officially reported to the *Veterinary Authority* or other *Competent Authority*.

Article 4.14.6.

Conditions for sanitation and disinfection or disinfestation of apicultural equipment

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

- 1) Any apicultural equipment kept in an *establishment* which has been recognised as being affected with a contagious disease of bees should be subjected to *sanitary measures* ensuring the elimination of pathogens.
- 2) In all cases, these measures comprise the initial cleaning of the equipment, followed by sanitation or *disinfection* or *disinfestation* depending on the disease concerned.
- 3) Any infested or contaminated equipment which cannot be subjected to the above-mentioned measures should be destroyed, preferably by burning.

- 4) The products and means used for sanitation and *disinfection* or *disinfestation* should be accepted as being effective by the *Veterinary Authority* or other *Competent Authority*. They should be used in such a manner as to exclude any risk of contaminating the equipment which could eventually affect the health of bees or adulterate the products of the hive.

Article 4.14.7.

Preparation of the international veterinary certificate for export

This certificate covers hives containing bees, brood-combs, royal cells, used apicultural equipment and bee products.

This document should be prepared in accordance with the model contained in Chapter 5.10. and taking into account the chapters on bee diseases.

NB: FIRST ADOPTED IN 1976; MOST RECENT UPDATE ADOPTED IN 2013.

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 paraveterinarians.

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*.

NB: FIRST ADOPTED IN 1982.

CHAPTER 4.16.

HIGH HEALTH STATUS HORSE SUBPOPULATION

Article 4.16.1.

General provisions

This chapter provides recommendations for the establishment of a *subpopulation* of horses that are moved internationally to compete in equestrian competitions, including thoroughbred races, and that have a high health status certified by the *Veterinary Authority*, in order to facilitate their safe temporary importation, onward movement and return to the country of usual residence.

For the purpose of the *Terrestrial Code*, a high health status horse *subpopulation* is one with a distinct status with respect to specified *listed diseases*, which has been established in accordance with the provisions in Chapter 4.4., by the application of documented health management practices and biosecurity measures to create and maintain a functional separation between horses within the defined *subpopulation* and all other equids at all times.

For the purpose of the *Terrestrial Code*, a high health, high performance (HHP) horse means one belonging to a high health status *subpopulation* and registered by the International Equestrian Federation (FEI) or the International Federation of Horseracing Authorities (IFHA) as eligible to take part in international competitions and races accompanied by a certificate for temporary international movement in accordance with the *Terrestrial Code*.

Horses that are moved internationally for the purpose of breeding or any other purpose not linked to competitions are excluded from the high health status *subpopulation*.

Article 4.16.2.

Criteria for the inclusion of horses in the high health status subpopulation

1. High health status

Each horse in the *subpopulation* is subjected to specific measures to establish its health status, and preserve its health status and that of the other horses in the *subpopulation*.

These measures comprise a specific set of *laboratory tests*, treatments, isolation periods and *vaccinations* appropriate to the disease status of the country or region of usual residence and temporary import of the horse. Records of all treatments and *vaccinations*, and results of tests and clinical examinations are documented in an individual passport that complies with Chapter 5.12.

2. Identification and traceability

Consistent with the provisions of Chapters 4.1. and 4.2., horses in the *subpopulation* are individually identified as follows:

- a) Each horse bears a permanent unique identifier, preferably a microchip.
- b) Each horse is accompanied at all times by its individual passport that contains information on the horse's unique identifier.
- c) Each horse has an attachment to its passport that identifies it as a member of the high health status *subpopulation*.
- d) Horses are registered in an international database that contains relevant information linked to the passport and the identifier to which *Veterinary Authorities* have access.

3. Management of the subpopulation

- a) In the course of each veterinary examination of a horse, its passport is checked, its identity verified and the details of any tests and treatments, including *vaccinations*, are recorded and signed by the examining *veterinarian*.
For certification purposes, the passport is examined, verified and signed by an *Official Veterinarian*, in accordance with Article 5.2.2. For international movements of not more than 90 days, HHP horses should be accompanied by an *international veterinary certificate* in accordance with the *Terrestrial Code*.
- b) The high health status of each horse in the *subpopulation* is maintained by ensuring compliance at all times with an international biosecurity plan approved by the *Veterinary Authorities* of the *importing* and *exporting countries*, in accordance with the relevant recommendations of the OIE. This compliance is assured and validated through continual veterinary supervision of horses at the *establishment* of usual residence, during transport and at competition venues. This supervision is provided by *veterinarians* authorised for that purpose by a *Veterinary Authority*. Non-compliance results in suspension of the high health status of the horse.
- c) An appropriate qualification period is required for entry or re-entry of a horse into the *subpopulation*. The procedures for qualification should be described in the international biosecurity plan.
- d) A maximum period is set for each absence of a horse from its country of usual residence, as specified in the international biosecurity plan.

Article 4.16.3.

Recommendations for the Veterinary Authorities

Organisations that are responsible for ensuring compliance with this chapter should be authorised and supervised by the *Veterinary Authorities*. *Veterinary Authorities* are encouraged to develop specific protocols for the temporary importation of horses of high health status entering the country for the purpose of competition at equestrian events or for their onward movement to other such events and for their return to their country of usual residence.

Veterinary Authorities are encouraged to recognise the international biosecurity plan developed by the FEI and IFHA on the basis of the OIE *Handbook for the Management of High Health, High Performance Horses*.

NB: FIRST ADOPTED IN 2014; MOST RECENT UPDATE ADOPTED IN 2017.

CHAPTER 4.17.

VACCINATION

Article 4.17.1.

Introduction and objectives

Vaccination is intended to prevent and control the occurrence of a disease and reduce the transmission of the pathogenic agent. Ideally, vaccines should induce immunity that prevents *infection*. However, some vaccines may only prevent clinical signs, or reduce multiplication and shedding of the pathogenic agent.

Vaccination may contribute to improvement of *animal* and human health, *animal welfare*, agricultural sustainability and to reduction of the use of *antimicrobial agents* in *animals*.

The objective of this chapter is to provide guidance to *Veterinary Services* for the use of *vaccination* in support of disease prevention and control programmes. The recommendations in this chapter may be refined by the specific approaches described in the *listed disease*-specific chapters of the *Terrestrial Code*. Furthermore, the recommendations in this chapter may also be used for any diseases for which a vaccine exists.

The *vaccination* strategy applied depends on biological, technical and policy considerations, available resources and the feasibility of implementation.

The prerequisites to enable a Member Country to successfully implement *vaccination* include compliance with:

- 1) the recommendations on *surveillance* in Chapter 1.4.;
- 2) the relevant provisions in Chapters 3.1. and 3.4.;
- 3) the recommendations on *vaccination* in the *listed disease*-specific chapters of the *Terrestrial Code*;
- 4) in vaccine-producing countries, the relevant general and specific recommendations for veterinary vaccine production and quality control in the *Terrestrial Manual*.

Article 4.17.2.

Definitions

For the purposes of this chapter:

'**Emergency vaccination**': means a *vaccination* programme applied in immediate response to an *outbreak* or increased risk of introduction or emergence of a disease.

'**Population immunity**': means the proportion of the target population effectively immunised at a specific time.

'**Systematic vaccination**': means an ongoing routine *vaccination* programme.

'**Vaccination coverage**': means the proportion of the target population to which vaccine was administered during a specified timeframe.

'**Vaccination programme**': means a plan to apply *vaccination* to an epidemiologically appropriate proportion of the susceptible animal *population* for the purposes of disease prevention or control.

Article 4.17.3.

Vaccination programmes

The objectives and strategy of a *vaccination* programme should be defined by the *Veterinary Authority* before the implementation of *vaccination*, taking into account the epidemiology of the disease, its impact and zoonotic potential, the species affected and their distribution.

If these factors indicate that the programme should be expanded beyond national boundaries, the *Veterinary Authority* should liaise with the *Veterinary Authorities* of neighbouring countries. When appropriate, a regional approach to harmonise *vaccination* programmes is recommended.

Veterinary Authorities should liaise, as relevant, with public health authorities when developing and implementing *vaccination* programmes against zoonoses.

Vaccination programmes may include systematic *vaccination* and emergency *vaccination*.

- 1) Systematic *vaccination* in infected countries aims to reduce the *incidence*, *prevalence* or impact of a disease with the objective of prevention, control and possible eradication. In free countries or *zones*, the objective of systematic *vaccination* is to prevent the introduction of a disease from an infected neighbouring country or *zone*, or to limit the impact in the case of the introduction of that disease.
- 2) Emergency *vaccination* provides an adjunct to the application of other essential *biosecurity* and disease control measures and may be applied to control *outbreaks*. Emergency *vaccination* may be used in response to:
 - a) an *outbreak* in a free country or *zone*;
 - b) an *outbreak* in a country or *zone* that applies systematic *vaccination*, but when revaccination is applied to boost existing immunity;
 - c) an *outbreak* in a country or *zone* that applies systematic *vaccination*, but when the vaccine employed does not provide protection against the strain of the pathogenic agent involved in the *outbreak*;
 - d) a change in the risk of introduction of a pathogenic agent or emergence of a disease in a free country or *zone*.

Vaccination programmes should be integrated with other ongoing animal health-related activities involving the target population. This can improve the efficiency of the programme and reduce the cost by optimisation of resources.

Article 4.17.4.

Launching a vaccination programme

When deciding whether to initiate a *vaccination* programme the *Veterinary Authority* should consider, among others, the following:

- 1) the epidemiology of the disease;
- 2) the probability that the disease cannot be rapidly contained by means other than *vaccination*;
- 3) the *incidence* and *prevalence* of the disease, if present;
- 4) the likelihood of introduction of a pathogenic agent or emergence of a disease;
- 5) the zoonotic potential of the disease;
- 6) the density of the exposed susceptible animal *population*;
- 7) the level of population immunity;
- 8) the risk of exposure of specific *subpopulations* of susceptible animals;
- 9) the suitability of a *vaccination* programme as an alternative to or an adjunct to other disease control measures such as a *stamping-out policy*;
- 10) the existence of an *animal identification system* to differentiate vaccinated from unvaccinated *subpopulations*;
- 11) the availability of a safe and effective vaccine;
- 12) the availability of human, financial, and material resources;
- 13) the cost-benefit analysis of the *vaccination* programme, including its impact on trade and public health.

Article 4.17.5.

Vaccination strategies

Different *vaccination* strategies may be applied alone or in combination, taking into account the epidemiological and geographical characteristics of occurrence of the disease. The following strategies may be applied:

- 1) '**Barrier vaccination**': means *vaccination* in an area along the border of an infected country or *zone* to prevent the spread of *infection* into or from a neighbouring country or *zone*.
- 2) '**Blanket vaccination**': means *vaccination* of all susceptible animals in an area or an entire country or *zone*.

- 3) '**Ring vaccination**': means *vaccination* of all susceptible animals in a delineated area surrounding the location where an *outbreak* has occurred.
- 4) '**Targeted vaccination**': means *vaccination* of a *subpopulation* of susceptible animals.

Article 4.17.6.

Choice of vaccine

Depending on the disease, several vaccines may be available. To achieve the objectives of the *vaccination* programme, the choice of a vaccine is a critical element that depends on several factors including:

1. Availability and cost

- a) Availability of the vaccine including relevant regulatory approvals and adequate quantities at the time required;
- b) capacity of the providers to supply the vaccine for the duration of the *vaccination* campaign and to respond to increased needs;
- c) flexibility in the number of doses per vial to match the structure of the target population;
- d) a comparison of the costs of vaccines that meet the technical specifications established in the *vaccination* programme.

2. Vaccine characteristics

a) Physical characteristics

- Route and ease of administration;
- volume of dose;
- type of adjuvant and other components.

b) Biological characteristics

- Immunity against circulating strains;
- live, inactivated or biotechnology-derived vaccines;
- number of strains and pathogens included in the vaccine;
- potency of the vaccine;
- onset of immunity;
- shelf-life and expiry date;
- thermotolerance;
- duration of the effective immunity;
- number of doses required to achieve effective immunity;
- ability to be monitored for vaccine-induced immunity;
- ability for vaccinated animals to be differentiated from infected animals, at the individual or group level;
- suitability of vaccine formulation for species, age or physiological status of animals in the target population;
- safety for the users, the consumers and the environment.

c) Side effects

- Adverse reactions;
- unintentional transmission of live vaccine strains.
- reversion of attenuated strains to virulence.

When a single vaccine only is available, the same factors listed above should be considered in deciding whether or not to launch a *vaccination* programme.

Article 4.17.7.

Other critical elements of a vaccination programme

In addition to the choice of vaccine, the *vaccination* programme should include the following other critical elements. The *vaccination* programme should be communicated to all stakeholders.

1. Legal basis

There should be a legal basis for the *vaccination* programme, including for possible compulsory compliance and for possible compensation of animal owners for adverse reactions in their animals.

2. Target population

The *vaccination* programme should define the animal *population* to be vaccinated and the geographical area where the target population is located.

The target population may include the entire susceptible population or an epidemiological relevant *subpopulation* depending on the likelihood of exposure, the consequences of the disease, the role of the different *subpopulations* in the epidemiology of the *infection* and the resources available. The target population may include *wildlife*.

Factors to consider in determining the target population may include species, age, health status, maternal immunity, sex, production types, geographical distribution as well as the number of populations and *herds*. These factors should be reviewed and updated regularly.

3. Vaccination coverage

It may be difficult to immunise the entire target population. The *vaccination* programme should define the minimum *vaccination* coverage necessary to achieve a sufficient population immunity to fulfil the objectives of the programme. The minimum population immunity required will vary according to the epidemiology of the disease, density of susceptible animals, and geographical factors.

Measuring population immunity during the monitoring of the *vaccination* programme may assist in identifying subsets of the target population that have not been adequately immunised.

4. Stakeholder involvement

Veterinary Services should demonstrate good governance of the *vaccination* programme by clearly identifying the involvement of different stakeholders including other governmental organisations, animal owners, farmer organisations, private sector veterinarians, non-governmental organisations, *veterinary paraprofessionals*, local government authorities and vaccine suppliers. Stakeholder acceptance of *vaccination* is crucial for the success of the *vaccination* programme. Different stakeholders should preferably be involved in the planning and implementation of *vaccination*, the awareness campaigns, the monitoring of *vaccination*, the production and delivery of vaccines and the financing of the *vaccination* programme.

5. Resources

Vaccination programmes may often span several years. To achieve the desired objective, human, financial and material resources should be available throughout the estimated duration of the *vaccination* programme.

6. Actions and timeline

The *vaccination* programme should describe the responsibilities, expected deliverables and timeline for each activity.

7. Timing of vaccination campaigns

The *vaccination* programme should describe the periodicity of any *vaccination* campaigns. Depending on the disease and type of vaccine, animals may be vaccinated once or several times during their lifetime.

The objective of a *vaccination* campaign should be to achieve the *vaccination* coverage necessary to attain or maintain the minimum population immunity in the target population within a defined timeframe. The *vaccination* campaign should be implemented in such a manner as to ensure that the majority of the target population is

immunised within as short a time as possible. The *vaccination* programme should include a detailed description of the implementation of *vaccination* campaigns, including frequency and starting and ending dates of each campaign.

The frequency, timing and duration of *vaccination* campaigns should be determined taking into consideration the following factors:

- a) vaccine characteristics and manufacturer's directions for use;
- b) vaccine storage facilities and delivery systems;
- c) accessibility of the target population;
- d) animal handling facilities;
- e) animal body condition and physiological state;
- f) geographical factors;
- g) climate conditions;
- h) *vector* activity;
- i) awareness, acceptance and engagement of stakeholders;
- j) types of production systems and animal movement patterns;
- k) timing of agricultural, social or cultural activities;
- l) availability of resources.

8. Auditing of vaccination campaigns

The *vaccination* programme should include periodic auditing of all the participants in any *vaccination* campaigns. Auditing ensures that all components of the system function and provide verifiable documentation of procedures. Auditing may detect deviations of procedures from those documented in the programme.

Indicators related to auditing of a *vaccination* campaign may include:

- a) proportion of the targeted population of animals and *herds* vaccinated within the defined timeframe;
- b) number of vaccine doses used compared with number of animals vaccinated;
- c) number of animals vaccinated compared to census figures for the relevant animal *population*;
- d) number of reports of breaches of the cold chain;
- e) performance of vaccinator teams in complying with the standard operating procedures;
- f) timing and duration of the campaign;
- g) overall cost and cost per individual animal vaccinated.

To enable auditing of the *vaccination* programme, a recording system should be in place to measure the indicators above.

Article 4.17.8.

Logistics of vaccination

Vaccination campaigns should be planned in detail and well in advance considering the following elements:

1. Procurement of vaccine

The vaccine selected for use in a *vaccination* programme should have been subjected to the relevant regulatory approval procedure of the country, which is congruent with the recommendation of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).

For systematic *vaccination* campaigns, the process of procurement of the selected vaccine should be initiated in advance to ensure timely delivery to meet the timeframe of the *vaccination* campaign.

National disease contingency plans should provide for emergency *vaccination*. These provisions may allow for simplified procedures to procure vaccine and grant authorisation for temporary use. If *vaccination* is to be used systematically, definitive relevant regulatory approval should be obtained.

Vaccine banks, established in accordance with Chapter 1.1.10. of the *Terrestrial Manual*, facilitate the timely procurement of vaccines.

2. Procurement of equipment and consumables

In addition to the vaccine itself, the planning of the *vaccination* campaigns should include the procurement of all necessary equipment and consumables.

3. Implementation of the vaccination programme

Standard operating procedures should be established to:

- a) implement the communication plan;
- b) establish, maintain and monitor the fixed and mobile components of the cold chain;
- c) store, transport and administer the vaccine;
- d) clean and disinfect equipment and *vehicles*, including heat sterilisation of reusable equipment;
- e) dispose of waste;
- f) determine the disposition of partially used or unused containers of vaccine, such as ampoules, vials and bottles;
- g) implement *biosecurity* to ensure *vaccination* teams do not transmit the pathogenic agent between *establishments*;
- h) identify vaccinated animals;
- i) ensure the safety and welfare of animals;
- j) ensure the safety of *vaccination* teams;
- k) record activities of *vaccinations* teams;
- l) document *vaccination*.

The availability of appropriate animal handling facilities is essential to ensure effective *vaccination* as well as safety and welfare of animals and *vaccination* teams.

4. Human resources

Vaccination should be conducted by appropriately trained and authorised personnel under the supervision of the *Veterinary Services*. The *vaccination* programme should provide for periodic training sessions including updated written standard operating procedures for field use.

The number of *vaccination* teams should be sufficient to implement the *vaccination* campaign within the defined timeframe. The *vaccination* teams should be adequately equipped and have means of transport to reach the places where *vaccination* is carried out.

5. Public awareness and communication

The *Veterinary Services* should develop a communication strategy in accordance with Chapter 3.3., which should be directed at all stakeholders and the public to ensure awareness and acceptability of the *vaccination* programme, its objectives and potential benefits.

The communication plan may include details on the timing and location of the *vaccination*, target population and other technical aspects that may be relevant for the public to know.

6. Animal identification

Animal identification allows for the differentiation of vaccinated from unvaccinated domestic animals and is required for the monitoring and certification of *vaccination*.

Identification can range from temporary to permanent identifiers and can be individual or group-based. *Animal identification* should be implemented in accordance with Chapters 4.1. and 4.2.

7. Record keeping and vaccination certificates

Vaccination programmes under the *Veterinary Service's* responsibility should provide for maintenance of detailed records of the vaccinated population.

Whenever needed, the *Veterinary Services* should consider issuing official certificates of the *vaccination* status of animals or groups of animals.

8. Additional animal health-related activities

In addition to *vaccination* against a specific pathogenic agent, *vaccination* programmes may include other animal health-related activities such as *vaccination* against other pathogenic agents, treatments, *biosecurity*, *surveillance*, *animal identification* and communication.

Including additional animal health-related activities may enhance the acceptability of the *vaccination* programme. These activities should not negatively affect the primary objective of the *vaccination* programme.

Simultaneous *vaccination* against multiple pathogenic agents may be conducted, provided that compatibility has been demonstrated and the efficacy of the immune response against each of the pathogenic agents is

Article 4.17.9.

Evaluation and monitoring of a vaccination programme

A *vaccination* programme should provide for outcome-based evaluation and monitoring to assess its achievements. Evaluation and monitoring should be carried out periodically during the campaign to enable the timely application of corrective measures and to enhance the sustainability of the *vaccination* programme.

Based on the objectives and targets of the *vaccination* programme, the following outcomes should be assessed:

- 1) *vaccination* coverage stratified by species, age, geographical location and type of production system;
- 2) population immunity measured by testing, stratified by species, geographical location and type of production system;
- 3) frequency and severity of side effects;
- 4) reduction of *incidence*, *prevalence* or impact of the disease.

If the objectives and targets of the *vaccination* programme are not achieved, the reasons for this should be identified and addressed.

Article 4.17.10.

Exit strategy of a vaccination programme

The *vaccination* programme may provide for an exit strategy to cease *vaccination*. The cessation of *vaccination* may apply to the entire target population or to a subset of it, as defined by the risk of exposure and as determined by the *Veterinary Authority*.

Criteria to cease *vaccination* may include:

- 1) eradication of the disease in a country or *zone* has been achieved;
- 2) *risk analysis* demonstrates sufficient reduction of likelihood of introduction of the pathogenic agent or emergence of the disease;
- 3) reduction of the *incidence*, *prevalence* or impact of the disease to a level where alternative measures such as a *stamping-out policy* may be more appropriate to achieve disease control;
- 4) inability of the programme to meet the desired objectives;
- 5) adverse public reaction to the *vaccination* programme;
- 6) a revised cost-benefit analysis leads to decision to cease the *vaccination* programme.

When the achievement of free status requires the cessation of *vaccination*, the *Veterinary Authority* should prohibit *vaccination* and take appropriate measures to control remaining vaccine stocks as well as vaccine importation.

The cessation of *vaccination* may require the revision of the contingency plan and enhanced *biosecurity*, *sanitary measures* and *surveillance* for early detection of disease.

Article 4.17.11.

Impact on disease status and management of vaccinated animals

Vaccination has proved its capacity to help prevent, control and eradicate several diseases in addition to or as alternative to *stamping-out policy*. However, depending on the disease and type of vaccine used, *vaccination* may mask underlying *infections*, affect disease *surveillance* and have implications for the movement of vaccinated animals and their products.

When appropriate, *vaccination* programmes should include provisions for the management of vaccinated animals such as '*vaccination to live*' or '*suppressiv vaccination*' policies. *Listed disease*-specific chapters of the *Terrestrial Code* provide additional recommendations on the management and trade of vaccinated animals and their products.

Free countries or *zones* applying systematic or emergency *vaccination* in response to an increased risk of introduction of a disease should inform trading partners and the OIE of their *vaccination* programme, as appropriate. Unless otherwise specified in the relevant *listed disease*-specific chapter, in the absence of *cases*, demonstrated by adequate *surveillance*, *vaccination* of animals does not affect the status of the country or *zone* and should not disrupt trade.

NB: FIRST ADOPTED IN 2018.

SECTION 5.

TRADE MEASURES, IMPORT/EXPORT PROCEDURES AND VETERINARY CERTIFICATION

CHAPTER 5.1.

GENERAL OBLIGATIONS RELATED TO CERTIFICATION

Article 5.1.1.

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

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

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

Certificates should be exact and concise, and should clearly convey the requirements 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 Chapter 5.2.

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

Article 5.1.2.

Responsibilities of the importing country

- 1) The import requirements included in the *international veterinary certificate* should assure that *commodities* introduced into the *importing country* comply with the standards of the OIE. *Importing countries* should align their requirements with the recommendations in the relevant standards of the OIE. If there are no such recommendations or if the country chooses a level of protection requiring measures more stringent than the standards of the OIE, these should be based on an import *risk analysis* conducted in accordance with Chapter 2.1.
- 2) The *international veterinary certificate* should not include requirements for the exclusion of pathogenic agents 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 pathogenic agent or disease should not be more stringent than those applied as part of the *official control programme* operating within the *importing country*.

- 3) The *international veterinary certificate* should not include measures against pathogenic agents 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 pathogenic agent 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 procedure is under the responsibility of *Veterinary Authorities*. However, it can be undertaken 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 in accordance with 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* or *flock*. 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 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 in accordance with the relevant legislation.

NB: FIRST ADOPTED IN 1982; MOST RECENT UPDATE ADOPTED IN 2015.

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 in accordance with 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* or *flock* 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 *veterinarians* should:

- 1) be authorised by the *Veterinary Authority* of the *exporting country* to sign *international veterinary certificates*;
- 2) only certify matters that are within their own knowledge at the time of signing the certificate, or that have been separately attested by another competent party;
- 3) sign only at the appropriate time certificates that have been completed fully and correctly; where a certificate is signed on the basis of supporting documentation, the certifying *veterinarian* should 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 exchange of data sent directly from the *Veterinary Authority* of the *exporting country* to the *Veterinary Authority* of the *importing country*.
 - a) Systems providing electronic certificates 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.
 - b) When exchanging electronic certificates and in order to fully utilise electronic data exchange the *Veterinary Authorities* should use internationally standardised language, message structure and exchange protocols. Guidance for electronic certification in standardised Extensible Markup Language (XML) as well as secure exchange mechanisms between *Veterinary Authorities* is provided by the United Nations Centre for Trade Facilitation and Electronic Business (UN/CEFACT).
 - c) A secure method of electronic data exchange should be ensured by digital authentication of the certificates, encryption, non-repudiation mechanisms, controlled and audited access and firewalls.
- 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.

NB: FIRST ADOPTED IN 1986; MOST RECENT UPDATE ADOPTED IN 2015.

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) specifically 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 implement *sanitary measures* more stringent than those in international standards, if these are deemed necessary to protect animal or human health and are scientifically justified by a *risk analysis*. In such circumstances, Members should adopt a consistent approach to *risk management*.

To promote transparency, the SPS Agreement, in Article 7, obliges WTO Members to notify changes in, and provide relevant information on, *sanitary measures* that may, directly or indirectly, affect international trade.

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

Article 5.3.2.

Introduction to the determination of the equivalence of sanitary measures

The importation of *animals* and animal products involves a degree of *risk* to animal and human health in an *importing country*. The estimation of that *risk* and the choice of the appropriate *risk management* options are made difficult by differences among the *animal health management* systems and animal production and processing systems in Member Countries. However, significantly different systems and measures may achieve equivalent animal and human health protection for the purpose of *international trade*.

The recommendations in this chapter are intended to assist Member Countries to determine whether *sanitary measures* arising from different systems achieve the same level of animal and human health protection. They discuss principles that may be utilised in a determination of equivalence, and outline a step-wise process for trading partners to follow. These provisions are applicable whether equivalence applies to specific measures or on a systems-wide basis, and whether equivalence applies to specific areas of trade or *commodities*, or in general.

Article 5.3.3.

General considerations on the determination of the equivalence of sanitary measures

Before trade in *animals* or their products occurs, an *importing country* should be assured that animal and human health in its territory will be appropriately protected. In most cases, the *risk management* measures adopted will rely in part on judgements made about the *animal health management* and animal production systems in the *exporting country* and the effectiveness of *sanitary measures* applied 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 in infrastructure, policies or operating procedures, *laboratory* systems, approaches to control of diseases, *infections* and *infestations* present, border security and internal movement controls.

If trading partners agree that the measures applied achieve the same level of health protection, these measures are considered equivalent. Benefits of applying equivalence may include:

- 1) minimising costs associated with *international trade* by allowing *sanitary measures* to be tailored 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.

The *Terrestrial Code* recognises equivalence by recommending alternative *sanitary measures* for many diseases, *infections* and *infestations*. Equivalence may be achieved, 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 determination of equivalence, Member Countries should base their *sanitary measures* on OIE standards and guidelines.

Member Countries should use *risk analysis* to establish the basis for a determination of equivalence.

Article 5.3.4.

Prerequisite considerations for the determination of equivalence

1) Application of risk assessment

Risk assessment provides a structured basis for judging equivalence among different *sanitary measures* as it allows a comparison of the effect of a measure on a particular step in the importation pathway with the effect of a proposed alternative measure.

A determination of equivalence should compare the effectiveness of the *sanitary measures* against the particular *risk* or group of *risks* against which they are designed to protect.

2) Categorisation of sanitary measures

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

Sanitary measures are described in the disease-specific chapter of the *Terrestrial Code* to manage *risks* posed by that disease, *infection* or *infestation*.

For the purposes of determining 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 *Veterinary Services*);
- b) programme design and 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).

Sanitary measures proposed for a determination of equivalence may fall into one or more of these categories, which are not mutually exclusive.

In some cases, such a method for inactivation of pathogenic agents, a comparison of specific technical requirements may suffice. In many instances, however, assessment of whether the same level of protection will be achieved may only be determined through an evaluation of all relevant components of an *exporting country's animal health management* systems and animal production systems.

Article 5.3.5.

Principles for determination of equivalence

Determination 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 in relation to human and animal life and health in its territory; this 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 *risk*;
- 3) an *importing country* should recognise that *sanitary measures* different from the ones it has proposed may be capable of achieving the same level of protection; in particular, it should consider the existence of *free zones* or *free compartments*, and of *safe commodities*;

- 4) the *importing country* should, upon request, consult with the *exporting country* with the aim of facilitating a determination of equivalence;
- 5) any *sanitary measure* or combination of *sanitary measures* can be proposed for determination 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, to minimise administrative burden, and to facilitate resolution of claims;
- 7) the *exporting country* should be able to demonstrate objectively how the alternative *sanitary measures* 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 determination by the *importing country*;
- 9) the *importing country* should evaluate submissions for equivalence in a timely, consistent, transparent and objective manner, and in accordance with 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 *importing country* should take into account any arrangements it has with other *exporting countries* on similar issues;
- 12) the *importing country* may also take into account any knowledge of the *exporting country's* arrangements with other *importing countries*;
- 13) the *exporting country* should provide access to enable the procedures or systems that are the subject of the equivalence determination to be examined and evaluated upon request of the *importing country*;
- 14) the *importing country* should be the sole judge of equivalence, but should provide to the *exporting country* a full explanation for its judgement;
- 15) to facilitate a determination of equivalence, Member Countries should base their *sanitary measures* on relevant OIE standards and guidelines, where these exist. However, they may choose to implement more stringent *sanitary measures* if these are scientifically justified by a *risk analysis*;
- 16) to allow the determination 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 that may bear on the determination of equivalence; and
- 17) appropriate technical assistance from an *importing country*, following a request by an *exporting country*, may facilitate the successful completion of a determination of equivalence.

Article 5.3.6.

Sequence of steps to be taken in determination of equivalence

There is no single sequence of steps that should be followed in all determinations of equivalence. The steps that trading partners choose will generally depend on the circumstances and their trading experience. Nevertheless, the interactive sequence of steps described below may be useful for assessing any *sanitary measures* irrespective of their categorisation as infrastructure, programme design and implementation or specific technical requirement components of an *animal health management* system or animal 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 for which it wishes to propose an alternative 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 *risk*;

- 2) the *importing country* explains the reason for the measure in terms that would facilitate comparison with an alternative *sanitary measure* and consistent with the principles set out in these provisions;
- 3) the *exporting country* demonstrates the case for equivalence of an alternative *sanitary measure* in a form that facilitates evaluation by an *importing country*;
- 4) the *exporting country* responds to any technical concerns raised by the *importing country* by providing relevant further information;
- 5) determination of equivalence by the *importing country* should take into account as appropriate:
 - a) the impact of biological variability and uncertainty;
 - b) the expected effect of the alternative *sanitary measure*;
 - c) OIE standard and guidelines;
 - d) the results of a *risk assessment*;
- 6) the *importing country* notifies the *exporting country* of its judgement and its reasons within a reasonable period of time. The judgement:
 - a) recognises the equivalence of the *exporting country's* alternative *sanitary measure*; or
 - b) requests further information; or
 - c) rejects the case for equivalence of the alternative *sanitary measure*;
- 7) an attempt should be made to resolve any differences of opinion over judgement of a case by using an agreed mechanism such as the OIE informal procedure for dispute mediation (Article 5.3.8.);
- 8) depending on the category of measures involved, the *importing country* and the *exporting country* may informally acknowledge the equivalence or enter into a formal agreement of equivalence giving effect to the judgement.

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

Article 5.3.7.

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

The terms 'zone' and 'zoning' in the *Terrestrial Code* have the same meaning as 'region', 'area' and 'regionalisation' in the SPS Agreement of the WTO.

The establishment of a disease-free *zone* or *compartment* is described in Chapter 4.3. and should be considered by trading partners when establishing *sanitary measures* for trade. Recommended steps are:

1. For zoning

- a) The *exporting country* identifies a geographical area within its territory, which, based on *surveillance*, it considers to contain an animal *subpopulation* with a distinct health status with respect to a specific disease, *infection* or *infestation*.
- b) The *exporting country* describes in the *biosecurity plan* for the *zone* the measures 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* or 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 concerned; and
 - iv) other relevant OIE standards or guidelines.
- e) The *importing country* notifies the *exporting country* of its judgement and its 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* by using an agreed mechanism 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 an 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*, and other premises operating under common management practices and a *biosecurity plan*. The *compartment* contains an identifiable animal *subpopulation* with a distinct health status with respect to a specific disease. 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 the disease in question.
- c) The *exporting country* describes the *compartment*, in accordance with Chapters 4.3. and 4.4.
- 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* or 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 concerned; and
 - iv) other relevant OIE standards or guidelines.

- f) The *importing country* notifies the *exporting country* of its judgement and its 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* by using an agreed mechanism 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 an agreement recognizing the *compartment*.

Article 5.3.8.

The OIE informal procedure for dispute mediation

OIE maintains a voluntary in-house mechanism for assisting Member Countries to resolve differences. In-house procedures that 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 submit a confidential report to the Director General of the OIE, who then transmits it to both parties.

NB: FIRST ADOPTED IN 2003; MOST RECENT UPDATE ADOPTED IN 2017.

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, oocytes, embryos and hatching eggs

Countries should only undertake the export from its territory of:

- 1) semen,
- 2) oocytes and embryos,
- 3) *hatching eggs*,

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

Article 5.4.3.

Notification

Countries exporting *animals*, semen, oocytes, embryos 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, oocytes, embryos, *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 5.13. 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. 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.

NB: FIRST ADOPTED IN 1968; MOST RECENT UPDATE ADOPTED IN 2014.

CHAPTER 5.5.

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

Article 5.5.1.

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

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

- 2) Any country through which transit is to take place may refuse if it considers that certain diseases exist in the *exporting country*, or in a *transit country* which precedes it in the itinerary, which are capable of being transmitted to its own *animals*.
- 3) Any *transit country* may require the presentation of *international veterinary certificates*. Such a country may, in addition, cause an examination to be made by an *Official Veterinarian* of the health status of *animals* in transit, except in cases where transport in sealed *vehicles* or *containers* is a condition of transit.
- 4) Any *transit country* may refuse passage through its territory of *animals* presented at one of its *border posts* if an examination carried out by an *Official Veterinarian* shows that the *animal* or consignment of *animals* in transit is affected by or infected with any of the notifiable epizootic diseases, or if the *international veterinary certificate* is inaccurate and/or unsigned.

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

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

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

Article 5.5.2.

- 1) Any *transit country* may require railway wagons and road *vehicles* used for the transit of *animals* through its territory to be so constructed as to prevent the escape and dispersion of excrement.
- 2) The *unloading* of *animals* in transit shall be permitted in the territory of the *transit country* only for purposes of watering and feeding or for welfare or other essential reasons. This must be under the effective control of an *Official Veterinarian* of the *transit country*, who should ensure that the *animals* have no contact with any other *animals*. The *importing country* shall be informed of any unforeseen *unloading* in the *transit country*.

Article 5.5.3.

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

- 1) semen,
- 2) oocytes or embryos,
- 3) *hatching eggs*,
- 4) brood-combs of bees,
- 5) animal products,

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

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

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

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

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

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

Article 5.5.4.

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

Article 5.5.5.

- 1) If, for reasons beyond the control of its captain, a ship or aircraft calls or lands somewhere other than at a port or airport, or at a port or airport other than that at which it should normally call or land, the captain of the ship or aircraft shall immediately notify the nearest *Veterinary Authority* or other public authority of the new port of call or place of landing.
- 2) As soon as the *Veterinary Authority* is notified of the calling or landing place, it shall take appropriate action.
- 3) Except for the circumstances mentioned in point 5) below, the *animals* and the attendants on board the ship or aircraft shall not be permitted to leave the vicinity of the docking or landing place. The removal from the vicinity, of any equipment, bedding or feedstuffs accompanying them shall not be permitted.
- 4) When the measures prescribed by the *Veterinary Authority* have been carried out, the ship or aircraft shall be permitted, for animal health purposes, to proceed to the port or airport at which it would normally have called or landed. If there are technical reasons why this cannot be done, it may be permitted to proceed to a port or an airport that is more suitable.
- 5) In an emergency, the captain of the ship or aircraft shall take all necessary measures to maintain the health and safety of the passengers, crew, attendants and *animals* on board.

NB: FIRST ADOPTED IN 1968.

CHAPTER 5.6.

BORDER POSTS AND QUARANTINE STATIONS IN THE IMPORTING COUNTRY

Article 5.6.1.

- 1) Countries and their *Veterinary Authorities* should, wherever possible, take the necessary action to ensure that the *border posts* and *quarantine stations* in their territory should be provided with an adequate organisation and sufficient equipment for the application of the measures recommended in the *Terrestrial Code*.
- 2) Each *border post* and *quarantine station* should be provided with facilities for the feeding and watering of *animals*.

Article 5.6.2.

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

- 1) making clinical examinations and obtaining specimens of material for diagnostic purposes from live *animals* or carcasses of *animals* affected or suspected of being affected by an epizootic disease, and obtaining specimens of animal products suspected of contamination;
- 2) detecting and isolating *animals* affected by or suspected of being affected by an epizootic disease;
- 3) carrying out *disinfection* and possibly *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* of the country or *zone*.

Article 5.6.3.

When required for the transit of *commodities* in *international trade*, airports should provide areas of direct transit. These should, however, comply with the conditions required by *Veterinary Authorities*, especially to prevent the contact between *animals* of different health status and the *risk* of introducing diseases transmitted by insects.

Article 5.6.4.

Each *Veterinary Authority*, when requested, should make available for the *Headquarters* and any interested country on request:

- 1) a list of *border posts*, *quarantine stations*, approved *slaughterhouses/abattoirs* and storage depots in its territory which are approved for *international trade*;
- 2) the period of time required for notice to be given for the application of the arrangements contained in point 2) of Articles 5.7.1. to 5.7.4.;
- 3) a list of airports in its territory which are provided with an area of direct transit, approved by the relevant *Veterinary Authority* and placed under its immediate control, where *animals* stay for a short time pending further transport to their final destination.

NB: FIRST ADOPTED IN 1968; MOST RECENT UPDATE ADOPTED IN 2010.

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) oocytes or embryos,
- 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.

NB: FIRST ADOPTED IN 1968.

CHAPTER 5.8.

INTERNATIONAL TRANSFER AND LABORATORY CONTAINMENT OF ANIMAL PATHOGENIC AGENTS

Article 5.8.1.

Object

To prevent the introduction and spread of animal diseases caused by pathogenic agents.

Article 5.8.2.

Introduction

- 1) The consequences of the introduction into a country of an infectious disease or an animal pathogenic agent or new strain of pathogenic agent 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 pathogenic agents from laboratories that are using them for various purposes such as research, diagnosis or the manufacture of vaccines. Such pathogenic agents 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 pathogenic agents 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 pathogenic agent in question.

Article 5.8.3.

Classification of pathogenic agents

Pathogenic agents should be categorised in accordance with 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 pathogenic agents

- 1) The importation of any animal pathogenic agent, pathological material or organisms carrying the pathogenic agent 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 pathogenic agent 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 pathogenic agent 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 pathogenic agent.

Article 5.8.5.

Laboratory containment of animal pathogenic agents

- 1) Guidance on the laboratory containment of animal pathogenic agents and on the import conditions applicable to them 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 pathogenic agents 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 pathogenic agents 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 pathogenic agent 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 pathogenic agents being handled at the laboratory for a specified period after visiting the laboratory. The length of this period will depend on the pathogenic agent.
- 3) Licences should specify:
 - a) how the pathogenic agent is to be transported and the disposal of the packaging;
 - b) the name of the person responsible for the work;
 - c) whether the pathogenic agent may be used *in vivo* (and if so whether in laboratory animals or other animals) and/or only *in vitro*;
 - d) how the pathogenic agent 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 pathogenic agents being used;
 - f) conditions for the transfer of pathogenic agents to other laboratories;
 - g) specific conditions relating to the appropriate containment level and *biosecurity* procedures and practices.

NB: FIRST ADOPTED IN 1998; MOST RECENT UPDATE ADOPTED IN 2008.

CHAPTER 5.9.

QUARANTINE MEASURES APPLICABLE TO NON-HUMAN PRIMATES

Article 5.9.1.

General principles

This 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 6.12.2., 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 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 6.12.4., 6.12.5. and 6.12.6., 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 6.12.7.

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.

NB: FIRST ADOPTED IN 1999; MOST RECENT UPDATE ADOPTED IN 2011.

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, oocytes, embryos, semen or brood combs are being exported. For products, name the countries 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 places from which the animals or products are being exported; and official approval or registration number when required. For animals and hatching eggs: the establishments, wildlife or hunting reserves. For semen: the artificial insemination centre. For oocytes and embryos: the name, address and official approval number of the collection team (not the premises of storage).

Chapter 5.10.- Model veterinary certificates for international trade in live animals, hatching eggs and products of animal origin

Box I.9. (contd)	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 numbers 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, oocytes, 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, oocytes, 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 oocytes, embryos and semen: Species (Scientific name); Identification mark in accordance with 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 establishments (e.g. slaughterhouse/abattoir; cutting plant; processing plant; cold store); Lot identification/date code; Quantity; Number of packages; Net weight.

3. Part II. Zoosanitary information

Box II.	Complete this part in accordance with the requirements agreed between the Veterinary Authorities of the importing and exporting countries in accordance with the recommendations in the Terrestrial Code.
Box II.a.	Reference number: see box I.2.
Official veterinarian	Name, address, official position, date of signature and official stamp of the Veterinary Services.

Article 5.10.2.

Model veterinary certificate for international trade in live animals and hatching eggs

COUNTRIES:

Part I: Details of dispatched consignment	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 <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> 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 <input type="checkbox"/> Competition <input type="checkbox"/> Slaughter <input type="checkbox"/> Wildlife management <input type="checkbox"/> Pets <input type="checkbox"/> Exhibition/education <input type="checkbox"/> Other <input type="checkbox"/>			
I.23. For import or admission: Definitive import <input type="checkbox"/> Re-entry <input type="checkbox"/> Temporary admission <input type="checkbox"/>			
I.24. Identification of commodities: Species (Scientific name): Breed*/Category*: Identification number/details: Age*: Quantity: Sex*:			

* Optional.

** If referenced in Part II.

COUNTRIES:

Part II: Zoosanitary information	II.a. Certificate reference number:
	The undersigned Official Veterinarian certifies that the animals and hatching eggs described above satisfy the following requirements:
	<p>Official Veterinarian:</p> <p>Name and address (in capital letters):</p> <p>Date:</p> <p>Stamp:</p> <p>Official position:</p> <p>Signature:</p>

Article 5.10.3.

Model veterinary certificate for international trade in oocytes, embryos or semen

COUNTRIES:

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 <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> 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. Temperature of the product: Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>	I.19. Total number of packages:	
		I.20. Identification of container/seal number:	I.21. Type of packaging:
	I.22. Commodities intended for use as: Human consumption <input type="checkbox"/> Other <input type="checkbox"/> Animal feed <input type="checkbox"/> Further processing <input type="checkbox"/> Technical use <input type="checkbox"/>		
	I.23.		
	I.24. Identification of commodities: Species (Scientific name): Nature of commodity*: Treatment type: Approval of number of establishments: Number of packages: Net weight: Lot ID/date code:		

* Optional.

** If referenced in Part II.

COUNTRIES:

Part II: Zoosanitary information	II.a. Certificate reference number:
	The undersigned Official Veterinarian certifies that the oocytes, embryos and semen described above satisfy the following requirements:
<p>Official Veterinarian:</p> <p>Name and address (in capital letters):</p> <p>Date:</p> <p>Stamp:</p> <p style="text-align: right;">Official position:</p> <p style="text-align: right;">Signature:</p>	

Article 5.10.4.

Model veterinary certificate for international trade in products of animal origin

COUNTRIES:

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 <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> 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. Temperature of the product: Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>	I.19. Total number of packages:	
	I.20. Identification of container/seal number:	I.21. Type of packaging:	
	I.22. Commodities intended for use as: Human consumption <input type="checkbox"/> Animal feed <input type="checkbox"/> Further processing <input type="checkbox"/> Technical use <input type="checkbox"/> Other <input type="checkbox"/>		
	I.23.		
	I.24. Identification of commodities: Species (Scientific name): Nature of the commodity: Treatment type: Approval number of establishments: Number of packages: Net weight: Lot ID/date code:		

* Optional.

** If referenced in Part II.

COUNTRIES:

Part II: Zoosanitary information	II.a. Certificate reference number:
	The undersigned Official Veterinarian certifies that the products of animal origin described above satisfy the following requirements:
	Official Veterinarian: Name and address (in capital letters): Date: Stamp:
	Official position: Signature:

Article 5.10.5.

Model veterinary certificate for international trade in bees and brood combs

COUNTRIES:

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 <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> 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 <input type="checkbox"/> Other <input type="checkbox"/>		
	I.23.		
	I.24. Identification of commodities: Category: Breed*/Variety* Quantity: Identification details:		

* Optional.

** If referenced in Part II.

COUNTRIES:

Part II: Zoosanitary information	II.a. Certificate reference number:
	The undersigned Official Veterinarian certifies that the bees and brood combs described above satisfy the following requirements:
	<p>Official Veterinarian:</p> <p>Name and address (in capital letters):</p> <p>Date:</p> <p>Stamp:</p> <p style="text-align: right;">Official position:</p> <p style="text-align: right;">Signature:</p>

NB: FIRST ADOPTED IN 1968; MOST RECENT UPDATE ADOPTED IN 2011.

CHAPTER 5.11.

**MODEL
VETERINARY CERTIFICATE FOR
INTERNATIONAL MOVEMENT OF
DOGS, CATS AND FERRETS
ORIGINATING FROM COUNTRIES
CONSIDERED INFECTED WITH RABIES**

I. OWNER

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

II. DESCRIPTION

Species of animal:.....
Age or date of birth:
Sex:.....
Breed:
Colour:
Coat type and marking/Distinguishing marks:.....
.....
.....
.....

Identification number, location on the animal and date of marking (see note 1)

--

III. ADDITIONAL INFORMATION

Country of origin:
.....
Countries visited
over the past six months
as declared by the owner
(give dates)
.....
.....

IV. VACCINATION (Rabies)

I the undersigned declare herewith that I have vaccinated the animal described in Part II, or I have seen evidence that the animal has been vaccinated against rabies as shown below.

Date of vaccination (dd/mm/yy)	Name of vaccine (see note 2)	1. Manufacturing laboratory 2. Batch number 3. Expiry date
		1. 2. 3.

PERIOD OF VALIDITY OF VACCINATION FOR INTERNATIONAL MOVEMENT (see note 3)		Name (in capital letters) and signature of the Certifying Veterinarian (see note 6)
from (dd/mm/yy)	to (dd/mm/yy)	

V. SEROLOGICAL TESTING (Rabies)

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

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)

PERIOD OF VALIDITY OF SEROLOGICAL TESTING FOR INTERNATIONAL MOVEMENT (see note 4)		Name (in capital letters) and signature of the Certifying Veterinarian (see note 6)
from (dd/mm/yy)	to (dd/mm/yy)	

VI. CLINICAL EXAMINATION (Rabies)

I the undersigned declare herewith that I have examined the animal described in Part II on the date indicated below, or that I have seen evidence that the animal was examined on that date, and that the animal was found to be free from clinical signs of rabies (see note 5).

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

NOTE

- 1) The identification should be by a permanent marking. The identification number stated in the certificate should be identical to that on the animal. When electronic identification is used, the type of microchip and the name of the manufacturer should be specified.
- 2) Only vaccines produced in compliance with the recommendations of the *Terrestrial Manual* should be used.
- 3) Vaccination or re-vaccination should be carried out in accordance with the recommendations of the manufacturer.
- 4) When serological testing is required, the animal should have been subjected not less than 3 months and not more than 12 months prior to its introduction into the importing country, to an antibody titration test carried out by an official diagnostic laboratory approved by the Competent Authority of the exporting country, as prescribed in the *Terrestrial Manual* with a positive result of at least 0.5 IU.
- 5) The clinical examination referred to in Part VI of the certificate must be carried out as per the requirements in Chapter 8.14.

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

- 6) The certification should be undertaken in accordance with Chapters 5.1. and 5.2.
- 7) If so required, the certificate should be written in the language of the importing country. In such circumstances, it should also be written in a language understood by the certifying veterinarian.

NB: FIRST ADOPTED IN 1968; MOST RECENT UPDATE ADOPTED IN 2012.

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 in accordance with 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 in accordance with 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 in accordance with 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 in accordance with 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	Details of ownership	Detalles del propietario
<p>1.La nationalité du cheval est celle de son propriétaire.</p>	<p>1.The nationality of the horse is that of its owner.</p>	<p>1.La nacionalidad del caballo es la nacionalidad de su propietario.</p>
<p>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.</p>	<p>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.</p>	<p>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.</p>
<p>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.</p>	<p>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.</p>	<p>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.</p>
<p>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.</p>	<p>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.</p>	<p>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.</p>

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

N° de identificación:

(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 téléphone: - N° de fax:

-Signature :

(nom en lettres capitales et qualité du signataire)

-Signature:

(Name in capital letters and capacity of signatory)

Firma:

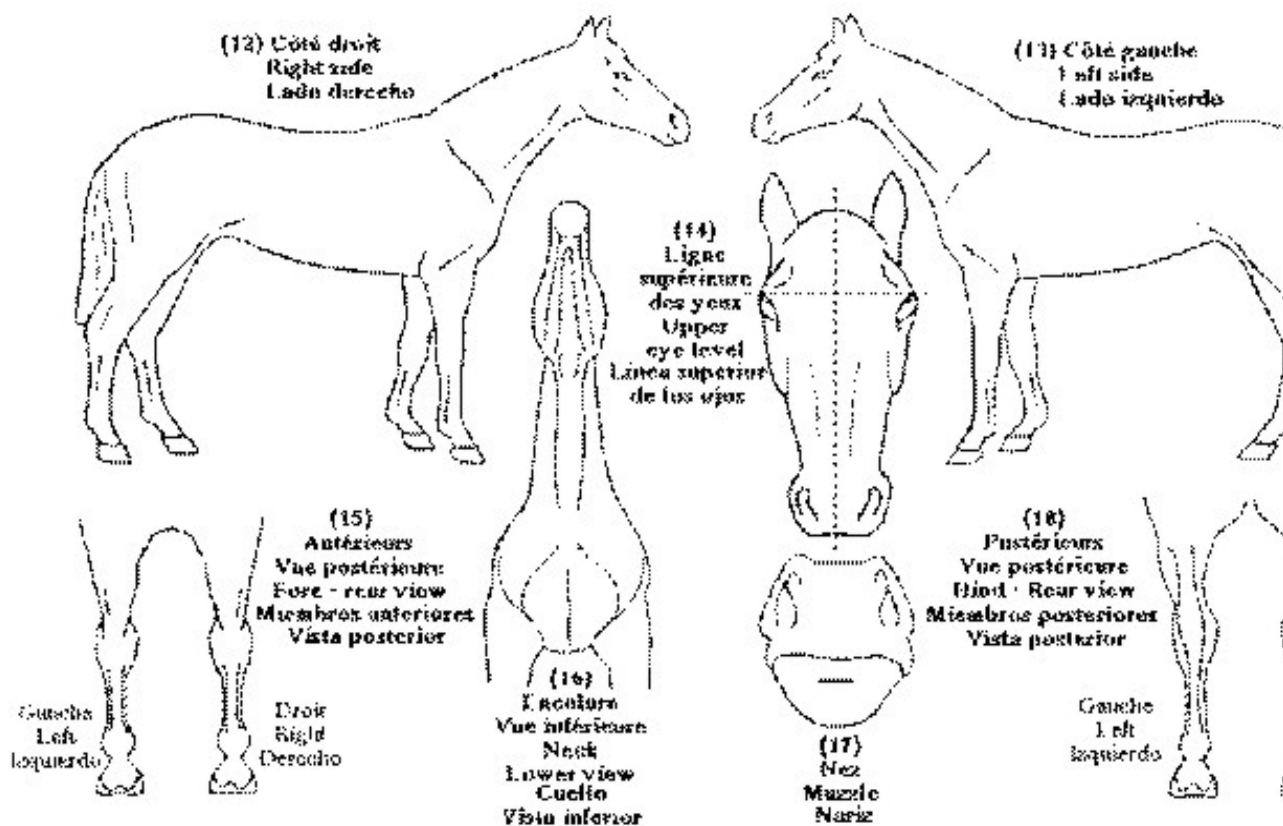
(Nombre en letras mayúsculas y calidad del firmante)

-Cachet

Stamp

Sello

Appendix C



(2)Nom :	(5)Race :	(3) Sexe :	(4)Robe :
Name:	Breed:	Sex:	Colour:
Nombre:	Raza:	Sexo:	Color:

(19) Signalement relevé sous la mère par :

Description taken with dam by:

Descripción registrada con la madre por:

Tête :

Head:

Cabeza:

Ant. G. :

Ant. D. :

Foreleg L.:

Foreleg R.:

Ant. I.:

Ant. D.:

Post. G. :

Post. D. :

Hindleg L.:

Hindleg R.:

Post. I.:

Post. D.:

Corps :

(21)Signature et cachet du vétérinaire agréé

Body:

(ou de l'autorité compétente)

Cuerpo:

Signature and stamp of qualified veterinary surgeon

(or competent authority)

Marques :

Firma y sello del veterinario autorizado

Markings:

(o de la autoridad competente)

Marcas:

(en lettres capitales)

(in capital letters)

(en letras mayúsculas)

Fait le (date) :

Date :

Made on (date):

Date:

A (fecha):

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.

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

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 GRIPPE 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
			Nom Name Nombre	Numéro de lot Batch number Número de lote	Maladie(s) Disease(s) Enfermedad(es)	Name (in capital letters) and signature of the veterinarian
						Nombre (en letras mayúsculas) y firma del veterinario

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 transmissible 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 transmissible;

(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 zoonosanitarias 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	Lieu	Pour des raisons épidémiologiques particulières, un certificat sanitaire séparé accompagne le présent passeport.	Nom en lettres capitales et signature du vétérinaire officiel
Date	Place	For special epizootic reasons a separate veterinary certificate accompanies this passport.	Name (in capital letters) and signature of official veterinarian
Fecha	Lugar	Por razones epidemiológicas particulares se adjunta al presente pasaporte un certificado sanitario.	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) Dourine
- 3) Glanders
- 4) Equine encephalomyelitis (all types)
- 5) Equine infectious anaemia
- 6) Rabies
- 7) Anthrax

NB: FIRST ADOPTED IN 1998; MOST RECENT UPDATE ADOPTED IN 2008.

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.*

CHAPTER 5.13.

MODEL VETERINARY CERTIFICATE FOR INTERNATIONAL TRADE IN LABORATORY ANIMALS

Article 5.13.1.

Introduction and scope

Transportation of laboratory animals between institutes is a specialised and important activity supporting scientific research. The use, and transportation, of laboratory animals is essential to some types of medical and veterinary research.

The majority of laboratory animals used and transported are rats, mice, and fish. Other species, including guinea pigs, ferrets, gerbils, hamsters, rabbits, cats, dogs, pigs, amphibians, and a few species of non-human primates are used in relatively small numbers.

This chapter applies to all *animals* except bees.

Article 5.13.2.

Notes for guidance on the use of the veterinary certificate

1. General

Please complete the certificate on paper in capitals. To confirm an option, mark the box with a cross (X). Ensure that no portion of certificate is left blank in a manner that would allow it to be amended. Non-applicable fields may be crossed out.

2. Part I. Details of consignment for export

Country:	Name of the country issuing the certificate.
Box I.1.	Name and full address of the natural or legal person dispatching the consignment. It is recommended to provide contact information, such as telephone and fax numbers or e-mail address.
Box I.2.	The certificate reference number used by the Veterinary Authority of the country issuing the certificate.
Box I.3.	Name of the Veterinary Authority.
Box I.4.	Name and full address of the natural or legal person to whom the consignment is destined.
Box I.5.	Name of the country from which the consignment is being exported. "ISO code" refers to the international standard two-letter code (ISO 3166-1 Alpha-2 Code) for a country produced by the International Organization for Standardization.
Box I.6.	Name of the zone or compartment of origin, if given in part III of the certificate (in accordance with Chapter 4.3. of the Terrestrial Code).
Box I.7.	Name of the country of destination. "ISO code" refers to the international standard two-letter code (ISO 3166-1 Alpha-2 Code) for a country produced by the International Organization for Standardization.
Box I.8.	Name of the zone or compartment of destination, if given in part III of the certificate (in accordance with Chapter 4.3. of the Terrestrial Code).

Box I.9.	Name and full address of the places from which the animals are being exported; and official approval or registration number when required.
Box I.10.	Name of the air, land or sea facility from which the consignment is being shipped.
Box I.11.	Date of departure and, if known, expected time of departure.
Box I.12.	Identify the means of transport if known at the time of issuance of the certificate. The flight number, airline and airport designation (for air transport). The name and address of the carrier (for road transport). The name and contact details of the emergency contact person.
Box I.13.	Name of border post to which the consignment is directed. It is also recommended to provide the border post's United Nations Code for Trade and Transport Locations - see http://live.unece.org/cefact/locode/service/location.html .
Box I.14.	If the species is listed in the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), provide permit numbers.
Box I.15.	Description of animals. World Customs Organization HS Code, if known, see: www.wcoomd.org .
Box I.16.	Total number of animals.
Box I.17.	Temperature around the shipping container should generally be maintained in the range 10-28°C during shipment. For animals with different requirements, the specific temperature range should be listed here.
Box I.18.	The total number of units (e.g. boxes, cages or stalls) in which the animals in the consignment are being transported.
Box I.19.	Identification of the containers and seal numbers, if provided.
Box I.20.	Details of the nature of the animals. Provide: species (scientific name); identification system; identification number or other relevant details; quantity and, if required, strain or stock designation, sex, and age or weight. When available, international designation conventions should be used, see for example: http://www.informatics.jax.org/mgihome/nomen/strains.shtml http://www.informatics.jax.org/mgihome/nomen/gene.shtml . For animals with an official international animal passport, the passport number should also be provided.

3. Part II. Classification of pathogen free status

Box II.	Conventional animals are those for which the presence or absence of specific microorganisms and parasites is unknown due to the absence of testing, treatment or vaccination. This category includes wild-caught animals and domestic animals maintained under uncontrolled microbiological conditions. Specific Pathogen Free (SPF) animals are free of one or more parasites or infectious microorganisms. SPF animals can be further subdivided into two categories.
	Conditioned SPF animals have undergone testing, treatment and/or vaccination to ensure the absence of one or more parasites or microbial agents. The agents are most commonly of human or agricultural significance or are species-specific infectious agents that are capable of producing significant clinical disease or research effects. Conditioned SPF animals are often not maintained in specialised housing to prevent introduction of other infectious agents and are usually shipped in unfiltered containers. Larger species such as nonhuman primates, dogs, and cats are often maintained as conditioned SPF animals.
	Barrier raised SPF animals have been raised in the absence of one or more parasites or microbial agents in specialised facilities to exclude these agents as well as agents of agricultural and human significance. Their pathogen free status has been established either by testing each individual animal or by sampling representative animals from the colony. Filtered SPF shipping containers are required for transport of these animals as are special procedures and equipment for packing, unpacking, and handling them. This subcategory also includes animals that are either axenic (microbe free) or possess only a few well defined species of microorganisms. They must be produced and maintained in a sterile environment (usually isolators) without contact with human, animal, or environmental commensal infectious microorganisms.

4. Part III. Zoosanitary information

Box III.	Complete this part in accordance with the requirements agreed between the Veterinary Authorities of the importing and exporting countries in accordance with the recommendations in the Terrestrial Code. Attestation of fitness for transportation subject to any conditions or special requirements stated in the certificate.
Box IIIa.	Certificate reference number: see box I.2.
Official veterinarian	Name, address, official position, date of signature and official stamp of the Veterinary Services for the country of export.

Article 5.13.3.

Model veterinary certificate for international trade in laboratory animals

COUNTRIES:

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. Primary means of transport: Aeroplane <input type="checkbox"/> Relevant details <input type="checkbox"/> Road vehicle <input type="checkbox"/> Vessel <input type="checkbox"/>	I.13. Expected border post:		
	I.14. CITES permit No(s)**:		
	I.15. Description of animals: *HS Code if known:	I.16. Total number of animals:	
	I.17. Temperature:	I.18. Total number of units:	
	I.19. Identification of container/seal number:		
	I.20. Details of the nature of the animals and quantity of each:		
	Species (Scientific name):	Identification system:	
Identification number/details:			
Strain/Stock (use international designation if known)*:	Passport numbers if issued*:		
Age or weight:			
Sex:			

* Optional.

** If referenced in Part III.

COUNTRIES:

Part II: Zoosanitary information	II.a. Certificate reference number:	
	II. Pathogen Free Status	
	Conventional:	
	Conditioned SPF:	
	Barrier raised SPF:	
Other - specify:		
III. Fitness for transportation		
The undersigned Official Veterinarian certifies that the consignment described above is fit for transport, subject to any conditions specified below, and that the animals satisfy the following zoosanitary requirements:		
Special conditions for transport; Yes <input type="checkbox"/> No <input type="checkbox"/>		
If there are special conditions for transport, provide complete information of these conditions.		
Official Veterinarian:		
Name and address (in capital letters):	Official position:	
Date:	Signature:	
Stamp:		

NB: FIRST ADOPTED IN 2012.

SECTION 6.
VETERINARY PUBLIC HEALTH

CHAPTER 6.1.
INTRODUCTION TO RECOMMENDATIONS FOR
VETERINARY PUBLIC HEALTH

Article 6.1.1.

Veterinary public health is a component of public health that focuses on the application of veterinary science and that includes all actions directly or indirectly linked with *animals*, their products and by-products, so long as they contribute to the protection and improvement of the physical, mental and social well-being of humans.

Veterinary science has a rich history of contributions to public health, especially with regard to the provision of safe and adequate food, the prevention, control and eradication of zoonoses, the improvement of *animal welfare* and contributing to biomedical research.

Veterinary Services play a key role in preventing, mitigating and controlling *risks* to public health at the origin or source of *infection*. In particular, *Veterinary Services* contribute to public health in several areas such as food security, food safety (with respect to foodborne diseases as well as residues and pollutants), control of zoonoses and responses to natural disasters and bioterrorism.

Furthermore, a number of anthropogenic factors influence the occurrence of *emerging diseases*, some of which are zoonotic. These factors include among others: population growth and changing food consumption patterns and their consequences such as increasing food demand and intensification of production systems; increased movements and trade of *animals* and their products and derived products; the use and misuse of *antimicrobial agents* generating resistance; the disruption of ecosystems; climate change.

In this context, *Veterinary Services* are integrated into the 'One Health' approach to the assessment, prevention, management and communication of health risks and preservation of the integrity of ecosystems for the benefit of human health, the health of domestic *animals* and *wildlife*, and biodiversity.

Veterinary training and education should take into account the role of *Veterinary Services* in public health at national, regional and global level in the development of veterinary public health capabilities.

NB: FIRST ADOPTED IN 2018.

CHAPTER 6.2.

THE ROLE OF THE VETERINARY SERVICES IN FOOD SAFETY SYSTEMS

Article 6.2.1.

Introduction

Veterinarians are trained in both animal health (including foodborne zoonoses) and food hygiene, which makes them uniquely equipped to play a central role in ensuring food safety, especially the safety of food of animal origin.

Close cooperation and effective communication between all participants in a food safety system, including *veterinarians*, other relevant professionals and stakeholders, is critical for the effective operation of the system. Indeed, the globalisation of the food supply demands a high level of engagement and collaboration between *Competent Authorities* responsible for animal health, food safety and public health, in line with the One Health approach. This provides a wider role and greater responsibilities for *Veterinary Services*.

Food safety activities performed by *Veterinary Services* should be integrated to the greatest extent possible with the activities of all other responsible agencies throughout the food chain.

Article 6.2.2.

Purpose and scope

The purpose of this chapter is to provide guidance to Member Countries on the role and responsibilities of *Veterinary Services* in food safety systems.

This chapter should be read in conjunction with Chapter 4.1., Chapter 4.2., and relevant chapters of Sections 6 and 7.

This chapter should also be read in conjunction with the Codex Alimentarius Principles and Guidelines for National Food Control Systems (CAC/GL 82-2013), General Principles of Food Hygiene (CAC/RCP 1-1969), Code of Hygienic Practice for Meat (CAC/RCP 58-2005), Code of Practice on Good Animal Feeding (CAC/RCP 54-2004), Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals (CAC/GL 71-2009), and other relevant Codex texts.

Article 6.2.3.

Characteristics of a food safety system

1. Food chain approach

Food safety is best assured by an integrated, multidisciplinary approach that considers the entire food chain. A food safety system should take into account the complexity of food production and the globalisation of the food supply, and should be risk-based. It should consider *hazards* and potential associated *risks* at each stage of the food chain, i.e. primary production, transport, processing, storage and distribution, and integrate *risk management* responses to such *risks* at the most appropriate points along the food chain.

The prevention, detection, and control of foodborne *hazards* throughout the food chain is generally more effective in reducing or eliminating the *risk* of unwanted health effects than relying on controls of the final product. The application of traceability systems and sharing food chain information enhance the effectiveness of a food safety system. Everyone involved in the food chain, including food business operators, *Veterinary Services* and consumers, has a responsibility to ensure that food is safe.

2. Risk-based food safety systems

Risk-based food safety systems include measures based on good practices (such as good agricultural practice, good hygienic practice), hazard analysis and critical control points (HACCP) principles and *risk analysis*. The design and application of a risk-based food safety system depends on the availability of adequate scientific information and effective utilisation of the technical resources of food business operators and *Competent Authorities*.

Monitoring food safety outcomes and reviewing control measures are essential to ensure the effective performance of a risk-based food safety system. For example, providing information on the occurrence of *infections* on the farm prior to dispatch of animals for *slaughter* may allow more targeted, risk-based inspection at the *slaughterhouse/abattoir*.

3. Responsibilities of food business operators for food safety

Food business operators, including *feed* producers, farmers, processors, wholesalers, distributors, importers, exporters and retailers, have primary responsibility for ensuring the safety of their products and should be able to demonstrate that they comply with relevant food safety regulatory requirements. Food business operators have a responsibility to inform the *Competent Authority* in their country of any non-compliance associated with their product and take action to manage the *risk* e.g. the withdrawal of the product.

4. Responsibilities of the relevant Competent Authorities

Competent Authorities are responsible for developing policies, legislation and regulations relevant to food safety. They should also take steps to communicate these within their country and with trading partners.

Competent Authorities should ensure that roles and responsibilities for food safety systems, including responses to foodborne disease *outbreaks*, are addressed in a coordinated manner.

The relevant *Competent Authorities* should verify that the control systems used by food business operators are appropriate, validated and effective, and operated in such a way that the regulatory requirements are met. This can be achieved through activities such as inspection and audit. In the event of noncompliance, appropriate corrective actions and sanctions should be applied.

If the *Competent Authority* delegates some control responsibilities to a third party, it should assess regularly that third party's competency.

Article 6.2.4.

Roles and responsibilities of Veterinary Services in a food safety system

1. Roles and responsibilities of Veterinary Services

Veterinary Authorities or other *Competent Authorities* should provide an appropriate institutional environment to allow *Veterinary Services* to implement the necessary policies and standards, and ensure adequate resources for them to carry out their tasks in a sustainable manner. *Veterinary Services* should have a clear chain of command and respective roles and responsibilities should be clearly defined and well documented.

Veterinary Services should be fully involved, in accordance with their mandate and organisational structure at the national level, in the design and implementation of a risk-based food safety system. In the implementation of food safety systems for food of animal origin, *Veterinary Services* should retain responsibility for verification and audit and facilitate a flexible approach to operational activities.

Veterinary Services should retain overall responsibility for the delivery and performance of any activities delegated to third party providers.

Where relevant, *Veterinary Services* should have an active role in other food safety-related activities, such as investigations of foodborne disease *outbreaks*, food defense, disaster management, and identifying emerging *risks*. In addition, *Veterinary Services* should have an active role in the development and management of coordinated *surveillance* and control programmes for foodborne pathogens of public health importance.

In order for *Veterinary Services* to make the best possible contribution to ensuring food safety, the education and training of *veterinarians* and *veterinary paraprofessionals* should include appropriate training in food safety systems and ongoing professional development.

2. Activities of Veterinary Services throughout the food chain

Depending on the responsibilities of the *Competent Authority*, the responsibilities of the *Veterinary Services* may be limited to the first part of the food chain, while in other cases the *Veterinary Services* may be responsible for the whole food chain.

a) Primary production

Through their presence on farms and collaboration with farmers, *Veterinary Services* play a key role in ensuring that *animals* are healthy and kept under good sanitary and hygienic conditions, as well as in *biosecurity* and early detection, *surveillance* and treatment of animal diseases, including conditions of public health significance.

Veterinary Services provide direction to farmers on practices that prevent or minimise physical and chemical hazards (for example, mycotoxins, environmental contaminants and pesticide residues) in primary production, including *feed*.

Veterinary Services play a central role in ensuring the responsible and prudent use of *veterinary medicinal products*, including *antimicrobial agents* in accordance with Chapter 6.10. in animal husbandry. This helps to minimise the likelihood of noncompliant levels of veterinary drug residues in food of animal origin and the development of antimicrobial resistance.

Veterinary Services also play an important role in ensuring traceability throughout the food chain by verifying *animal identification* in accordance with Chapters 4.1. and 4.2.

b) Slaughter, processing and distribution

Activities at the *slaughterhouse/abattoir* should be designed and implemented according to an integrated, risk-based approach in accordance with Chapter 6.3. *Veterinary Services* have an essential role in ensuring that these activities, including *meat* inspection, minimise foodborne *risks* to public health. This may be provided by supervision and verification of process control and direct involvement in operational activities such as ante- and post-mortem inspection. *Slaughterhouse/abattoir* inspection of live animals and their carcasses plays a key role both in the *surveillance* network for animal diseases and zoonoses, and in ensuring the safety and suitability of *meat* and by-products for their intended uses. Control or reduction of biological hazards of public health and animal health importance by ante- and post-mortem *meat* inspection is a core responsibility of *Veterinary Services*.

Veterinary Services may be responsible for overseeing the control measures during processing and distribution of food of animal origin. They also play an important role in raising the awareness of food producers, processors and distributors regarding measures required to assure food safety.

c) Assurance schemes and certification of food of animal origin for international trade

Veterinary Services have an important role in overseeing assurance schemes and an essential role in certifying that food of animal origin complies with animal health and food safety standards.

Other *Competent Authorities* may also be involved in providing assurances and certification of food of animal origin (for example, pasteurisation of *milk products*) for *international trade*.

3. Foodborne disease outbreaks

Veterinary Services play a key role in the investigation of, and response to, foodborne disease *outbreaks* which may be attributable to or involve animal products, including the implementation of control measures. This work should be carried out in close collaboration with public health professionals, analysts, epidemiologists, food producers, processors and traders and any others involved.

Because of the global nature of the food trade, *Veterinary Services* should work with other national agencies in reporting to international emergency foodborne disease networks, such as the International Network of Food Safety Authorities (INFOSAN), and in utilising such information for preparedness.

NB: FIRST ADOPTED IN 2008; MOST RECENT UPDATE ADOPTED IN 2018.

CHAPTER 6.3.

CONTROL OF BIOLOGICAL HAZARDS OF ANIMAL HEALTH AND PUBLIC HEALTH IMPORTANCE THROUGH ANTE- AND POST-MORTEM MEAT INSPECTION

Article 6.3.1.

Introduction

Food-borne 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 6.3.2.

Purpose

These recommendations provide a basis for future development of OIE standards for animal production food safety.

Article 6.3.3.

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/abattoir* inspection activities deliver in terms of animal and public health.

The CHPM does not provide inspection measures for specific *hazards*, which remain the responsibility of national competent authorities. The animal and public health *risks* associated with livestock populations vary across regions and animal husbandry systems, and ante- and post-mortem inspection needs to be tailored to the individual country situation and its animal and public health objectives.

The CHPM provides a platform for development of *meat* hygiene systems that are based on *risk assessment*. There are few *risk assessment* models and little relevant scientific information available on public health *hazards* derived specifically from *animals* and their products, making difficult the development of *risk*-based standards for food-borne diseases and zoonoses. While this scientific information is being accumulated, ante- and post-mortem inspection systems will remain dependent on traditional approaches.

Article 6.3.4.

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 6.3.5.

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* or *flock* level as part of ante- and post-mortem inspection should be used to support *surveillance*, as well as *risk assessment* of prioritised food-borne *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 food-borne 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 6.3.6.

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 6.3.7.

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 6.3.8.

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 6.3.9.

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.

NB: FIRST ADOPTED IN 2006.

CHAPTER 6.4.

THE CONTROL OF HAZARDS OF ANIMAL HEALTH AND PUBLIC HEALTH IMPORTANCE IN ANIMAL FEED

Article 6.4.1.

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 pathogenic 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 food-borne zoonoses and animal feeding, complementing relevant CAC texts.

Article 6.4.2.

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 6.4.3.

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 6.4.4.

General principles

1. Roles and responsibilities

The *Competent Authority* has the legal power to set and enforce regulatory animal feeding requirements, and has final responsibility for verifying that these requirements are met. The *Competent Authority* may establish regulatory requirements for relevant parties to provide it with information and assistance. Refer to Chapters 3.1. and 3.2.

Those involved in the production and use of animal *feed* and *feed ingredients* have the primary responsibility to ensure that these products meet regulatory requirements. Records and, as appropriate, contingency plans should be in place to enable tracing and recall of non-compliant products. All personnel involved in the manufacture, storage and handling of *feed* and *feed ingredients* should be adequately trained and aware of their role and responsibility in preventing the introduction or spread of hazards. Manufacturing equipment, storage and transport facilities should be adequate and maintained in good working order and in a sanitary condition.

Those providing specialist services to producers and to the *feed* industry (e.g. private *veterinarians*, nutritionists and laboratories) may be required to meet specific regulatory requirements pertaining to the services they provide (e.g. disease reporting, quality standards, transparency).

2. Regulatory safety standards

All *feed* and *feed ingredients* should meet regulatory safety standards. Scientific evidence, including the sensitivity of analytical methods and on the characterisation of risks, should be taken into account in defining limits and tolerances for hazards.

3. Risk analysis (risk assessment, risk management and risk communication)

Internationally accepted principles and practices on *risk analysis* (Section 2 of the *Terrestrial Code* and relevant Codex texts) should be used in developing and applying the regulatory framework.

Application of a generic framework should provide a systematic and consistent process for managing all *biosecurity* risks, while recognising the different *risk assessment* methodologies used in animal and public health.

4. Good practices

Where national guidelines exist, good agricultural practices and good manufacturing practices (including good hygienic practices) should be followed. Countries without such guidelines are encouraged to develop them or adopt suitable international standards or recommendations.

Where appropriate, Hazard Analysis and Critical Control Point (HACCP) principles should be followed to control hazards that may occur in the manufacture, distribution and feeding of *feed* and feed additives and *feed ingredients*.

5. Geographic and environmental considerations

Epidemiological links between potential sources of hazards for animal health or food safety should be considered when assessing water sources, land or facilities for suitability for the production of animal *feed* and *feed ingredients*. Animal health considerations include factors such as disease status, location of quarantined premises and existence of *zones/compartments* of specified health status. Food safety considerations include factors such as industrial operations that generate pollutants and waste treatment plants.

6. Zoning and compartmentalisation

Feed is an important component of *biosecurity* and needs to be considered when defining a *compartment* or *zone* in accordance with Chapter 4.3.

7. Sampling and analysis

Sampling and analysis should be based on scientifically recognised principles and procedures.

8. Labelling

Labelling should be informative, unambiguous, legible and conspicuously placed on the package if sold in package form and on the waybill and other sales documents if sold in bulk, un-packaged form, and should comply with regulatory requirements and Section 4.2.10 Labelling of Codex Code of Practice on Good Animal Feeding (CAC/RCP 54-2004), including listing of ingredients and instructions on the handling, storing and use. All claims made on a label should be able to be substantiated.

9. Design and management of inspection programmes

In meeting animal and public health objectives prescribed in national legislation or required by *importing countries*, *Competent Authorities* contribute through the inspection or through the auditing of animal and public health activities conducted by other agencies or the private sector.

Feed and *feed ingredients* business operators and other relevant parts of industry should practice self-regulation to secure compliance with required standards for procurement, handling, storage, processing, distribution and use. Operators have full responsibility for implementing systems for quality control. The *Competent Authority* should verify that process control systems and safety standards achieve all regulatory requirements.

10. Assurance and certification

Feed business operators are responsible for demonstrating the safety of the establishments under their control. *Competent Authorities* are responsible for providing assurances domestically and to trading partners that regulatory safety standards have been met. For *international trade* in animal product based *feed*, *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 pathogenic 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 6.8. to 6.11.

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.).

NB: FIRST ADOPTED IN 2009; MOST RECENT UPDATE ADOPTED IN 2011.

CHAPTER 6.5.

BIOSECURITY PROCEDURES IN POULTRY PRODUCTION

Article 6.5.1.

Introduction

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

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

Article 6.5.2.

Purpose and scope

This chapter deals with *biosecurity* procedures in intensive *poultry* production. It should be read in conjunction with the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005), Code of Hygienic Practice for Eggs and Egg Products (CAC/RCP 15-1976) and Guidelines for the control of *Campylobacter* and *Salmonella* in chicken meat (CAC/GL 78-2011).

This chapter identifies several *biosecurity* measures. The choice of measures to be implemented will vary in accordance with 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 6.5.3.

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 6.5.4.

Recommendations on the location and construction of poultry establishments

1. All establishments (poultry farms and hatcheries)
 - a) A suitably isolated geographical location is recommended. Factors to consider include the location of other *poultry* and livestock *establishments*, *wild* bird concentrations and the distance from roads used to transport *poultry*.
 - b) *Poultry establishments* should be located and constructed to provide adequate drainage for the site. Run-off or untreated site waste water should not discharge into waterfowl habitats.
 - c) *Poultry* houses and hatcheries should be designed and constructed (preferably of smooth impervious materials) so that cleaning and *disinfection* can be carried out effectively. Ideally, the area immediately

surrounding the *poultry* houses and hatcheries should be paved with concrete or other impervious material to facilitate cleaning and *disinfection*.

- d) The *establishment* should be surrounded by a security fence to prevent the entry of unwanted animals and people.
- e) A sign indicating restricted entry should be posted at the entrance to the *establishment*.

2. Additional measures for poultry farms

- a) *Establishments* should be designed to house a single species and a single production type. The design should also consider the 'all-in all-out' single age group principle. If this is not feasible, the *establishment* should be designed so that each *flock* can be managed as a separate *epidemiological unit*.
- b) *Poultry* houses, and buildings used to store *feed*, eggs or other material, should be constructed and maintained to prevent the entry of *wild* birds, rodents and arthropods.
- c) Where feasible, the floors of *poultry* houses should be constructed using concrete or other impervious materials and designed so that cleaning and *disinfection* can be carried out effectively.
- d) Where feasible, *feed* should be delivered into the farm from outside the security fence.

3. Additional measures for hatcheries

- a) The design of the hatchery should take account of work flow and air circulation needs, with 'one way flow' movement of eggs and *day-old birds* and one way air flow in the same direction.
- b) The hatchery buildings should include physical separation of areas used for the following:
 - i) personnel changing, showering and sanitary facilities;
 - ii) receipt, storage and transfer of eggs;
 - iii) incubation;
 - iv) hatching;
 - v) sorting, sexing and other handling of *day-old birds*;
 - vi) storage of egg boxes and boxes for *day-old birds*, egg flats, chick box liners, chemicals and other items;
 - vii) equipment washing;
 - viii) waste disposal;
 - ix) dining facilities for personnel;
 - x) office space.

Article 6.5.5.

Recommendations applicable to the operation of poultry establishments

1. All establishments (poultry farms and hatcheries)

- a) All *establishments* should have a written *biosecurity plan*. Personnel in the *establishments* should have access to basic training in *biosecurity* relevant to *poultry* production and understand the implications to animal health, human health and food safety.
- b) There should be good communication between personnel involved in the *poultry* production chain to ensure that steps are taken to minimise the introduction and dissemination of infectious agents.
- c) Traceability at all levels of the *poultry* production chain should be possible.
- d) Records should be maintained on an individual *flock* basis and include data on bird health, production, medications, *vaccination*, mortality and *surveillance*. In hatcheries, records should include data on fertility,

hatchability, *vaccination* and treatments. Records should be maintained on cleaning and *disinfection* of farm and hatchery buildings and equipment. Records should be readily available for inspection on site.

- e) Monitoring of *poultry* health on the *establishment* should be under the supervision of a *veterinarian*.
- f) To avoid the development of antimicrobial resistance, *antimicrobial agents* should be used in accordance with relevant directions of the *Veterinary Services* and manufacturer's instructions and in accordance with Chapters 6.9., 6.10., 6.11. and 6.12.
- g) *Establishments* should be free from unwanted vegetation and debris that could attract or harbour pests.
- h) Procedures for the prevention of entry of *wild* birds into *poultry* houses and buildings, and the control of vermin such as rodents and arthropods should be implemented.
- i) Access to the *establishment* should be controlled to ensure only authorised persons and *vehicles* enter the site.
- j) 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. Entry of visitors and *vehicles* should be registered by the *establishment*.
- k) 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.
- l) Any *vehicle* entering an *establishment* should be cleaned and disinfected in accordance with 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, in accordance with the manufacturer's instructions.
- c) Any equipment should be cleaned and sanitized before being taken into a *poultry* house.
- d) Animals, other than *poultry* of the appropriate (resident) species and age, should not be permitted access to *poultry* houses. No animals should have access to other buildings, such as those used to store *feed*, eggs or other material.
- e) The drinking water supply to *poultry* houses should be potable in accordance with the World Health Organization or to the relevant national standard, and microbiological quality should be monitored if there is any reason to suspect contamination. The water delivery system should be cleaned and disinfected between *flocks* when the *poultry* house is empty.
- f) Birds used to stock a *poultry* house should preferably be obtained from breeder *flocks* and hatcheries that are free from vertically transmitted infectious agents.
- g) Heat treated *feed* with or without the addition of other bactericidal or bacteriostatic treatments, such as addition of organic acids, are recommended. Where heat treatment is not possible, the use of bacteriostatic or bactericidal treatments is recommended.
Feed should be stored in a manner to prevent access by *wild* birds and rodents. Spilled *feed* should be cleaned up immediately to remove attractants for *wild* birds and rodents. The movement of *feed* between *flocks* should be avoided.
- h) The litter in the *poultry* house should be kept dry and in good condition.
- i) Dead birds should be removed from *poultry* houses as quickly as possible but at least daily. These should be disposed of in a safe and effective manner.
- j) Personnel involved in the catching of birds should be adequately trained in bird handling and basic *biosecurity* procedures.
- k) To minimise stress *poultry* should be transported in well ventilated *containers* and should not be over crowded. Exposure to extreme temperatures should be avoided.
- l) *Containers* should be cleaned and disinfected between each use, or disposed of in a safe manner.

- m) When a *poultry* house is depopulated, it is recommended that all faeces and litter be removed from the house and disposed of in a safe manner to minimise the risk of dissemination of infectious agents.

If litter is not removed and replaced between *flocks* then the litter should be treated in a manner to minimise the risk of dissemination of infectious agents from one *flock* to the next.

After removal of faeces and litter, cleaning and *disinfection* of the *poultry* house and equipment should be done in accordance with Chapter 4.13.

- n) For *poultry flocks* that are allowed to range outdoors, feeders, *feed* and other items which may attract *wild* birds should be kept indoors. *Poultry* should not be allowed access to sources of contamination, such as household waste, litter storage areas, other animals, stagnant water and water of unknown quality. The nesting area should be inside the *poultry* house.

3. Additional measures for layers

Refer to Section 3 of the Codex Alimentarius Code of Hygienic Practice for Eggs and Egg Products (CAC/RCP 15-1976).

4. Additional measures for breeders

- a) Nest box litter and liners should be kept clean.
- b) *Hatching eggs* should be collected at frequent intervals, at least daily, and placed in new or clean and disinfected packaging materials.
- c) Grossly dirty, cracked, broken, or leaking eggs should be collected separately and should not be used as *hatching eggs*.
- d) *Hatching eggs* should be cleaned and sanitized as soon as possible after collection using an approved sanitising agent, in accordance with the manufacturer's instructions.
- e) *Hatching eggs* or their packaging materials should be marked to assist traceability and veterinary investigations.
- f) The *hatching eggs* should be stored in a dedicated room as soon as possible after cleaning and sanitisation. Storage conditions should minimise the potential for microbial contamination and growth and ensure maximum hatchability. The room should be well ventilated, kept clean, and regularly disinfected using disinfectants approved for this purpose.

5. Additional measures for hatcheries

- a) Dead in shell embryos should be removed from hatcheries as soon as they are found and disposed of in a safe and effective manner.
- b) All hatchery waste, garbage and discarded equipment should be contained or at least covered while on site and removed from the hatchery and its environs as soon as possible.
- c) After use, hatchery equipment, tables and surfaces should be promptly and thoroughly cleaned and disinfected with an approved disinfectant.
- d) Egg handlers and sexers and handlers of *day-old birds* should wash their hands with soap and water before commencing work and between working with batches of *hatching eggs* or *day-old birds* from different breeder *flocks*.
- e) *Hatching eggs* and *day-old birds* from different breeder *flocks* should be identifiable during incubation, hatching, sorting and transportation.
- f) *Day-old birds* should be delivered to the farm in new *containers* or in clean, disinfected *containers*.

Article 6.5.6.

Prevention of further dissemination of infectious agents of poultry

When a *flock* is suspected or known to be infected, a *veterinarian* should be consulted immediately and, in addition to the general biosecurity measures described previously, management procedures should be adjusted to effectively isolate it from other *flocks* on the *establishment* and other epidemiologically related *establishments*. The following measures are recommended:

- 1) Personnel should manage *flocks* to minimise the risk of dissemination of infectious agents to other *flocks* and *establishments*, and to humans. Relevant measures include handling of an infected *flock* separately, last in sequence and the use of dedicated personnel, clothing and equipment.
- 2) When *infection* has been confirmed, epidemiological investigations should be carried out to determine the origin and route of transmission of the infectious agent.
- 3) *Poultry* carcasses, litter, faeces and other potentially contaminated farm waste should be disposed of in a safe manner to minimise the risk of dissemination of infectious agents. The disposal method used will depend on the infectious agent involved.
- 4) Depending on the epidemiology of the disease, the results of a *risk assessment*, and public and animal health policies, destruction or *slaughter* of a *flock* before the end of the normal production period may be used. When infected *flocks* are destroyed or slaughtered, they should be processed in a manner to minimise exposure of humans and other *flocks* to the infectious agent, and in accordance with recommendations of the *Veterinary Service* and relevant chapters in the *Terrestrial Code*. Based on *risk assessment*, non-infected, high risk *flocks* may be destroyed or slaughtered before the end of their normal production period.

Before restocking, the *poultry* house including equipment should be cleaned, disinfected and tested to verify that the cleaning has been effective. Special attention should be paid to *feed* equipment and water systems.

Microbiological monitoring of the efficacy of *disinfection* procedures is recommended when pathogenic agents have been detected in the previous *flock*.

- 5) Depending on the epidemiology of the disease, *risk assessment*, vaccine availability and public and animal health policies, *vaccination* is an option to minimise the dissemination of the infectious agent. When used, vaccines should be administered in accordance with the directions of the *Veterinary Services* and the manufacturer's instructions. Recommendations in the *Terrestrial Manual* should be followed as appropriate.

Article 6.5.7.

Recommendations to prevent the dissemination of infectious agents to and from live bird markets

- 1) Personnel should be educated on the significance of infectious agents and the need to apply *biosecurity* practices to prevent dissemination of these agents. Education should be targeted to personnel at all levels of operations in these markets, such as drivers, owners, handlers and processors. Programmes should be implemented to raise consumer awareness about the risks associated with activities of live bird markets.
- 2) Personnel should wash their hands with soap and water before and after handling birds.
- 3) Birds from diseased *flocks* should not be transported to live bird markets.
- 4) All *containers* and *vehicles* should be cleaned and disinfected every time they leave the market.
- 5) Live birds that leave the market and go to a farm should be kept separately from other birds for a period of time to minimise the potential dissemination of infectious agents of *poultry*.
- 6) Periodically the market should be emptied, cleaned and disinfected. This is of particular importance when an infectious agent of *poultry* deemed significant by the *Veterinary Services* has been identified in the market or the region.
- 7) Where feasible, *surveillance* should be carried out in these markets to detect infectious agents of *poultry*. The *surveillance* programme should be determined by the *Veterinary Services*, and in accordance with recommendations in relevant chapters of the *Terrestrial Code*.
- 8) Efforts should be made to ensure the possibility of tracing all birds entering and leaving the markets.

NB: FIRST ADOPTED IN 1982; MOST RECENT UPDATE ADOPTED IN 2013.

CHAPTER 6.6.

PREVENTION, DETECTION AND CONTROL OF *SALMONELLA* IN POULTRY

Article 6.6.1.

Introduction

This chapter provides recommendations on the prevention, detection and control of *Salmonella* in *poultry*.

Salmonellosis is one of the most common food-borne bacterial diseases in the world. The great majority of *Salmonella* infections in humans are food-borne 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 food-borne *infection*. In the latter case, this can occur when *meat* and eggs, or their products, enter the food chain thus producing contaminated food.

Article 6.6.2.

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), Code of Hygienic Practice for Eggs and Egg Products (CAC/RCP 15-1976) and Guidelines for the control of *Campylobacter* and *Salmonella* in chicken meat (CAC/GL 78-2011). 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 food-borne pathogens in eggs and *meat*.

Hygiene and *biosecurity* procedures to be implemented in *poultry* farms and hatcheries are described in Chapter 6.5. 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 6.6.3.

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 6.6.4.

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 samples collected from different areas in the *poultry* house or caecal samples collected at the *slaughterhouse/abattoir*.

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*.

3. Laboratory methods

Refer to the *Terrestrial Manual*.

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 pathogenic agent. 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/abattoir*. 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 should be carried out after depopulation, cleaning and *disinfection*.

Results from *surveillance* may lead to the implementation of additional prevention and control measures to reduce the risk of transmission of *Salmonella* to humans:

- 1) In breeders, control measures may be implemented to reduce the transmission of *Salmonella* to the next generation, especially for trans-ovarian transmitted serotypes such as *S. Enteritidis*.
- 2) In layer *flocks*, control measures will reduce and may eliminate contamination of eggs with *Salmonella*.
- 3) In *poultry* for *meat* production, control measures may be implemented at *slaughter* or further down the food chain.

Article 6.6.5.

Prevention and control measures

Salmonella prevention and control may be achieved by adopting Good Agricultural Practices and Hazard Analysis Critical Control Point (HACCP) principles, and general measures detailed in Chapter 6.5., 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 in accordance with 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 in accordance with 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 *feed* 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 bactericidal 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.
Treated *feed* should be handled and stored in such a way as to avoid recontamination.

- 4) Competitive exclusion may be used in *day-old birds* to reduce colonisation by *Salmonella*.

Competitive exclusion products should be administered in accordance with 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 in accordance with 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 in accordance with 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 pathogenic agents.

- 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 ovarian transmission. 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 6.6.6.

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 6.5.:

- 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 transported and 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 6.6.7.

Recommendations for introduction of live poultry (other than day-old birds)

Introduced live *poultry* (other than *day-old birds*) should:

- 1) originate from a *flock* that participates in a *Salmonella surveillance* programme in accordance with the recommendations in Article 6.6.4.;
- 2) originate from a *flock* in which no evidence of *S. Enteritidis* and *S. Typhimurium* has been detected prior to movement and have had no contact with birds or other material from *flocks* that do not comply with this chapter;
- 3) originate from a *flock* that complies with the recommendations in Chapter 6.5.

Article 6.6.8.

Recommendations for introduction of day-old birds

Introduced *day-old birds* should:

- 1) show no clinical sign of salmonellosis on the day of shipment;
- 2) originate from a breeder *flock* and a hatchery that participate in a *Salmonella surveillance* programme in accordance with the recommendations in Article 6.6.4.;
- 3) originate 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) originate from a breeder *flock* and a hatchery that comply with the recommendations in Chapter 6.5.;
- 5) be transported in new or clean *containers*.

Article 6.6.9.

Recommendations for introduction of hatching eggs

Introduced *hatching eggs* should:

- 1) originate from a breeder *flock* that participates in a *Salmonella surveillance* programme in accordance with the recommendations in Article 6.6.4.;
- 2) originate 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) originate from a breeder *flock* that complies with the recommendations in Chapter 6.5.;
- 4) be transported in new or clean packaging materials.

NB: FIRST ADOPTED IN 2009; MOST RECENT UPDATE ADOPTED IN 2015.

CHAPTER 6.7.

INTRODUCTION TO THE RECOMMENDATIONS FOR CONTROLLING ANTIMICROBIAL RESISTANCE

Article 6.7.1.

Objective

The purpose of Chapters 6.8., 6.9., 6.10. and 6.11. is to provide methodologies for Member Countries to appropriately address the emergence or spread of resistant bacteria from the use of *antimicrobial agents* in *animals* and to contain antimicrobial resistance through controlling the use of *antimicrobial agents*.

These chapters should be read in conjunction with the standards, codes of practice and guidelines on antimicrobial resistance developed by the Codex Alimentarius Commission.

Antimicrobial agents are essential drugs for human and animal health and welfare. The OIE recognises the need for access to *antimicrobial agents* in veterinary medicine: *antimicrobial agents* are essential for treating and controlling infectious diseases in *animals*. The OIE therefore considers that ensuring continued access to effective *antimicrobial agents* is important.

The OIE recognises that antimicrobial resistance is a global public and animal health concern that is influenced by the usage of *antimicrobial agents* in humans, *animals* and elsewhere. Those working in the human, animal and plant sectors have a shared responsibility to prevent or minimise pressures for the selection of antimicrobial resistance factors in humans and *animals*. Arising from its mandate for the protection of animal health and food safety, the OIE developed these chapters to provide guidance to Member Countries in regard to risks in all animal sectors.

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.

NB: FIRST ADOPTED IN 2009; MOST RECENT UPDATE ADOPTED IN 2014.

CHAPTER 6.8.

HARMONISATION OF NATIONAL ANTIMICROBIAL RESISTANCE SURVEILLANCE AND MONITORING PROGRAMMES

Article 6.8.1.

Objective

This chapter provides criteria for the development of national antimicrobial resistance surveillance and monitoring programmes, and the harmonisation of existing national antimicrobial resistance surveillance and monitoring programmes in food-producing animals and in products of animal origin intended for human consumption.

Article 6.8.2.

Purpose of surveillance and monitoring

Active surveillance and monitoring are core parts of national antimicrobial resistance surveillance programmes. Passive surveillance and monitoring may offer additional information (refer to Chapter 1.4.). The OIE encourages cooperation among all Member Countries conducting antimicrobial resistance surveillance and monitoring.

Surveillance and monitoring of antimicrobial resistance is necessary to:

- 1) assess and determine the trends and sources of antimicrobial resistance in bacteria;
- 2) detect the emergence of new antimicrobial resistance mechanisms;
- 3) provide the data necessary for conducting *risk analyses* as relevant to animal and human health;
- 4) provide a basis for policy recommendations for animal and human health;
- 5) provide information for evaluating antimicrobial prescribing practices and for prudent use recommendations;
- 6) assess and determine effects of actions to combat antimicrobial resistance.

Article 6.8.3.

General aspects of antimicrobial resistance surveillance and monitoring programmes

Surveillance of antimicrobial resistance and monitoring of the prevalence of, and trends in, resistance in bacteria from *animals*, food, environment and humans, constitutes a critical part of animal health and food safety strategies aimed at limiting the spread of antimicrobial resistance and optimising the choice of *antimicrobial agents* used in therapy. *Feed* should also be considered according to national priorities.

Surveillance or monitoring of bacteria from products of animal origin intended for human consumption collected at different steps of the food chain, including processing, packing and retailing, should also be considered.

National antimicrobial resistance monitoring and surveillance programmes should be scientifically based and may include the following components:

- 1) statistically based surveys;
- 2) sampling and testing of food-producing animals on the farm, at live animal markets or at *slaughter*;
- 3) organised sentinel programme, for example targeted sampling of food-producing animals, *herds*, *flocks*, and *vectors* (e.g. birds, rodents);
- 4) analysis of veterinary practice and diagnostic *laboratory* records;
- 5) sampling and testing of products of animal origin intended for human consumption;
- 6) sampling and testing of *feed ingredients* or *feed*.

Article 6.8.4.

Sampling

1. Sampling strategies

- a) Sampling should be conducted on a statistical basis. The sampling strategy should ensure:
- the sample is representative of the population of interest and meets the objectives of the surveillance;
 - the robustness of the sampling method.
- b) The following criteria are to be considered:
- sample source such as food-producing animal, food, animal *feed*;
 - animal species;
 - category of *animal* within species such as age group, production type;
 - health status of the *animals* such as healthy, diseased;
 - sample selection method such as targeted, systematic random, non-random;;
 - type of sample such as faeces, caeca, carcass, food product;
 - sample size.

2. Sample size

The sample size should be large enough to allow detection or determine prevalence of, or trends in, existing and emerging antimicrobial resistance phenotypes.

The sample should avoid bias and be representative of the animal *population*, process, product or other unit of interest whilst taking into account the expected prevalence of the bacteria in the sample type, the expected prevalence of the resistance phenotype and the desired level of precision and confidence.

The sample size calculation should be based on independent samples. However, if there is any clustering at the *establishment* or animal level, the sample size should be adjusted accordingly. At low levels of expected prevalence, exact methods of sample size calculation should be preferred to approximate methods. Samples from which bacteria were not isolated cannot be used in the calculation of prevalence of the resistance phenotype.

3. Sample sources (Table 1)

Member Countries should examine their livestock production systems on the basis of available information and assess which sources are likely to contribute most to a potential *risk* to animal and human health.

a) Food-producing animals

Categories of food-producing animals considered for sampling should be relevant to the country's production system. Resource allocation should be guided by criteria such as production volume of the food-producing animal species and the prevalence of resistant bacteria..

b) Food

Member Countries should consider including products of animal origin intended for human consumption, produced locally or imported, in surveillance and monitoring programmes, as foodborne transmission is considered to be an important route for the transfer of antimicrobial resistance.

c) Feed

Member Countries should consider including *feed* in surveillance and monitoring programmes as they may become contaminated with antimicrobial resistant bacteria, e.g. *Salmonella*.

d) Environment

Member Countries should consider including the environment in surveillance and monitoring programmes as the environment of animals can be an important route for transfer or persistence of antimicrobial resistance.

4. Type of sample to be collected (Table 1))

Faecal samples should be collected in amounts sufficient for isolation of the resistant bacteria of concern (at least 5 g from bovine and porcine and whole caeca from *poultry*).

Feed samples representative of the batch should be collected in amounts sufficient for isolation of resistant bacteria of concern (at least 25 g) and should be linked to any pathogen *surveillance* programme that may be in place.

Existing food processing microbiological monitoring, risk-based management and other food safety programmes may provide useful samples for surveillance and monitoring of resistance in the food chain after *slaughter*.

Table 1. Examples of sampling sources, sample types and output

Source	Type	Output	Additional information required or additional stratification
Herd or flock of origin	Faeces or bulk milk	Prevalence of resistant bacteria originating from animal populations (of different production types) Relationship between resistance and antimicrobial use	Age categories, production types, etc. Antimicrobial use over time
Slaughterhouse/Abattoir	Faeces	Prevalence of resistant bacteria originating from animals at slaughter	
	Caeca or intestines	As above	
	Carcass	Prevalence of resistant bacteria after carcass dressing, representative of the hygiene of the process and the contamination during slaughter	
Processing, packing	Food products	Prevalence of resistant bacteria after processing, representative of the hygiene of the process and the contamination during processing and handling	
Point of sale (Retail)	Food products	Prevalence of resistant bacteria originating from food, exposure data for consumers	
Various origins	Animal feed	Prevalence of resistant bacteria originating from animal feed, exposure data for animals	
Various origins	Environment	Occurrence of resistant bacteria originating from the animal-immediate or the wider environment	

Article 6.8.5.

Bacteria subjected to surveillance and monitoring

The following categories of bacteria may be included in surveillance and monitoring programmes:

1. Animal bacterial pathogens relevant to the countries' priorities

a) Surveillance and monitoring of antimicrobial resistance in animal bacterial pathogens is important to:

- detect emerging resistance that may pose a concern for animal and human health;
- detect changes in susceptibility patterns;
- provide information for *risk analysis*;
- provide data for *veterinarians* to inform their treatment decisions;
- provide information for epidemiological studies and trend analysis.

b) Information on the occurrence of antimicrobial resistance in animal bacterial pathogens is in general either derived from clinical material sent to veterinary diagnostic *laboratories* or from an active monitoring programme. Although antimicrobial resistance information provided by diagnostic *laboratories* is primarily for treatment purposes, it is also useful for identification of novel resistance patterns and can possibly assist in identifying emerging resistance. However, in order to estimate accurately the prevalence of antimicrobial

resistance in the bacterial pathogen, in a larger population of animals, an active sampling programme should be implemented.

- c) To promote a harmonised global approach to the selection of animal bacterial pathogens for inclusion in national surveillance and monitoring programmes, bacteria should be selected using one or more of the following criteria:
- impact on animal health and welfare;
 - implication of antimicrobial resistance in the bacterial pathogen on therapeutic options in veterinary practice;
 - impact on food security and on production (economic importance of associated diseases);
 - bacterial diseases responsible for the majority of veterinary antimicrobial usage (stratified by usage of different classes or their importance);
 - existence of validated susceptibility testing methodologies for the bacterial pathogen;
 - existence of quality assurance programmes or other pathogen reduction options that are non-antimicrobial, such as vaccines and Good Agricultural Practices.

The table below, derived using the above criteria, lists suggested animal bacterial pathogens for inclusion in a surveillance or monitoring programme of food-producing animals. This list is not exhaustive and should be adapted according to the situation in the country.

Table 2. Examples of target animal species and animal bacterial pathogens that may be included in resistance surveillance and monitoring programmes

Source	Respiratory pathogens	Enteric pathogens	Udder pathogens	Other pathogens
Cattle	<i>Pasteurella multocida</i>	<i>Escherichia coli</i>	<i>Staphylococcus aureus</i>	
	<i>Mannheimia haemolytica</i>	<i>Salmonella</i> spp.	<i>Streptococcus</i> spp.	
Pigs	<i>Actinobacillus pleuropneumoniae</i>	<i>Escherichia coli</i>		<i>Streptococcus suis</i>
		<i>Salmonella</i> spp.		
Poultry		<i>Salmonella</i> spp.		<i>Escherichia coli</i>

2. Zoonotic bacteria

a) *Salmonella*

Salmonella should be sampled from food-producing animals, animal-derived food products and, if relevant, *feed*. For the purposes of consistency and harmonisation, animal samples should preferably be taken from healthy animals at the *slaughterhouse/abattoir* and *feed* samples should preferably be taken at the *feed* mill.

Surveillance and monitoring programmes may also include sampling of the environment at places where animals are kept or handled or bacterial isolates originating from other sources obtained from designated *laboratories*.

Isolation and identification of bacteria and bacterial strains should follow nationally or internationally standardised procedures.

Serovars of public health importance such as *S. Typhimurium* and *S. Enteritidis* should be included in surveillance and monitoring programmes. The inclusion of other relevant serovars will depend on the epidemiological situation in each country.

All *Salmonella* isolates should be characterised by serotype and, where appropriate, by genotype at designated *laboratories*.

b) *Campylobacter*

Campylobacter should be isolated from food-producing animals or associated food products. Isolation and identification of these bacteria should follow nationally or internationally standardised procedures. *Campylobacter* isolates should be identified to the species level.

c) Other bacteria that are pathogenic for humans

Other bacteria that are pathogenic for humans, such as methicillin-resistant *Staphylococcus aureus* (MRSA) and *Listeria monocytogenes*, may be included in resistance surveillance and monitoring programmes.

3. Commensal bacteria

E. coli and *enterococci* (*Enterococcus faecium* and *E. faecalis*) may be sampled from feed, food-producing animals, their environment and products of animal origin intended for human consumption.

These bacteria are commonly used in surveillance and monitoring programmes as indicators, providing information on the potential reservoir of antimicrobial resistance genes, which may be transferred to pathogenic bacteria. For the purposes of consistency and harmonisation, these bacteria should preferably be isolated from healthy animals, at the *slaughterhouse/abattoir*.

Article 6.8.6.

Storage of bacterial strains

If possible, isolates should be preserved at least until reporting is completed. Preferably, appropriate isolates should be permanently stored. Bacterial strain collections, established by storage of all isolates from certain years, will provide the possibility of conducting retrospective studies.

Article 6.8.7.

Antimicrobial susceptibility testing

Clinically important *antimicrobial agents* or classes used in human and veterinary medicine should be included in antimicrobial resistance surveillance programmes. Member Countries should refer to the OIE list of antimicrobials of veterinary importance for surveillance and monitoring purposes, recognising that the number of tested *antimicrobial agents* may have to be limited according to financial resources.

Appropriately validated antimicrobial susceptibility testing methods should be used in accordance with Chapter 3.1. of the *Terrestrial Manual*, concerning laboratory methodologies for bacterial antimicrobial susceptibility testing. Antimicrobial susceptibility data should be reported not only qualitatively (susceptible or resistant), but also quantitatively (minimum inhibitory concentrations [MICs] or inhibition zone diameters).

Article 6.8.8.

Recording, storage and interpretation of data

- 1) 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.
- 2) The storage of raw (primary, non-interpreted) data is essential to allow the evaluation in response to various kinds of questions, including those arising in the future.
- 3) Consideration should be given to the technical requirements of computer systems when an exchange of data between different systems (comparability or compatibility of automatic recording of laboratory data and transfer of these data between and within resistance surveillance and monitoring programmes) is envisaged. Results should be collected in a suitable national database and recorded quantitatively:
 - a) as distributions of MICs in micrograms per millilitre;
 - b) or inhibition zone diameters in millimetres.
- 4) The information to be recorded should include, where possible, the following aspects:
 - a) sampling programme;
 - b) sampling date;
 - c) animal species and production type;
 - d) type of sample;
 - e) purpose of sampling;
 - f) type of antimicrobial susceptibility testing method used;
 - g) geographical origin (geographical information system data where available) of *herd, flock* or animal;

- h) animal factors such as age, condition, health status, identification, sex;
 - i) exposure of animals to *antimicrobial agents*;
 - j) bacterial isolation rate.
- 5) The reporting of laboratory data should include the following information:
- a) identity of *laboratory*,
 - b) isolation date,
 - c) reporting date,
 - d) bacterial species,
- and, where relevant, other typing characteristics, such as:
- e) serotype or serovar,
 - f) phage type,
 - g) antimicrobial susceptibility result or resistance phenotype,
 - h) genotype.
- 6) The number of isolates regarded as resistant should be reported as a proportion of the number of isolates tested, including the defined interpretive criteria used.
- 7) In the clinical setting, breakpoints are used to categorise bacterial strains as susceptible, intermediate or resistant. These clinical breakpoints may be elaborated on a national basis and may vary between Member Countries.
- 8) The bacterial isolation methods, antimicrobial susceptibility testing methods, standards and guidelines used should be recorded.
- 9) For surveillance and monitoring purposes, use of the microbiological breakpoint (also referred to as epidemiological cut-off point), which is based on the distribution of MICs or inhibition zone diameters of the specific bacterial species tested, is preferred. When using microbiological breakpoints, only the bacterial population with acquired resistance that clearly deviates from the distribution of the normal susceptible population will be designated as resistant. Clinical breakpoints, when available, should also be reported.
- 10) Ideally, data should be collected at the individual isolate level. This will allow antimicrobial resistance patterns to be recorded over time, along with, when available, relevant data on usage of *antimicrobial agents* and management practices.

Article 6.8.9.

Reference laboratory and annual reports

- 1) Member Countries should designate a national reference centre that assumes the responsibility to:
 - a) coordinate the activities related to the antimicrobial resistance surveillance and monitoring programmes;
 - b) coordinate and collect information from participating laboratories within the country;
 - c) produce an annual report on the antimicrobial resistance situation in the country.
- 2) The national reference centre should have access to the:
 - a) raw data;
 - b) complete results of quality assurance and inter-laboratory calibration activities;
 - c) inter-laboratory proficiency testing results;
 - d) information on the structure of the surveillance or monitoring system;
 - e) information on the chosen laboratory methods.

NB: FIRST ADOPTED IN 2003; MOST RECENT UPDATE ADOPTED IN 2018.

CHAPTER 6.9.

MONITORING OF THE QUANTITIES AND USAGE PATTERNS OF ANTIMICROBIAL AGENTS USED IN FOOD-PRODUCING ANIMALS

Article 6.9.1.

Purpose

The purpose of the recommendations in this chapter is to describe an approach to the monitoring of the quantities of *antimicrobial agents* used in food-producing animals.

In order to evaluate antimicrobial exposure in food-producing animals, quantitative information should be collected to monitor usage patterns by animal species, *antimicrobial agents* or class of *antimicrobial agents*, route of administration and type of use: veterinary medical (to treat, control or prevent infectious disease) or non veterinary medical (including growth promotion).

Article 6.9.2.

Definitions

For the purposes of the *Terrestrial Code*:

'Veterinary medical use of antimicrobial agents': means the administration of an *antimicrobial agent* to an individual or a group of *animals* to treat, control or prevent infectious disease:

- 'to treat': means to administer an *antimicrobial agent* to an individual or a group of *animals* showing clinical signs of an infectious disease;
- 'to control': means to administer an *antimicrobial agent* to a group of *animals* containing sick *animals* and healthy *animals* (presumed to be infected), to minimise or resolve clinical signs and to prevent further spread of the disease;
- 'to prevent': means to administer an *antimicrobial agent* to an individual or a group of *animals* at risk of acquiring a specific *infection* or in a specific situation where infectious disease is likely to occur if the drug is not administered.

'Non veterinary medical use of antimicrobial agents': means the administration of *antimicrobial agents* to *animals* for any purpose other than to treat, control or prevent infectious disease; it includes growth promotion.

'Growth promotion': means the administration of *antimicrobial agents* to *animals* only to increase the rate of weight gain or the efficiency of feed utilisation.

Article 6.9.3.

Objectives

The information provided in these recommendations is essential for antimicrobial resistance *risk analyses* and planning purposes and should be read in conjunction with Chapters 6.8. and 6.11. This information is necessary for interpreting antimicrobial resistance surveillance data and can assist in responding to problems of antimicrobial resistance in a precise and targeted way. The continued collection of this basic information will also help to give an indication of trends in the use of *antimicrobial agents* in animals over time and potential associations with antimicrobial resistance in animals. This information may also assist in *risk management* to evaluate the effectiveness of efforts to ensure responsible and prudent use and mitigation strategies (for example, by identifying changes in veterinary prescribing practices) and to indicate where change of antimicrobial usage practices might be appropriate. The publication of these data is important to ensure transparency and to allow all interested parties to assess trends, to perform *risk assessments* and for *risk communication* purposes.

Article 6.9.4.

Development and standardisation of antimicrobial monitoring systems

Systems to monitor antimicrobial usage consist of the following elements:

1. Sources of antimicrobial data

a) Basic sources

Sources of data will vary from country to country. Such sources may include customs, import and export data, manufacturing and sales data.

b) Direct sources

Data from *veterinary medicinal product* registration authorities, wholesalers, retailers, pharmacists, *veterinarians*, *feed* stores, *feed* mills and pharmaceutical industry associations can be efficient and practical sources. A possible mechanism for the collection of this information is to make the provision of appropriate information by pharmaceutical manufacturers to the regulatory authority one of the requirements of antimicrobial registration.

c) End-use sources (veterinarians and food animal producers)

This may be appropriate when basic or direct sources cannot be used for the routine collection of the information or when more accurate and locally specific information is required (such as off label use).

Periodic collection of this type of information may be sufficient.

Collection, storage and processing of data from end-use sources should be carefully designed, well managed and have the capability to produce accurate and targeted information.

d) Other sources

Non-conventional sources including Internet sales data related to *antimicrobial agents* could be collected where available.

Member Countries may wish to consider, for reasons of cost and administrative efficiency, collecting medical, food-producing animal, agricultural and other antimicrobial use data in a single programme. A consolidated programme would also facilitate comparisons of animal use with human use data for *risk analysis* purposes and help to promote optimal usage of *antimicrobial agents*.

2. Types and reporting formats of antimicrobial usage data

a) Type of antimicrobial use data

The data collected at minimum should be the weight in kilograms of the active ingredient of the antimicrobial(s) used in food-producing animals per year. It is possible to estimate total usage by collecting sales data, prescribing data, manufacturing data, import and export data or any combination of these.

The total number of food-producing animals by species, type of production and their weight in kilograms for food production per year (as relevant to the country of production) is essential basic information.

Information on dosage regimens (dose, dosing interval and duration of the treatment) and route of administration are elements to include when estimating antimicrobial usage in food-producing animals.

b) Reporting formats of antimicrobial use data

The *antimicrobial agents*, classes or sub-classes to be included in data reporting should be based on current known mechanisms of antimicrobial activity and antimicrobial resistance data.

Nomenclature of *antimicrobial agents* should comply with international standards where available.

For active ingredients present in the form of compounds or derivatives, the mass of active entity of the molecule should be recorded. For *antimicrobial agents* expressed in International Units, the factor used to convert these units to mass of active entity should be stated.

The reporting of antimicrobial use data may be further organised by species, by route of administration (specifically in-feed, in-water, injectable, oral, intramammary, intra-uterine and topical) and by type of use (veterinary medical or non veterinary medical).

Regarding data coming from end-use sources, further breakdown of data for analysis of antimicrobial use at the regional, local, *herd* and individual *veterinarian* or veterinary practice levels may be possible.

Article 6.9.5.

Interpretation

According to the OIE *risk assessment* guidelines (refer to Chapter 6.11.), factors such as the number or percentage of animals treated, treatment regimes, type of use and route of administration are key elements to consider.

When comparing antimicrobial use data over time, changes in the size and composition of animal populations should also be taken into account.

The interpretation and communication of results should take into account factors such as seasonality and disease conditions, animal species and age affected, agricultural systems (e.g. extensive range conditions and feedlots), animal movements, and dosage regimens with *antimicrobial agents*.

NB: FIRST ADOPTED IN 2003; MOST RECENT UPDATE ADOPTED IN 2018.

CHAPTER 6.10.

RESPONSIBLE AND PRUDENT USE OF ANTIMICROBIAL AGENTS IN VETERINARY MEDICINE

Article 6.10.1.

Purpose

This document provides guidance for the responsible and prudent use of *antimicrobial agents* in veterinary medicine, with the aim of protecting both animal and human health as well as the environment. It defines the respective responsibilities of the *Competent Authority* and stakeholders such as the veterinary pharmaceutical industry, *veterinarians*, animal *feed* manufacturers, distributors and food animal producers who are involved in the authorisation, production, control, importation, exportation, distribution and use of *veterinary medicinal products* (VMP) containing *antimicrobial agents*.

Responsible and prudent use is determined taking into account the specifications detailed in the marketing authorisation and their implementation when *antimicrobial agents* are administered to *animals* and is part of good veterinary and good agricultural practice.

Activities associated with the responsible and prudent use of *antimicrobial agents* should involve all relevant stakeholders.

Coordination of these activities at the national or regional level is recommended and may support the implementation of targeted actions by the stakeholders involved and enable clear and transparent communications.

Article 6.10.2.

Objectives of responsible and prudent use

Responsible and prudent use includes implementing practical measures and recommendations intended to improve animal health and *animal welfare* while preventing or reducing the selection, emergence and spread of antimicrobial-resistant bacteria in *animals* and humans. Such measures include:

- 1) ensuring the rational use of *antimicrobial agents* in *animals* with the purpose of optimising both their efficacy and safety;
- 2) complying with the ethical obligation and economic need to keep *animals* in good health;
- 3) preventing or reducing the transfer of resistant micro-organisms or resistance determinants within animal populations, the environment and between *animals* and humans;
- 4) contributing to the maintenance of the efficacy and usefulness of *antimicrobial agents* used in *animal* and human medicine;
- 5) protecting consumer health by ensuring the safety of food of animal origin with respect to residues of *antimicrobial agents*.

Article 6.10.3.

Responsibilities of the Competent Authority

1. Marketing authorisation

All Member Countries should combat the unauthorised manufacture, compounding, importation, advertisement, trade, distribution, storage and use of unlicensed, adulterated and counterfeit products, including bulk active ingredients, through appropriate regulatory controls and other measures.

The *Competent Authority* is responsible for granting marketing authorisation which should be done in accordance with the provisions of the *Terrestrial Code*. It has a significant role in specifying the terms of this authorisation and in providing the appropriate information to *veterinarians* and all other relevant stakeholders.

The *Competent Authority* should establish and implement efficient statutory registration procedures that evaluate the quality, safety and efficacy of VMP containing *antimicrobial agents*. According to Article 3.1.2., the *Competent Authority* should be free from any commercial, financial, hierarchical, political or other pressures which might affect its judgement or decisions.

Member Countries lacking the necessary resources to implement an efficient registration procedure for VMP containing *antimicrobial agents*, and which are importing them, should undertake the following measures:

- a) evaluate the efficacy of administrative controls on the import of these VMP;
- b) evaluate the validity of the registration procedures of the exporting and manufacturing country as appropriate;
- c) develop the necessary technical co-operation with experienced relevant authorities to check the quality of imported VMP as well as the validity of the recommended conditions of use.

The *Competent Authorities of importing countries* should request the pharmaceutical industry to provide quality certificates prepared by the *Competent Authority* of the exporting and manufacturing country as appropriate.

Marketing authorisation is granted on the basis of the data submitted by the pharmaceutical industry or applicant and only if the criteria of safety, quality and efficacy are met.

Member Countries are encouraged to apply the existing guidelines established by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).

An evaluation of the potential risks and benefits to both *animals* and humans resulting from the use of *antimicrobial agents*, with particular focus on use in food-producing animals, should be carried out. The evaluation should focus on each individual *antimicrobial agent* and the findings should not be generalised to the antimicrobial class to which the particular active ingredient belongs. Guidance on usage should be provided for all target, route of administration, dosage regimens, withdrawal period and different durations of treatment that are proposed.

The *Competent Authority* should expedite the process for new *antimicrobial agents* in order to address a specific need for the treatment of animal disease.

2. Quality control of antimicrobial agents and VMP containing 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 registration documentations (such as monographs) approved by the relevant *Competent Authority*;
- c) to ensure that the quality of *antimicrobial agents* in the marketed dosage forms is maintained until the expiry date, established under the recommended storage conditions;
- d) to ensure the stability of *antimicrobial agents* when mixed with *feed* or drinking water;
- e) to ensure that all *antimicrobial agents* and the VMP containing them are manufactured to the appropriate quality and purity in order to guarantee their safety and efficacy.

3. Assessment of therapeutic efficacy

a) Preclinical trials

i) Preclinical trials should:

- establish the spectrum of activity of *antimicrobial agents* against relevant pathogenic agents and non-pathogenic agents (commensals);
- assess the capacity of the *antimicrobial agents* to select for resistance *in vitro* and *in vivo*, taking into consideration intrinsically resistant and pre-existing resistant strains;
- establish an appropriate dosage regimen (dose, dosing interval and duration of the treatment) and route of administration necessary to ensure the therapeutic efficacy of the *antimicrobial agents* 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 microorganism should be established by pharmacodynamics. The following criteria should be taken into account:

- spectrum of activity and mode of action;
- minimum inhibitory and bactericidal concentrations against recent isolates;
- time- or concentration-dependent activity or co-dependency;
- activity at the site of *infection*.

iii) The dosage regimens allowing maintenance of effective antimicrobial levels should be established by pharmacokinetics. The following criteria should be taken into account:

- bio-availability in accordance with the route of administration;
- distribution of the *antimicrobial agents* in the treated *animal* and concentration at the site of *infection*;
- metabolism;
- excretion routes.

Use of combinations of *antimicrobial agents* should be scientifically supported.

b) Clinical trials

Clinical trials in the target animal species should be performed to confirm the validity of the claimed therapeutic indications and dosage regimens established during the preclinical phase. The following criteria should be taken into account:

- i) diversity of the clinical cases encountered when performing multi-centre trials;
- ii) compliance of protocols with good clinical practice;
- iii) eligibility of studied clinical cases, based on appropriate criteria of clinical and bacteriological diagnoses;
- iv) parameters for qualitatively and quantitatively assessing the efficacy of the treatment.

4. Assessment of the potential of antimicrobial agents to select for resistance

Other studies may be requested in support of the assessment of the potential of *antimicrobial agents* to select for resistance. The party applying for market authorisation should, where possible, supply data derived in target animal species under the intended conditions of use.

For this the following may be considered:

- a) the concentration of either active *antimicrobial agents* or metabolites in the gut of the *animal* (where the majority of potential food-borne pathogenic agents reside) at the defined dosage level;
- b) pathway for the human exposure to antimicrobial resistant microorganisms;
- c) the degree of cross-resistance;
- d) the intrinsic and pre-existing, baseline level of resistance in the pathogenic agents of human health concern in both *animals* and humans.

5. Establishment of acceptable daily intake (ADI), maximum residue limit (MRL) and withdrawal periods in food-producing animals

- a) When setting the ADI and MRL for an *antimicrobial agent*, the safety evaluation should also include the potential biological effects on the intestinal flora of humans.
- b) The establishment of an ADI for each *antimicrobial agent*, and an MRL for each animal-derived food, should be undertaken before a VMP containing it is granted marketing authorisation.

- c) For all VMP containing *antimicrobial agents*, withdrawal periods should be established for each animal species in order to ensure compliance with the MRLs, taking into account:
 - i) the MRLs established for the *antimicrobial agent* in the target *animal* edible tissues;
 - ii) the composition of the product and the pharmaceutical form;
 - iii) the dosage regimen;
 - iv) the route of administration.
- d) The applicant should describe methods for regulatory testing of residues in food based on the established marker residues.

6. Protection of the environment

An assessment of the impact of the proposed antimicrobial use on the environment should be conducted.

7. Establishment of a summary of product characteristics for each VMP containing antimicrobial agents

The summary of product characteristics contains the information necessary for the appropriate use of VMP containing *antimicrobial agents* and constitutes the official reference for their labelling and package insert. This summary should contain the following items:

- a) active ingredient and class;
- b) pharmacological properties;
- c) any potential adverse effects;
- d) target animal species and, as appropriate, age or production category;
- e) therapeutic indications;
- f) target micro-organisms;
- g) dosage regimen and route of administration;
- h) withdrawal periods;
- i) incompatibilities and interactions;
- j) storage conditions and shelf-life;
- k) operator safety;
- l) particular precautions before use;
- m) particular precautions for the proper disposal of un-used or expired products;
- n) information on conditions of use relevant to the potential for selection of resistance;
- o) contraindication.

8. Post-marketing antimicrobial surveillance

The information collected through existing pharmacovigilance programmes, including lack of efficacy, and any other relevant scientific data, should form part of the comprehensive strategy to minimise antimicrobial resistance. In addition to this, the following should be considered:

a) General epidemiological surveillance

The surveillance of animal microorganisms resistant to *antimicrobial agents* is essential. The relevant authorities should implement a programme in accordance with Chapter 1.4.

b) Specific surveillance

Specific surveillance to assess the impact of the use of a specific *antimicrobial agent* may be implemented after the granting of marketing authorisation. The surveillance programme should evaluate not only resistance in target animal pathogenic agents, but also in food-borne pathogenic agents, and commensals if relevant and possible. This will also contribute to general epidemiological surveillance of antimicrobial resistance.

9. Supply and administration of the VMP containing antimicrobial agents

The relevant authorities should ensure that all the VMP containing *antimicrobial agents* used in *animals* are:

- a) prescribed by a *veterinarian* or other suitably trained person authorised to prescribe VMP containing *antimicrobial agents* in accordance with the national legislation and under the supervision of a *veterinarian*;
- b) supplied only through licensed or authorised distribution systems;

- c) administered to *animals* by a *veterinarian* or under the supervision of a *veterinarian* or by other authorised persons.

The relevant authorities should develop effective procedures for the safe collection and disposal or destruction of unused or expired VMPs containing *antimicrobial agents*. Their labels should have appropriate instructions for disposal and destruction.

10. Control of advertising

All advertising of *antimicrobial agents* should be compatible with the principles of responsible and prudent use and should be controlled by codes of advertising standards. The relevant authorities must ensure that the advertising of these products:

- a) complies with the marketing authorisation granted, in particular regarding the content of the summary of product characteristics;
- b) is restricted to a *veterinarian* or other suitably trained person authorised to prescribe VMP containing *antimicrobial agents* in accordance with the national legislation and under the supervision of a *veterinarian*.

11. Training on the usage of antimicrobial agents

The training on the usage of *antimicrobial agents* should include all the relevant organisations, such as the *Competent Authority*, pharmaceutical industry, veterinary schools, research institutes, veterinary professional organisations and other approved users such as food animal owners and manufacturers of medicated animal *feed*. This training should focus on preserving the effectiveness of *antimicrobial agents* and include:

- a) information on disease prevention, management and mitigation strategies;
- b) the ability of *antimicrobial agents* to select for resistant microorganisms in *animals* and the relative importance of that resistance to public and animal health;
- c) the need to observe responsible use recommendations for the use of *antimicrobial agents* in animal husbandry in agreement with the provisions of the marketing authorisations;
- d) appropriate storage conditions, proper disposal of unused or expired VMP;
- e) record keeping.

12. Research

The relevant authorities should encourage public- and industry-funded research, for example on methods to identify and mitigate the public health risks associated with specific *antimicrobial agent* uses, or on the ecology of antimicrobial resistance.

Article 6.10.4.

Responsibilities of the veterinary pharmaceutical industry with regards to VMP containing antimicrobial agents

1. Marketing authorisation

The veterinary pharmaceutical industry has responsibilities to:

- a) supply all the information requested by the national *Competent Authority*;
- b) guarantee the quality of this information in compliance with the provisions of good manufacturing, laboratory and clinical practices;
- c) implement a pharmacovigilance programme and on request, specific surveillance for bacterial susceptibility and resistance data.

2. Marketing and export

For the marketing and export of VMP containing *antimicrobial agents*:

- a) only licensed and officially approved VMP containing *antimicrobial agents* should be sold and supplied, and then only through licensed/authorised distribution systems;
- b) the pharmaceutical industry should provide quality certificates prepared by the *Competent Authority* of the exporting and manufacturing countries to the *importing country*;
- c) the national regulatory authority should be provided with the information necessary to evaluate the amount of *antimicrobial agents* marketed.

3. Advertising

The veterinary pharmaceutical industry should respect principles of responsible and prudent use and should comply with established codes of advertising standards, including to:

- a) distribute information in compliance with the provisions of the granted authorisation;
- b) not advertise VMP containing *antimicrobial agents* directly to the food animal producer.

4. Training

The veterinary pharmaceutical industry should participate in training programmes as defined in point 11) of Article 6.10.3.

5. Research

The veterinary pharmaceutical industry should contribute to research as defined in point 12) of Article 6.10.3.

Article 6.10.5.

Responsibilities of wholesale and retail distributors

- 1) Distributors of VMP containing *antimicrobial agents* should only do so on the prescription of a *veterinarian* or other suitably trained person authorised to prescribe VMP containing *antimicrobial agents* in accordance with the national legislation and under the supervision of a *veterinarian*. All products should be appropriately labelled.
- 2) The recommendations on the responsible and prudent use of VMP containing *antimicrobial agents* should be reinforced by retail distributors who should keep detailed records of:
 - a) date of supply;
 - b) name of prescriber;
 - c) name of user;
 - d) name of product;
 - e) batch number;
 - f) expiration date;
 - g) quantity supplied;
 - h) copy of prescription.
- 3) Distributors should also be involved in training programmes on the responsible and prudent use of VMP containing *antimicrobial agents*, as defined in point 11) of Article 6.10.3.

Article 6.10.6.

Responsibilities of veterinarians

The *veterinarian's* responsibility is to promote public health, animal health and *animal welfare*, including identification, prevention and treatment of animal diseases. The promotion of sound animal husbandry methods, hygiene procedures, *biosecurity* and *vaccination* strategies can help to minimise the need for antimicrobial use in food-producing animals.

Veterinarians should only prescribe *antimicrobial agents* 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) administer or prescribe *antimicrobial agents* only when necessary and taking into consideration the OIE list of *antimicrobial agents* of veterinary importance;
- b) make an appropriate choice of *antimicrobial agents* based on clinical experience and diagnostic laboratory information (pathogenic agent isolation, identification and antibiogram) where possible;
- c) provide a detailed treatment protocol, including precautions and withdrawal times, especially when prescribing extra-label or off-label use.

2. Choosing antimicrobial agents

- a) The expected efficacy of the treatment is based on:
- i) the clinical experience of the *veterinarians*, their diagnostic insight and therapeutic judgement;
 - ii) diagnostic laboratory information (pathogenic agent isolation, identification and antibiogram);
 - iii) pharmacodynamics including the activity towards the pathogenic agents involved;
 - iv) the appropriate dosage regimen and route of administration;
 - v) pharmacokinetics and tissue distribution to ensure that the selected therapeutic agent is effective at the site of *infection*;
 - vi) the epidemiological history of the rearing unit, particularly in relation to the antimicrobial resistance profiles of the pathogenic agents involved.

Should a first-line antimicrobial treatment fail or should the disease recur, a second line treatment should be based on the results of diagnostic tests. In the absence of such results, an appropriate *antimicrobial agent* belonging to a different class or sub-class should be used.

In emergencies, a *veterinarian* may treat *animals* without recourse to an accurate diagnosis and antimicrobial susceptibility testing, to prevent the development of clinical disease and for reasons of *animal welfare*.

- b) Use of combinations of *antimicrobial agents* should be scientifically supported. Combinations of *antimicrobial agents* may be used for their synergistic effect to increase therapeutic efficacy or to broaden the spectrum of activity.

3. Appropriate use of the VMP containing antimicrobial agents chosen

A prescription for VMP containing *antimicrobial agents* should indicate precisely the dosage regimen, the withdrawal period where applicable and the amount of VMP containing *antimicrobial agents* to be provided, depending on the dosage and the number of *animals* to be treated.

The extra-label or off-label use of VMP containing *antimicrobial agents* may be permitted in appropriate circumstances and should be in agreement with the national legislation in force including the withdrawal periods to be used, as applicable. It is the *veterinarian's* responsibility to define the conditions of responsible use in such a case including the dosage regimen, the route of administration and the withdrawal period.

The use of compounded VMP containing *antimicrobial agents* and extra-label or off-label use of registered VMP containing *antimicrobial agents* should be limited to circumstances where an appropriate registered product is not available.

4. Recording of data

Records on VMP containing *antimicrobial agents* should be kept in conformity with the national legislation. Information records should include the following:

- a) quantities of VMP used per animal species;
- b) a list of all VMP supplied to each food-producing animal holding;
- c) treatment schedules including animal identification and withdrawal period;
- d) antimicrobial susceptibility data;
- e) comments concerning the response of *animals* to treatment;
- f) the investigation of adverse reactions to antimicrobial treatment, including lack of response due to possible antimicrobial resistance. Suspected adverse reactions should be reported to the appropriate regulatory authorities.

Veterinarians should also periodically review farm records on the use of VMP containing *antimicrobial agents* to ensure compliance with their directions or prescriptions and use these records to evaluate the efficacy of treatments.

5. Labelling

All VMP supplied by a *veterinarian* should be labelled in accordance with the national legislation.

6. Training and continued professional development

Veterinary professional organisations should participate in the training programmes as defined in point 11) of Article 6.10.3. It is recommended that veterinary professional organisations develop for their members species-specific clinical practice recommendations on the responsible and prudent use of VMP containing *antimicrobial agents*.

Article 6.10.7.

Responsibilities of food animal producers

- 1) Food animal producers, with the assistance and guidance of a *veterinarian*, are responsible for implementing animal health and *animal welfare* programmes on their farms in order to promote animal health and food safety.
- 2) Food animal producers should:
 - a) draw up a health plan with the attending *veterinarian* that outlines preventive measures (e.g. feedlot health plans, mastitis control plans, endo- and ectoparasite control, *vaccination* programmes and biosecurity measures);
 - b) use VMP containing *antimicrobial agents* only on the prescription of a *veterinarian* or other suitably trained person authorised to prescribe VMP containing *antimicrobial agents* in accordance with the national legislation and under the supervision of a *veterinarian*;
 - c) use VMP containing *antimicrobial agents* in accordance with product label instructions, including storage conditions, or the instructions of the attending *veterinarian*;
 - d) isolate sick *animals*, when appropriate, to avoid the transfer of pathogenic agents; dispose of dead or dying *animals* promptly under conditions approved by the relevant authorities;
 - e) address on-farm biosecurity measures and take basic hygiene precautions as appropriate;
 - f) comply with and record the recommended withdrawal periods to ensure that residue levels in animal-derived food do not present a risk for the consumer;
 - g) use VMP containing *antimicrobial agents* within the expiry date and dispose of unused and expired surplus VMP containing *antimicrobial agents* under conditions safe for the environment;
 - h) maintain all the laboratory records of bacteriological and susceptibility tests; these data should be made available to the *veterinarian* responsible for treating the *animals*;
 - i) keep adequate records of all VMP containing *antimicrobial agents* used, including the following:
 - i) name of the product and active substance, batch number and expiry date;
 - ii) name of prescriber and 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 including the end-date of the withdrawal periods;
 - viii) result of laboratory tests;
 - ix) effectiveness of therapy;
 - j) inform the responsible *veterinarian* of recurrent disease problems.
- 3) Training

Food animal producers should participate in the training programmes as defined in point 11) of Article 6.9.3. It is recommended that food animal producer organisations work in cooperation with the veterinary professional organisations to implement existing guidelines for the responsible and prudent use of VMP containing *antimicrobial agents*.

Article 6.10.8.

Responsibilities of animal feed manufacturers

- 1) The supply of medicated *feed* containing *antimicrobial agents* to farmers keeping food-producing animals by animal *feed* manufacturers should be allowed only on the prescription of a *veterinarian*. Alternatively, such medicated *feed* may be prescribed by other suitably trained persons authorised to prescribe VMP containing *antimicrobial agents* in accordance with the national legislation and under the supervision of a *veterinarian*. Animal *feed* manufacturers preparing medicated *feed* should do so following rules put in place by the *Competent Authority* in accordance with the national legislation. All medicated *feed* and medicated premixes should be appropriately labelled.
- 2) The regulations and recommendations on the responsible and prudent use of VMP containing *antimicrobial agents* should be reinforced by animal *feed* manufacturers who should keep detailed records.
- 3) Use only approved sources of medications: Animal *feed* manufacturers preparing medicated *feed* should ensure that only approved sources of medications are added to *feed* at a level, and for a species and purpose as permitted by the drug premix label or a veterinary prescription.

- 4) Ensure appropriate labelling with product identification, direction for use and withdrawal time: Animal *feed* manufacturers preparing medicated *feed* should ensure that medicated animal *feed* are labelled with the appropriate information (e.g. level of medication, approved claim, intended species, directions for use, warning, cautions) so as to ensure effective and safe use by the producer.
- 5) Implement appropriate production practices to prevent contamination of other *feed*: Animal *feed* manufacturers preparing medicated *feed* should implement appropriate production practices to avoid unnecessary carry over and unsafe cross contamination of unmedicated *feed*.

NB: FIRST ADOPTED IN 2003; MOST RECENT UPDATE ADOPTED IN 2014.

CHAPTER 6.11.

RISK ANALYSIS FOR ANTIMICROBIAL RESISTANCE ARISING FROM THE USE OF ANTIMICROBIAL AGENTS IN ANIMALS

Article 6.11.1.

Recommendations for analysing the risks to animal and human health from antimicrobial resistant microorganisms of animal origin

1. Introduction

Antimicrobial resistance is a naturally occurring phenomenon influenced by many factors. However, problems related to antimicrobial resistance are inherently related to *antimicrobial agent* use in any environment, including human, animal and other uses.

Antimicrobial resistance associated with the use of *antimicrobial agents* for therapeutic and non-therapeutic purposes has led to the selection and dissemination of antimicrobial resistant microorganisms, with a resulting loss of therapeutic efficacy in animal and human medicine of one or several *antimicrobial agents*.

2. Objective

For the purpose of this chapter, the principal aim of *risk analysis* is to provide Member Countries with a transparent, objective and scientifically defensible method of assessing and managing the human and animal health *risks* associated with the selection and dissemination of resistance arising from the use of *antimicrobial agents* in *animals*.

Guidance on the issue of food-borne antimicrobial resistance related to the non-human use of *antimicrobial agents* is covered by the Codex Guidelines for risk analysis of food-borne antimicrobial resistance (CAC/GL77-2011).

3. The risk analysis process

The components of *risk analysis* described in this chapter are *hazard* identification, *risk assessment*, *risk management* and *risk communication*.

The chapter includes factors to be considered at various steps of the *risk analysis* process. These factors are not intended to be exhaustive and not all elements may be applicable in all situations.

4. Hazard identification

For the purpose of this chapter, the *hazard* is the resistant microorganism or resistance determinant that emerges as a result of the use of a specific *antimicrobial agent* in *animals*. This definition reflects the potential for resistant microorganisms to cause adverse health effects, as well as the potential for horizontal transfer of genetic determinants between microorganisms. The conditions under which the *hazard* might produce adverse consequences include any scenarios through which humans or *animals* could become exposed to an antimicrobial resistant pathogenic agent, fall ill and then be treated with an *antimicrobial agent* that is no longer effective.

5. Risk assessment

The assessment of the risk to human and animal health from antimicrobial resistant microorganisms resulting from the use of *antimicrobial agents* in *animals* should examine:

- a) the likelihood of emergence of resistant microorganisms arising from the use of an *antimicrobial agent*, or more particularly, dissemination of the resistance determinants if transmission is possible between microorganisms;
- b) consideration of all pathways and their importance, by which humans and *animals* could be exposed to these resistant microorganisms or resistance determinants, together with the likelihood of exposure;
- c) the consequences of exposure in terms of *risks* to human and animal health.

The general principles of *risk assessment* apply equally to both *qualitative* and *quantitative risk assessment*. At a minimum, a *qualitative risk assessment* should always be undertaken.

Article 6.11.2.

Analysis of risks to human health

1. Definition of the risk

The infection of humans with microorganisms that have acquired resistance due to antimicrobial usage in *animals*, and resulting in the loss of benefit of antimicrobial therapy used to manage the human infection.

2. Hazard identification

- Microorganisms that have acquired resistance (including multiple resistance) arising from the use of an *antimicrobial agent* in *animals*.
- Microorganisms having obtained a resistance determinant from other microorganisms which have acquired resistance arising from the use of an *antimicrobial agent* in *animals*.

The identification of the *hazard* should include consideration of the class or subclass of the *antimicrobial agent*. This definition should be read in conjunction with point 4) of Article 6.11.1.

3. Release assessment

A release assessment describes the biological pathways that may lead to the release of resistant microorganisms or resistance determinants into a particular environment due to the use of a specific *antimicrobial agent* in *animals*. It also estimates 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:

- animal species, category such as food producing, zoo, entertainment or companion animal, and, where appropriate, production type such as veal calves or dairy cattle, broilers or laying hens, treated with the *antimicrobial agent* in question;
- number of *animals* treated and their age, geographical distribution and, where appropriate, sex;
- prevalence of *infection* or disease for which the *antimicrobial agent* is indicated in the target animal population;
- data on trends in *antimicrobial agent* use and changes in farm production systems;
- data on extra-label or off-label use;
- methods and routes of administration of the *antimicrobial agent*;
- dosage regimen (dose, dosing interval and duration of the treatment);
- pharmacokinetics and relevant pharmacodynamics of the *antimicrobial agent*;
- prevalence of pathogenic agents that are likely to develop resistance in an animal species;
- prevalence of commensal bacteria which are able to transfer resistance to human pathogenic agents;
- mechanisms and pathways of direct or indirect transfer of resistance;
- potential linkage of virulence attributes and resistance;
- cross-resistance or co-resistance with other *antimicrobial agents*;
- data on trends and occurrence of resistant microorganisms obtained through surveillance of *animals*, products of animal origin and animal waste products.

4. Exposure assessment

An exposure assessment describes the biological pathways necessary for exposure of humans to the resistant microorganisms or resistance determinants released from a given antimicrobial use in *animals*, and estimates 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, species and other characteristics of the human populations exposed.

The following factors should be considered in the exposure assessment:

- human demographics, including population subgroups, and food consumption patterns, including traditions and cultural practices with respect to the preparation and storage of food;
- prevalence of resistant microorganisms in food at the point of consumption;
- microbial load in contaminated food at the point of consumption;
- environmental contamination with resistant microorganisms;

- occurrence in animal *feed* of resistant microorganisms that have the capacity to become established in the *animals*, thus leading to contamination of food of animal origin;
- transfer of resistant microorganisms and their resistance determinants between humans, *animals* and the environment;
- measures taken for microbial decontamination of food;
- survival capacity and dissemination of resistant microorganisms during the food production process (including slaughtering, processing, storage, transportation and retailing);
- disposal practices for waste products and the likelihood for human exposure to resistant microorganisms or resistance determinants through those waste products;
- capacity of resistant microorganisms to become established in humans;
- human-to-human transmission of the microorganisms under consideration;
- capacity of resistant microorganisms to transfer resistance to human commensal microorganisms and zoonotic agents;
- amount and type of *antimicrobial agents* used to treat humans;
- pharmacokinetics, such as metabolism, bioavailability and distribution to the gastrointestinal flora.

5. Consequence assessment

A consequence assessment describes the relationship between specified exposures to resistant microorganisms or resistance determinants 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.

The following factors should be considered in the consequence assessment:

- microbial dose and subsequent host response interactions;
- variation in susceptibility of exposed populations or subgroups of the population;
- variation and frequency of human health effects resulting from loss of efficacy of *antimicrobial agents* and associated costs;
- potential linkage of virulence attributes and resistance;
- changes in food consumption patterns due to loss of confidence in the safety of food products and any associated secondary *risks*;
- interference with antimicrobial therapy in humans;
- importance of the *antimicrobial agent* in human medicine;
- prevalence of resistance in human bacterial pathogenic agents 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 infected with antimicrobial resistant microorganisms;
- adverse effects on vulnerable human sub-population (children, immunocompromised persons, elderly, pregnant, etc.);
- increased severity or duration of infectious disease;
- number of person/days of illness per year;
- deaths (total per year; probability per year or reduced life expectancy for a random member of the population or a member of a specific sub-population) linked to antimicrobial resistant microorganisms when compared with deaths linked to sensitive microorganisms of the same species;
- severity of the disease caused by the target resistant microorganisms;
- availability and cost of alternative antimicrobial therapy;
- potential impact of switching to an alternative *antimicrobial agent* (e.g. alternatives with potential increased toxicity);
- occurrence of antimicrobial resistance in target pathogenic agents observed in humans;
- consequences of the overall *risk* impacts (e.g. illness and hospitalisation).

7. Risk management components

The OIE defines *risk management* as consisting of the steps described below.

- a) *Risk evaluation* - the process of comparing the *risk* estimated in the *risk assessment* with the reduction in *risk* expected from the proposed *risk management* measures.
- b) *Option evaluation*
A range of *risk management* options is available to minimise the emergence and dissemination of antimicrobial resistance and these include both regulatory and non-regulatory options, such as the development of codes of practice for the use of *antimicrobial agents* 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 animal diseases can have the dual benefits of reducing *risks* to human health associated with both the bacterial pathogenic agent under consideration and antimicrobial resistance.
- c) *Implementation*
Risk managers should develop an implementation plan that describes how the decision will be implemented, by whom and when. *Competent Authorities* should ensure an appropriate regulatory framework and infrastructure.
- d) *Monitoring and review*
Risk management options should be continuously monitored and reviewed in order to ensure that the objectives are being achieved.

8. Risk communication

Communication with all interested parties should be promoted at the earliest opportunity and integrated into all phases of a *risk analysis*. This will provide all interested parties, including *risk managers*, with the better understanding of *risk management* approaches. *Risk communication* should be also well documented.

Article 6.11.3.

Analysis of risks to animal health

1. Definition of the risk

The *infection of animals* with microorganisms that have acquired resistance due to antimicrobial usage in *animals*, and resulting in the loss of benefit of antimicrobial therapy used to manage the animal *infection*.

2. Hazard identification

- Microorganisms that have acquired resistance (including multiple resistance) arising from the use of an *antimicrobial agent* in *animals*;
- microorganisms having obtained a resistance determinant from another microorganism which has acquired resistance arising from the use of an *antimicrobial agent* in *animals*.

The identification of the *hazard* should include considerations of the class or subclass of the *antimicrobial agent*. This definition should be read in conjunction with point 4) of Article 6.11.1.

3. Release assessment

The following factors should be considered in the release assessment:

- animal species, category such as food producing, zoo, entertainment or companion animal and, where appropriate, production type, such as veal calves or dairy cattle, broilers or laying hens treated with the *antimicrobial agent* in question;
- number of *animals* treated, and their age, geographical distribution and, where appropriate, sex;
- prevalence of *infection* or disease for which the *antimicrobial agent* is indicated in the target animal population;
- data on trends in *antimicrobial agent* use and changes in farm production systems;
- data on extra-label or off-label use;
- dosage regimen (dose, dosing interval and duration of the treatment);
- methods and routes of administration of the *antimicrobial agent*;
- the pharmacokinetics and relevant pharmacodynamics of the *antimicrobial agent*;
- site and type of *infection*;

- development of resistant microorganisms;
- mechanisms and pathways of resistance transfer;
- cross-resistance or co-resistance with other *antimicrobial agents*;
- data on trends and occurrence of resistant microorganisms obtained through surveillance of *animals*, products of animal origin and animal waste products.

4. Exposure assessment

The following factors should be considered in the exposure assessment:

- prevalence and trends of resistant microorganisms in clinically ill and clinically unaffected *animals*;
- occurrence of resistant microorganisms in *feed* and in the animal environment;
- animal-to-animal transmission of the resistant microorganisms and their resistance determinants (animal husbandry practices and movement of *animals*);
- number or percentage of *animals* treated;
- quantity and trends of *antimicrobial agents* used in *animals*;
- survival capacity and dissemination of resistant microorganisms;
- exposure of *wildlife* to resistant microorganisms;
- disposal practices for waste products and the likelihood of animal exposure to resistant microorganisms or resistance determinants through those products;
- capacity of resistant microorganisms to become established in *animals*;
- exposure to resistance determinants from other sources such as water, effluent, waste pollution, etc.;
- pharmacokinetics, such as metabolism, bioavailability, distribution to the gastrointestinal flora;
- transfer of resistant microorganisms and their resistance determinants between humans, *animals* and the environment.

5. Consequence assessment

The following factors should be considered in the consequence assessment:

- microbial dose and subsequent host response interactions;
- 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 *antimicrobial agents* and associated costs;
- potential linkage of virulence attributes and resistance;
- importance of the *antimicrobial agent* in animal health (see OIE list of antimicrobial agents of veterinary importance).

6. Risk estimation

The following factors should be considered in the *risk* estimation:

- additional burden of disease due to antimicrobial resistant microorganisms;
- number of therapeutic failures due to antimicrobial resistant microorganisms;
- increased severity and duration of infectious disease;
- impact on *animal welfare*;
- estimation of the economic impact and cost on animal health and production;
- deaths (total per year; probability per year or reduced life expectancy for a random member of the population or a member of a specific sub-population) linked to antimicrobial resistant microorganisms when compared with deaths linked to sensitive microorganisms of the same species;
- availability and cost of alternative antimicrobial therapy;
- potential impact of switching to an alternative *antimicrobial agent*, e.g. alternatives with potential increased toxicity.

7. Risk management components

The relevant provisions in point 7) of Article 6.11.2. apply.

8. Risk communication

The relevant provisions in point 8) of Article 6.11.2. apply.

NB: FIRST ADOPTED IN 2004; MOST RECENT UPDATE ADOPTED IN 2015.

CHAPTER 6.12.

ZOONOSES TRANSMISSIBLE FROM NON-HUMAN PRIMATES

Article 6.12.1.

Introduction

There are about 376 different species of non-human primates belonging to three suborders which are split into 15 families. The tree shrew family (previously considered as belonging to the primates) has not been included in these recommendations.

All non-human primate species are included in Appendix I or Appendix II of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) and may be transported internationally only if accompanied by the permits or certificates required under CITES.

Most imported non-human primates are destined for research, educational or breeding purposes and their sourcing should be in accordance with Article 7.8.7. Before non-human primates are used for any purpose, all alternatives to their use should be explored.

Public health and safety, *animal welfare* and pathogenic agent introduction to wild populations are the primary issues of concern in the importation and keeping of non-human primates. This is especially true where close contact between humans and animals, their body fluids, faeces and tissues is likely to occur. Minimising the *risk* requires well-trained personnel and the following of stringent personal hygiene standards.

The likelihood of carrying zoonotic pathogenic agents is related to the taxonomic position and the region of origin of the species concerned. It can be considered to increase from prosimians to marmosets and tamarins, then to other New World monkeys, to Old World monkeys and apes. The likelihood of carrying zoonotic agents is also greater in wild-caught non-human primates than in captive-bred animals which have been maintained in a well-defined environment under veterinary supervision. For non-human primates taken from the wild, usually only very limited health related information can be given by the supplier and by the *Veterinary Authority* of the *exporting country*.

Most pathogenic agents referred to in this chapter are not included in the OIE List, and there is, consequently, no requirement to report them on a regular basis within the OIE animal disease reporting system. However, the requirement to report exceptional epidemiological events remains in effect.

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

Article 6.12.2.

General recommendations

Veterinary Authorities of *exporting countries* should issue *international veterinary certificates* only upon presentation of valid CITES documentation.

Veterinary Authorities should make sure that the animals are individually identified by approved methods that assure traceability and to avoid transmission of disease (see Chapter 4.15.).

For reasons of public health, *animal welfare* and pathogenic agent introduction to wild populations, *Veterinary Authorities* of *importing countries* should not authorise the import of non-human primates for the purpose of being kept as pets.

In the case of a non-human primate being imported directly from a country within the natural range of the animal's species concerned, and where only limited diagnostic testing is available, *Veterinary Authorities* of *importing countries* should place more emphasis on quarantine procedures and less on veterinary certification. As a matter of principle, limited health guarantees given by the supplier or the *Veterinary Authority* of the country of origin should not constitute an obstacle to imports, but very strict post import quarantine requirements should be imposed. Particularly, the quarantine should meet the standards set in Chapter 5.9., and should be of sufficient length to minimise the *risk* of transmission of diseases where tests are not readily available or of limited value.

Veterinary Authorities of importing countries may reduce the quarantine requirements for non-human primates imported from premises with permanent veterinary supervision provided that the animals were born or have been kept for at least two years on these premises, are individually identified and accompanied by proper certification issued by qualified officials, and the official certification is supplemented by a complete documentation of the clinical history of each animal and its group of origin.

In cases where it is necessary to import non-human primates which are known or suspected to be carriers of a zoonotic disease, the import should not be restricted by any of these recommendations, provided that the *Veterinary Authority* of the *importing country* requires the placing of the animals in an establishment located on its territory which has been approved to receive them and which meets the standards set in Chapter 5.9.

Article 6.12.3.

General certification and transportation requirements

Veterinary Authorities of importing countries should require:

for all non-human primates

- 1) the presentation of an *international veterinary certificate* attesting that the animals:
 - a) have been individually identified (the means of identification should be stated in the certificate); and
 - b) have been examined on the day of shipment and found to be healthy, free from clinical signs of contagious disease, and fit for transport;
- 2) the attachment to the *international veterinary certificate* of all relevant records, including all *vaccinations*, tests and treatments performed during the lifetime of each primate before shipment;
- 3) the necessary CITES permit from the relevant *wildlife* authority;
- 4) the transport of the animals by air in accordance with the Live Animals Regulations of the International Air Transport Association or by rail or road under equivalent standards for surface transport.

Article 6.12.4.

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 6.12.3.;
- 2) the immediate placement of the animals in a *quarantine station* meeting the standards set in Chapter 5.9. for at least 12 weeks; and during this quarantine:
 - a) all animals to be monitored daily for signs of illness and, if necessary, be subjected to a clinical examination;
 - b) all animals dying for any reason to be subjected to complete post-mortem examination at a *laboratory* approved for this purpose;
 - c) any cause of illness or death to be determined before the group to which the animals belong is released from quarantine;

d) animals to be subjected to the following diagnostic tests and treatments in accordance with Chapter 4.15.:

Disease/agent	Animal groups	Schedule	Methods
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.
Tuberculosis (<i>Mycobacterium tuberculosis</i> complex)	Marmosets and tamarins	Two tests at an interval of 2 to 4 weeks.	Skin test or serology. In-vitro gamma interferon assay or polymerase chain reaction (PCR) assay. The skin test using mammalian tuberculin (old tuberculin) is the most reliable of all. Skin tests in marmosets, tamarins or small prosimians should be performed in the abdominal skin rather than in the eyelid. In some species (e.g. orang utan), skin tests for tuberculosis are notorious for false positive results. Comparative tests using both mammalian and avian PPD, together with cultures, radiography, ELISA, in-vitro gamma interferon assay and PCR of gastric or bronchial lavage, faeces or tissues may eliminate confusion.
	Prosimians, New World monkeys, Old World monkeys, gibbons and great apes	At least three tests at intervals of 2 to 4 weeks.	
Other bacterial pathogenic agents (<i>Salmonella</i> , <i>Shigella</i> and <i>Yersinia</i> and others as appropriate)	All species	Daily test for 3 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 should be cultured immediately or be placed immediately in the appropriate transportation medium.
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.

Veterinary Authorities of importing countries should recognise the public health importance of zoonoses listed in the table below as well as measles (a human disease, sometimes affecting non-human primates), hepatitis A, monkey pox, Marburg disease or Ebola/Reston virus, retroviruses, etc., even though this article does not recommend specific testing or treatment protocols for these agents during the quarantine period. *Veterinary Authorities* should recognise that, if animals are infected, the importation and spread of many such agents will be best controlled by the detection of clinical signs of disease during a 12-week quarantine period.

Certain endemic viruses, such as herpesviruses or retroviruses, may be present in both wild and captive populations of primates. These viruses are often asymptomatic in primate species. If animals are being imported to be introduced to other populations of the same species, it may be advisable to determine if the animals selected for importation have similar viral profiles to the established population.

Article 6.12.5.

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 6.12.3., and that the animals:
 - a) are either born in the premises of origin or have been kept there for at least two years;
 - b) come from premises which are under permanent veterinary supervision, and where a suitable health monitoring programme is followed, including microbiological and parasitological tests as well as necropsies;
 - c) have been kept in buildings and enclosures in which no case of tuberculosis has occurred during the last two years prior to shipment;
- 2) a description of the health monitoring programme implemented by the establishment of origin;

- 3) the placement of the animals in a *quarantine station* meeting the standards set in Chapter 5.9. for at least 30 days; and during this period:
 - a) all animals to be monitored daily for signs of illness and, if necessary, be subjected to a clinical examination;
 - 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 pathogenic agents (<i>Salmonella</i> , <i>Shigella</i> and <i>Yersinia</i> and others as appropriate)	All species	Daily test for 3 days after arrival.	Faecal culture. (See further comments in the Table of Article 6.12.4.)
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 infections or for tuberculosis. However, stringent precautions to ensure human health and safety should be followed as recommended in Article 6.12.7.

Article 6.12.6.

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 6.12.3., and that the *animals*:
 - a) are either born in the premises of origin or have been kept there for at least two years;
 - b) come from premises which are under permanent veterinary supervision, and where a suitable health monitoring programme is followed, including microbiological and parasitological tests as well as necropsies;
 - c) have been kept in buildings and enclosures in which no case of tuberculosis has occurred during the last two years prior to shipment;
 - d) come from premises in which no case of tuberculosis or other major zoonoses including rabies has occurred during the last two years prior to shipment in the building where the *animals* were kept;
 - e) were subjected to a 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 determined before the group to which the *animals* belong is released from quarantine;
 - d) *animals* to be subjected to the following diagnostic tests and treatments in accordance with Chapter 4.15.:

Disease/agent	Animal groups	Schedule	Methods
Tuberculosis (<i>Mycobacterium tuberculosis</i> complex)	All species	One test.	Skin test or serology. In-vitro gamma interferon assay or polymerase chain reaction (PCR) assay. (See further comments in the Table of Article 6.12.4.)
Other bacterial pathogenic agents (<i>Salmonella</i> , <i>Shigella</i> and <i>Yersinia</i> and others as appropriate)	All species	Daily test for 3 days after arrival, and another test at least one week later.	Faecal culture. (See further comments in the Table of Article 6.12.4.)
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 may not normally require any tests for viral diseases. However, stringent precautions to ensure human health and safety should be followed as recommended in Article 6.12.7.

Article 6.12.7.

Precautionary measures to be followed by staff exposed to non-human primates or to their body fluids, faeces and tissues

The presence in most non-human primates of some zoonotic agents is almost unavoidable, even after release from quarantine. The relevant Authorities should, therefore, encourage the management of institutions whose staff are exposed to non-human primates or their body fluids, faeces or tissues (including when performing necropsies) to comply with the following recommendations:

- 1) to provide staff with training in the proper handling of primates, their body fluids, faeces and tissues, with respect to zoonoses containment and personal safety;
- 2) to inform their staff that certain species should be considered as having lifelong *infections* with some zoonotic agents, e.g. Asian macaques with Herpes B virus;
- 3) to ensure that the staff follows personal hygiene practices, including the use of protective clothing, and the prohibition of eating, drinking and smoking in potentially infective areas;
- 4) to implement a screening programme for personnel health, including monitoring for tuberculosis, pathogenic enteric bacteria and endoparasites and other agents that are deemed necessary;
- 5) to implement an immunisation programme as appropriate, including e.g. tetanus, measles, poliomyelitis, rabies, hepatitis A and B, and other diseases, such as yellow fever, endemic in the area of origin of the African and American non-human primates;
- 6) to develop guidelines for the prevention and treatment of zoonoses that may be transmitted by bites and scratches, e.g. rabies and herpes viruses;
- 7) to issue to their staff a card which states that they work with non-human primates or with their body fluids, faeces or tissues, and which may be presented to the medical profession in case of illness;
- 8) to dispose of carcasses, body fluids, faeces and tissues in a manner which is not detrimental to public health.

NB: FIRST ADOPTED IN 1998; MOST RECENT UPDATE ADOPTED IN 2013.

CHAPTER 6.13.

PREVENTION AND CONTROL OF *SALMONELLA* IN COMMERCIAL BOVINE PRODUCTION SYSTEMS

Article 6.13.1.

Introduction

Nontyphoidal salmonellosis is one of the most common foodborne bacterial diseases in the world with *Salmonella* Enteritidis and *S. Typhimurium* (including monophasic variants) being the predominant serotypes identified in humans in most countries. *S. Enteritidis* is primarily associated with *poultry* while *S. Typhimurium* may be present in many mammalian and avian hosts. These serotypes and several others occur at variable *prevalence* in bovines depending on the region. In some countries *S. Dublin* and *S. Newport* may also cause salmonellosis in humans.

Salmonella infection in bovines is mostly subclinical, although clinical disease such as enteritis, septicaemia or abortion may occur. Subclinical *infection*, including a carrier state, can be of variable duration and can play an important role in the spread of *Salmonella* within and between *herds* and pose a public health *risk*.

Herd size and stocking density may influence the likelihood of introduction, dissemination or persistence of *Salmonella*; however, this is also dependent on geographical region, husbandry and other factors such as season and age.

Salmonella serotypes and their *prevalence* in bovines may vary considerably within and between farms, countries and regions. It is important for *Veterinary Authorities* and producers to consider serotypes of *Salmonella*, their occurrence and the disease burden in bovine and human populations when they develop and implement strategies for the prevention and control of *Salmonella* in commercial bovine production systems.

Article 6.13.2.

Definitions

For the purposes of this chapter:

'Commercial bovine production systems': means those systems in which the purpose of the operation includes some or all of the following: breeding, rearing and management of bovines for the production of *meat* or *milk*.

'Intensive bovine production systems': means commercial systems in which bovines are in confinement and are fully dependent on humans to provide for basic animal needs such as food, shelter and water on a daily basis.

'Extensive bovine production systems': means commercial systems in which bovines have the freedom to roam outdoors, and where the bovines have some autonomy over diet selection (through grazing), water consumption and access to shelter.

Article 6.13.3.

Purpose and scope

This chapter provides recommendations for the prevention and control of *Salmonella* in commercial bovine production systems in order to reduce the burden of disease in bovines and the *risk* of human illness through foodborne contamination as well as human *infections* resulting from direct or indirect contact with infected bovines.

For the purposes of this chapter a bovine means *Bos taurus*, *B. indicus*, *B. javanicus* and *B. grunniens*, water buffaloes (*Bubalus bubalis*) and bison (*Bison bison* and *B. bonasus*).

This chapter applies to bovines kept in commercial bovine production systems.

This chapter should be read in conjunction with the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005), Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57-2004), Code of Practice on Good Animal

Feeding (CAC/RCP 54-2004), and the Guidelines for the Control of Nontyphoidal *Salmonella* spp. in Beef and Pork Meat (CAC/GL 87-2016), and the OIE/FAO Guide to Good Farming Practices for Animal Production Food Safety.

Article 6.13.4.

Objectives of prevention and control measures

Prevention and control measures may focus on those serotypes of *Salmonella* of greatest consequence to bovines and public health. These measures will also contribute to the reduction of other serotypes.

Prevention and control measures in commercial bovine production systems may:

- 1) reduce the *prevalence* and amount of *Salmonella* entering the *slaughterhouse/abattoir* and therefore decrease the challenge to the *slaughter* and dressing procedures and the likelihood of bovine *meat* contamination;
- 2) reduce the likelihood of *Salmonella* contamination in *milk*;
- 3) reduce *Salmonella* contamination of the environment via bovine faecal waste, which in turn will limit *infection* of animals (including *wildlife*);
- 4) reduce the likelihood of *infections* in humans through contact with infected bovines or contaminated materials or water.

While control in the primary production phase can decrease the number of animals carrying or shedding *Salmonella*, controls after primary production are also important to minimise the contamination and cross-contamination of carcasses and *meat products*.

Good farming practices and, when appropriate, the principles of hazard analysis and critical control points (HACCP) should be taken into account when designing prevention and control measures.

Articles 6.13.5. to 6.13.16. provide recommendations for the prevention and control of *Salmonella* in commercial bovine production systems. These recommendations may also contribute to the prevention and control of some other *infections*.

Article 6.13.5.

Biosecurity

Biosecurity is essential to prevent and control *Salmonella*. A *biosecurity plan* should be developed according to the commercial bovine production system employed. The applicability of the measures, described below, will vary according to the type of commercial bovine production system.

When including *Salmonella* as part of a *biosecurity plan* the following should be addressed:

- 1) location, design and management of the *establishment*;
- 2) veterinary supervision of bovine health;
- 3) management of the introduction and mixing of bovines;
- 4) training of personnel in their responsibilities and their role in animal health, human health and food safety;
- 5) prevention of contamination of *feed* and water, including for irrigation;
- 6) maintenance of records including data on bovine health, production, movements, feeding, water supply, medications, *vaccination*, mortality, and cleaning and *disinfection* of farm buildings and equipment;
- 7) availability of test results to the farm operator when *Salmonella surveillance* is conducted;
- 8) removal of unwanted vegetation and debris that could attract or harbour pests around premises for bovines;
- 9) minimising the entry of domestic animals and *wild* birds into buildings for bovines and *feed* stores;
- 10) cleaning and *disinfection* procedures for buildings in which bovines are handled or housed, in accordance with Chapter 4.13.;
- 11) control of pests such as rodents and arthropods and regular assessment of effectiveness;
- 12) control and hygienic procedures for entry and movement of persons and *vehicles*;
- 13) cleaning and *disinfection* of equipment and *vehicles* identified as posing a *risk*;
- 14) storage and disposal of dead animals, bedding, faeces and other potentially contaminated farm waste in a manner that minimises the likelihood of dissemination of *Salmonella* and prevents the direct or indirect exposure of humans, livestock and *wildlife* to *Salmonella*. Particular care should be taken when bedding and faeces of bovines are applied to land used for horticultural crops intended for human consumption;

- 15) procedures for prevention of dissemination of *Salmonella* when an animal is suspected or known to be infected.

Article 6.13.6.

Location and design of establishments for bovines

When making decisions on the location and design of *establishments* for bovines, it is recommended that reduction of the likelihood of transfer of pathogenic agents, including *Salmonella*, from major sources of contamination be considered. Sources of *Salmonella* may include other livestock *establishments* or areas of application or disposal of contaminated waste or effluent. Other sources and *vectors* of *Salmonella* include *vehicles*, equipment, water-courses, personnel, domestic animals, birds, rodents, flies and *wildlife*.

The design of intensive bovine production systems should consider the following:

- 1) management of faecal waste to minimise contamination of the *establishment*;
- 2) adequate drainage for the site and control of run-off water and untreated waste water;
- 3) use of materials for construction that facilitate effective cleaning and *disinfection*;
- 4) control of entry and movement of *vehicles*, equipment and persons;
- 5) preventing contamination of *feed* and water during storage and distribution;
- 6) handling and movements of bovines to minimise stress and spread of *Salmonella*;
- 7) separation of bovines according to likelihood of *infection* with, or susceptibility to, *Salmonella*;
- 8) restriction of entry of domestic animals, birds, rodents, flies and other relevant *wildlife*.

In extensive bovine production systems, location and design options may be limited; however, applicable *biosecurity* should be considered.

Article 6.13.7.

Management of introductions of bovines into the establishment

To minimise the likelihood of introducing *Salmonella* through introductions of bovines:

- 1) good communication within the bovine industry should be encouraged to raise awareness of the likelihood of introducing *Salmonella* through cattle introductions;
- 2) consideration should be given to minimising the number of sources of replacement bovines;
- 3) new genetic material should be introduced through the use of semen and embryos whenever practicable;
- 4) if possible, bovines should be sourced directly from *herds* of origin because live animal markets or other places where bovines from multiple properties are mixed for resale may increase the likelihood of spread of *Salmonella* and other infectious agents among bovines;
- 5) newly introduced bovines should be kept separate from the rest of the *herd* for a suitable period before mixing with other bovines;
- 6) when appropriate, testing of animals for *Salmonella* prior to introduction or mixing with other bovines should be considered to inform subsequent control measures, for example, when introducing bovines of unknown status.

Article 6.13.8.

Management of bovines on farm

To reduce the likelihood of transferring *Salmonella* among bovines:

- 1) bovines with suspected salmonellosis or otherwise sick should be separated from healthy bovines;
- 2) care of healthy bovines should be carried out prior to care of bovines with suspected salmonellosis;
- 3) priority should be given to the hygienic management of calving areas, for example keeping perinatal bovines separated from sick bovines and maintaining a clean environment;
- 4) bovines should be segregated according to age;
- 5) when possible, the 'all-in-all-out' principle for production cohorts should be used. In particular, the unnecessary mixing of different age groups, especially of calves, should be avoided;

- 6) consideration should be given to the potential for between-herd transmission of *Salmonella* via breeding, rearing and grazing of bovines from multiple sources on a single site, for example shared pasture, heifer rearing or sharing of bulls;
- 7) consideration should be given to the potential for between-herd transmission of *Salmonella* through direct contact between bovines across boundary lines or indirectly, for example through contamination of water courses.

Article 6.13.9.

Feed and feed ingredients

Feed and feed ingredients can be sources of *Salmonella* infection for bovines. For the effective control of *Salmonella*:

- 1) when appropriate, *feed and feed ingredients* should be produced, handled, stored, transported and distributed according to Good Manufacturing Practices, considering Hazard Analysis Critical Control Points (HACCP) principles and recommendations in accordance with Chapter 6.4.;
- 2) *feed and feed ingredients* should be transported, stored and fed in a manner that minimises contamination by faecal waste and, where practicable, minimises access by domestic animals, birds, rodents and *wildlife*.

Article 6.13.10.

Water

Water for drinking should be of an appropriate quality. When there is reason to be concerned about *infection* of bovines with *Salmonella* from contaminated water, measures should be taken to evaluate and minimise the *risk*. For example sediment in water troughs may act as a reservoir for contamination. Where practicable, untreated surface water should be avoided as a water source.

Article 6.13.11.

Additional prevention and control measures

- 1) The immune status of calves is important and therefore care should be taken to ensure that newborn calves consume adequate amounts of high quality colostrum in accordance with Article 7.9.5. (point 3 c) and Article 7.11.7. (point 9)). Raw *milk* from infected cows should not be fed to calves.
- 2) *Vaccination* may be considered as part of a *Salmonella* control programme. Vaccine production and use should be in accordance with Chapter 1.1.6. of the *Terrestrial Manual*. The protective effect of vaccines is generally serotype-specific and is influenced by factors such as timing of *vaccination* in relation to exposure.
- 3) A number of conditions, for example liver fluke and *infection* with bovine viral diarrhoea virus, may increase the susceptibility of bovines to *Salmonella*; therefore, control of such conditions is recommended.
- 4) Stress may increase the susceptibility of bovines to *Salmonella*. Management of potentially stressful situations, such as mixing of groups of bovines, may reduce the likelihood of clinical disease or shedding of *Salmonella*.
- 5) *Antimicrobial agents* may modify normal flora in the gut and increase the likelihood of colonisation by *Salmonella*. In circumstances when *antimicrobial agents* are considered necessary for the treatment of clinical salmonellosis, they should be used in accordance with Chapter 6.10. Furthermore, *antimicrobial agents* should not be used to control subclinical *infection* with *Salmonella* in bovines because the effectiveness of the treatment is limited, they may increase the *risk* of *Salmonella* colonisation, and their use can contribute to the development of antimicrobial resistance.

Article 6.13.12.

Transportation

Vehicles should be properly cleaned and disinfected after transportation of animals, in accordance with Chapter 4.13.

When transporting animals from multiple *establishments*, the *Salmonella* status of the *establishments* should be considered to avoid cross-contamination of bovines.

In addition, the relevant recommendations in Chapters 7.2., 7.3. and 7.4. apply.

Article 6.13.13.

Lairage

Relevant aspects of *lairage* management include consideration of effective cleaning and *disinfection* between groups, minimising mixing of animals that have not continuously been kept together and managing stress.

In addition, the relevant recommendations in Articles 7.5.1., 7.5.3. and 7.5.4. apply.

Article 6.13.14.

Cleanliness of hides

Cleanliness of hides can be achieved by applying suitable practices during housing (for example additional clean bedding), transport and *lairage*. Dirty hides increase the *risk* of microbial contamination of carcasses during the *slaughter* process.

Article 6.13.15.

Surveillance for *Salmonella* in commercial bovine production systems

Surveillance data provide information to assist the *Competent Authorities* in their decision making regarding the requirement for, and design of, control programmes and in setting and verifying performance objectives.

Standards for diagnostic tests are described in the *Terrestrial Manual*. In addition, other sampling and testing methodologies such as testing of bulk *milk* or serum samples by ELISA may provide useful information on *herd* or individual animal status. Boot swab samples from communal areas in housing for bovines, slurry samples, or caecal or lymph node samples collected post-mortem can also be useful for microbiological testing. Some serotypes of *Salmonella* such as *S. Dublin* can be difficult to detect using microbiological methods.

If serology is used as the *surveillance* method, it may not be possible to distinguish between vaccinated and infected bovines.

Article 6.13.16.

Prevention and control in low prevalence regions

In regions where *Salmonella infection* of bovines is uncommon, it may be possible to maintain low *prevalence* status or eliminate *infection* from *herds* through a combination of good farming practices, *herd surveillance*, individual testing, movement controls, and removal of persistent carriers.

NB: FIRST ADOPTED IN 2017.

CHAPTER 6.14.

PREVENTION AND CONTROL OF *SALMONELLA* IN COMMERCIAL PIG PRODUCTION SYSTEMS

Article 6.14.1.

Introduction

Nontyphoidal salmonellosis is one of the most common foodborne bacterial diseases in the world with *Salmonella* Enteritidis and *S. Typhimurium* (including monophasic variants) being the predominant serotypes identified in humans in most countries. *S. Enteritidis* is primarily associated with *poultry* while *S. Typhimurium* may be present in many mammalian and avian hosts. These serotypes and several others occur at variable *prevalence* in pigs depending on the region. In some countries *S. Infantis* and *S. Choleraesuis* may cause salmonellosis in humans.

Salmonella infection in pigs is mostly subclinical, although clinical disease such as enteritis and septicaemia in weaned pigs may occur. Subclinical *infection*, including a carrier state, can be of variable duration and can play an important role in the spread of *Salmonella* within and between *herds* and pose a public health *risk*.

Salmonella serotypes and their *prevalence* in pigs may vary considerably within and between farms, countries and regions. It is important for *Veterinary Authorities* and producers to consider serotypes of *Salmonella*, their occurrence and the disease burden in pig and human populations when they develop and implement strategies for the prevention and control of *Salmonella* in commercial pig production systems.

Article 6.14.2.

Definitions

For the purpose of this chapter:

'Commercial pig production systems': means those systems in which the purposes of the operation include some or all of the following: breeding, rearing and management of pigs for the production and sale of pigs or pig *meat*.

Article 6.14.3.

Purpose and scope

This chapter provides recommendations for the prevention and control of *Salmonella* in commercial pig production systems, including outdoor pig production systems, where practicable, in order to reduce the burden of *infection* in pigs and the *risk* of human illness through foodborne contamination as well as human *infections* resulting from direct or indirect contact with infected pigs.

This chapter should be read in conjunction with the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005), Code of Good Animal Feeding (CAC/RCP 54-2004), and the Guidelines for the Control of Nontyphoidal *Salmonella* spp. in Beef and Pork Meat (CAC/GL 87-2016), and the OIE/FAO Guide to Good Farming Practices for Animal Production Food Safety.

Article 6.14.4.

Objectives of prevention and control measures

Prevention and control measures may focus on those serotypes of *Salmonella* of greatest consequence to pigs and public health. These measures will also contribute to the reduction of other serotypes.

Prevention and control measures in commercial pig production systems may:

- 1) reduce the *prevalence* and amount of *Salmonella* entering the *slaughterhouse/abattoir* and therefore decrease the challenge to the *slaughter* and dressing procedures and the likelihood of pig *meat* contamination;
- 2) reduce *Salmonella* contamination of the environment via pig faecal waste, which in turn will limit *infection* of animals (including *wildlife*);
- 3) reduce the likelihood of *infections* in humans through contact with infected pigs or contaminated materials or water.

While control in the primary production phase can decrease the number of animals carrying or shedding *Salmonella*, controls after primary production are also important to minimise the contamination and cross-contamination of carcasses and *meat products*.

Good farming practices and, when appropriate, the principles of hazard analysis and critical control points (HACCP) should be taken into account when designing prevention and control measures.

Articles 6.14.5. to 6.14.15. provide recommendations for the prevention and control of *Salmonella* in commercial pig production systems. These recommendations may also contribute to the prevention and control of some other *infections*.

Article 6.14.5.

Biosecurity

Biosecurity is essential to prevent and control *Salmonella*. A *biosecurity plan* should be developed according to the commercial pig production system employed. The choice of specific measures will vary according to the type of commercial pig production system.

When including *Salmonella* as part of a *biosecurity plan* the following should be addressed:

- 1) location, design and management of the *establishment*;
- 2) veterinary supervision of pig health;
- 3) management of the introduction and mixing of pigs;
- 4) training of personnel in their responsibilities and their role in animal health, human health and food safety;
- 5) prevention of contamination of *feed* and water, including for irrigation;
- 6) maintenance of records including data on pig health, production, movements, feeding, water supply, medications, *vaccination*, mortality, and cleaning and *disinfection* of farm buildings and equipment;
- 7) availability of test results to the farm operator when *Salmonella surveillance* is conducted;
- 8) removal of unwanted vegetation and debris that could attract or harbour pests around pig housing;
- 9) minimising the entry of domestic animals and *wild* birds into pig buildings and *feed* stores;
- 10) cleaning and *disinfection* procedures for buildings in which pigs are handled or housed in accordance with Chapter 4.13.;
- 11) control of pests such as rodents and arthropods, and regular assessment of effectiveness;
- 12) control and hygienic procedures for entry and movement of persons and *vehicles*;
- 13) *biosecurity* applied to all personnel and visitors entering the *establishment*. As a minimum, this should include hand washing and changing into clean clothes and footwear provided by the *establishment*. Similar precautions are recommended when they move between separate *epidemiological units* on large farms;
- 14) cleaning and *disinfection* of equipment and *vehicles* identified as posing a *risk*;
- 15) storage and disposal of dead animals, bedding, faeces and other potentially contaminated farm waste in a manner that minimises the likelihood of dissemination of *Salmonella* and prevents the direct or indirect exposure of humans, livestock and *wildlife* to *Salmonella*. Particular care should be taken when pig bedding and faeces are applied to land used for horticultural crops intended for human consumption;
- 16) procedures for prevention of dissemination of *Salmonella* when an animal is suspected or known to be infected.

Article 6.14.6.

Location and design of pig establishments

When making decisions on the location and design of pig *establishments*, reduction of the likelihood of transfer of pathogenic agents, including *Salmonella*, from major sources of contamination should be considered. Sources of

Salmonella may include other livestock *establishments* or areas of application or disposal of contaminated waste or effluent. Other sources and *vectors* of *Salmonella* include *vehicles*, equipment, water-courses, personnel, domestic animals, birds, rodents, flies and *wildlife*.

The design of commercial pig production systems should consider the following:

- 1) proximity of other livestock *establishments*, and *wild* bird and rodent populations;
- 2) management of faecal waste to minimise contamination of the *establishment*;
- 3) adequate drainage for the site and control of run-off water and untreated waste water;
- 4) use of smooth impervious materials for construction of pig houses to enable effective cleaning and *disinfection*;
- 5) paving the area immediately surrounding pig houses or indoor *establishments* with concrete or other impervious material. This will facilitate rodent control and minimise recontamination after cleaning and *disinfection*;
- 6) a control of entry and movement of *vehicles*, equipment and persons, for example, locate delivery and collection points away from pig housing or *feed* storage;
- 7) preventing contamination of *feed* and water during storage and distribution;
- 8) pig handling and movements to minimise stress and spread of *Salmonella*;
- 9) restriction of entry of domestic animals, *wild* birds, rodents, flies and other relevant *wildlife*.

Article 6.14.7.

Management of pig introductions into the establishment

Introduction of pigs into a *herd* is a *risk* factor, especially in moderate and high *prevalence* regions. To minimise the likelihood of introducing *Salmonella* by replacement pigs:

- 1) good communication along the pig production chain should be encouraged to raise awareness of the *risk* of introducing *Salmonella* through pig introductions;
- 2) consideration should be given to minimising the number of sources for both replacement breeding stock and rearing pigs, and matching *Salmonella* *herd* status in terms of *Salmonella* freedom or occurrence of priority serotypes such as *S. Typhimurium*;
- 3) new genetic material should be introduced through the use of semen whenever practicable;
- 4) if possible, pigs should be sourced directly from *herds* of origin because live animal markets or other places where pigs from multiple properties are mixed for resale may increase the likelihood of spread of *Salmonella* and other infectious agents among pigs;
- 5) newly introduced pigs should be kept separate from the rest of the *herd* for a suitable period before mixing with other pigs;
- 6) when appropriate, testing of pigs for *Salmonella* prior to introduction or mixing with other pigs should be considered to inform subsequent control measures, for example, when introducing pigs of unknown status.

Article 6.14.8.

Moving and mixing of pigs

The moving and mixing of pigs increases the likelihood of spread of *Salmonella*. To minimise the spread of *Salmonella*:

- 1) the number of pig movements and mixing of pigs should be minimised;
- 2) if possible, the 'all-in-all-out' system with a single age group of pigs should be used. In particular, the addition to younger groups of pigs held back from older groups should be avoided;
- 3) sick pigs should be segregated from healthy ones.

Article 6.14.9.

Feed and feed composition

1. Feed and feed ingredients

Feed and feed ingredients can be sources of *Salmonella* for pigs. This is especially important in *herds*, countries or regions of low *prevalence*. To minimise the spread of *Salmonella* through *feed*:

- a) *feed* and *feed ingredients* should be produced, handled, stored, transported and distributed in accordance with Chapter 6.4.;
- b) *feed* and *feed ingredients* should be transported, stored and fed in a manner that minimises contamination by faecal waste and, where practicable, minimises access by domestic animals, birds, rodents and *wildlife*;
- c) when practicable, *feed* should be treated with heat, or with approved bactericidal or bacteriostatic treatments such as organic acids.

2. Feed composition

When *Salmonella* is present in a pig *herd*, the composition of *feed* may influence the occurrence of *Salmonella* in individual pigs.

For the control of *Salmonella* the following be considered:

- a) liquid *feed* that is fermented or containing *milk products* has a protective effect due to the presence of beneficial bacteria and lowered pH;
- b) coarsely ground *feed* may reduce the occurrence of *Salmonella* by slowing gastric transit (thereby increasing exposure to gastric acid) and reducing dysbacteriosis. Coarsely ground *feed ingredients* may be fed alongside pelleted *feed*;
- c) fine grinding needed to produce heat treated pellets may result in dysbacteriosis which favours the colonisation and multiplication of *Salmonella* in the intestine. Therefore, heat treated pellets are more appropriate for situations in which *Salmonella* is uncommon;
- d) when wheat is the predominant *feed ingredient*, reducing the proportion of this ingredient may reduce the occurrence of *Salmonella* because the rapid fermentation of wheat promotes dysbacteriosis.

Article 6.14.10.

Water

Water for drinking should be of an appropriate quality. To minimise the spread of *Salmonella* through water:

- 1) the water supply should be monitored and controlled to maintain it free from *Salmonella* contamination;
- 2) water holding tanks should be enclosed;
- 3) water supply and delivery systems should not be accessible to birds, rodents or *wildlife*;
- 4) the water delivery system should be regularly cleaned and disinfected. For example in an 'all-in-all-out' system this occurs before restocking.

Article 6.14.11.

Additional prevention and control measures

- 1) *Vaccination* may be considered as part of a *Salmonella* control programme. Vaccine production and use should be in accordance with Chapter 1.1.6. of the *Terrestrial Manual*. The protective effect of vaccines is generally serotype-specific and is influenced by factors such as timing of *vaccination* in relation to exposure.
- 2) *Antimicrobial agents* may modify normal flora in the gut and increase the likelihood of colonisation by *Salmonella*. In circumstances when *antimicrobial agents* are considered necessary for the treatment of clinical salmonellosis, they should be used in accordance with Chapter 6.10. Furthermore, *antimicrobial agents* should not be used to control subclinical *infection* with *Salmonella* in pigs because the effectiveness of the treatment is limited, they may increase the *risk* of *Salmonella* colonisation, and their use can contribute to the development of antimicrobial resistance.
- 3) Where approved by the *Competent Authority*, organic acids, probiotics and prebiotics may be added to *feed* or water to reduce shedding of *Salmonella* by pigs. However, efficacy is variable.

Article 6.14.12.

Transportation

Vehicles should be properly cleaned and disinfected after transportation of animals, in accordance with Chapter 4.13.

When transporting animals from multiple *establishments*, the *Salmonella* status of the *establishments* should be considered to avoid cross-contamination of pigs.

In addition, the relevant recommendations in Chapters 7.2., 7.3. and 7.4. apply.

Article 6.14.13.

Lairage

Lairage may be used at various stages in pig production, for example accumulation of weaned pigs before movement to nursery *herds*, holding finisher pigs before transport to *slaughter* and holding pigs at the *slaughterhouse/abattoir* before *slaughter*. Relevant aspects of *lairage* management include consideration of effective cleaning and *disinfection* between groups, minimising mixing of animals that have not continually been kept together and managing stress.

In addition, the relevant recommendations in Articles 7.5.1., 7.5.3. and 7.5.4. apply.

Article 6.14.14.

Surveillance for *Salmonella* in commercial pig production systems

Surveillance data provide information to assist the *Competent Authorities* in their decision making regarding the requirement for, and design of, control programmes and in setting and verifying performance objectives. Harmonised *surveillance* systems to determine the occurrence of *Salmonella* at *herd* level are in place in some countries. Communication between *slaughterhouses/abattoirs*, *Veterinary Services* and the *herd* manager or *veterinarian* of the results of *Salmonella surveillance* systems is an important element of a *Salmonella* control programme.

Standards for diagnostic tests are described in the *Terrestrial Manual*. Serological testing, usually using 'meat juice' at *slaughter*, is one method for assessing exposure to *Salmonella* in pig *herds*. Benefits of serological testing include low cost per test, high throughput capability and the potential for automation of tests. Collection of samples at the *slaughterhouse/abattoir* enables centralised sampling of multiple *herds*. While serology is a useful tool for *risk* ranking of *herds*, serological testing does not detect exposure to all serotypes or differentiate between different serotypes within the serogroups included in the antigenic range of the test or the level of *Salmonella* in pigs at *slaughter*. If serology is used as the *surveillance* method, it may not be possible to distinguish between vaccinated and infected pigs.

Serological testing gives no indication of excretion of *Salmonella* in the *herd* and does not reflect how infectious is the tested group.

Microbiological testing, with additional phenotyping or genotyping, identifies serotypes of *Salmonella* present in pig *herds* and can provide epidemiological information on likely sources of *Salmonella* and on the presence of strains with enhanced virulence or resistance to *antimicrobial agents*. Bacteriological sampling of individual pigs has low sensitivity but this can be overcome by sampling at *herd* level or repeated sampling of individual animals. Pooling of samples (such as individual faecal samples or mesenteric lymph nodes) or sampling naturally pooled material (such as sampling of faeces from the floor of pig pens) will decrease the costs. Some serotypes of *Salmonella* such as *S. Choleraesuis* can be difficult to detect using microbiological methods.

Article 6.14.15.

Prevention and control in low prevalence regions

In regions where *Salmonella infection* of pigs is uncommon, it may be possible to maintain low *prevalence* status or eliminate *infection* from *herds* through a combination of good farming practices, *herd surveillance*, individual testing, movement controls, and removal of persistent carriers.

In individual *herds*, for example valuable breeding *herds*, in higher *prevalence* regions, the success of this approach is dependent upon a low likelihood of reintroduction of *infection*.

Article 6.14.16.

Outdoor pig production

For outdoor pigs in commercial production systems, in addition to the prevention and control measures described in Articles 6.14.5. to 6.14.15., it is recommended that:

- 1) field rotation programmes be used to minimise *Salmonella* contamination and accumulation in soil and surface water and therefore ingestion by pigs;
- 2) systems used to provide *feed*, and where possible water, be designed to minimise attraction of, or access by, *wildlife*;
- 3) the location of other outdoor pig *herds* and the concentration and behaviour of *wildlife* in the area be considered.

NB: FIRST ADOPTED IN 2017; MOST RECENT UPDATE ADOPTED IN 2018.

SECTION 7.

ANIMAL WELFARE

CHAPTER 7.1.

INTRODUCTION TO THE RECOMMENDATIONS FOR ANIMAL WELFARE

Article 7.1.1.

General considerations

Animal welfare means the physical and mental state of an *animal* in relation to the conditions in which it lives and dies.

An *animal* experiences good welfare if the *animal* is healthy, comfortable, well nourished, safe, is not suffering from unpleasant states such as pain, fear and distress, and is able to express behaviours that are important for its physical and mental state.

Good *animal welfare* requires disease prevention and appropriate veterinary care, shelter, management and nutrition, a stimulating and safe environment, humane handling and humane *slaughter* or *killing*. While *animal welfare* refers to the state of the *animal*, the treatment that an *animal* receives is covered by other terms such as animal care, animal husbandry, and humane treatment.

Article 7.1.2.

Guiding principles for animal welfare

- 1) That there is a critical relationship between animal health and *animal welfare*.
- 2) That the internationally recognised 'five freedoms' (freedom from hunger, thirst and malnutrition; freedom from fear and distress; freedom from physical and thermal discomfort; freedom from pain, injury and disease; and freedom to express normal patterns of behaviour) provide valuable guidance in *animal welfare*.
- 3) That the internationally recognised 'three Rs' (reduction in numbers of *animals*, refinement of experimental methods and replacement of *animals* with non-animal techniques) provide valuable guidance for the use of *animals* in science.
- 4) That the scientific assessment of *animal welfare* involves diverse elements which need to be considered together, and that selecting and weighing these elements often involves value-based assumptions which should be made as explicit as possible.
- 5) That the use of *animals* in agriculture, education and research, and for companionship, recreation and entertainment, makes a major contribution to the wellbeing of people.
- 6) That the use of *animals* carries with it an ethical responsibility to ensure the welfare of such *animals* to the greatest extent practicable.
- 7) That improvements in farm *animal welfare* can often improve productivity and food safety, and hence lead to economic benefits.
- 8) That equivalent outcomes based on performance criteria, rather than identical systems based on design criteria, be the basis for comparison of *animal welfare* standards and recommendations.

Article 7.1.3.

Scientific basis for recommendations

- 1) Welfare is a broad term which includes the many elements that contribute to an animal's quality of life, including those referred to in the 'five freedoms' listed above.
- 2) The scientific assessment of *animal welfare* has progressed rapidly in recent years and forms the basis of these recommendations.
- 3) Some measures of *animal welfare* involve assessing the degree of impaired functioning associated with injury, disease and malnutrition. Other measures provide information on *animals'* needs and affective states such as hunger, pain and fear, often by measuring the strength of *animals'* preferences, motivations and aversions. Others assess the physiological, behavioural and immunological changes or effects that *animals* show in response to various challenges.
- 4) Such measures can lead to criteria and indicators that help to evaluate how different methods of managing *animals* influence their welfare.

Article 7.1.4.

Guiding principles for the use of measures to assess animal welfare

- 1) For the OIE *animal welfare* standards to be applicable globally, they should emphasise favourable outcomes for the *animals*, although, in some circumstances, it may be necessary to recommend specific conditions of the *animals'* environment and management. Outcomes are generally measured by assessing the extent to which *animals* experience the "five freedoms" described in Article 7.1.2.
- 2) For each principle listed in Article 7.1.4., the most relevant criteria (or measurables), ideally comprising animal-based measures, should be included in the standard. Any given animal-based measure may be linked to more than one principle.
- 3) Recommendations should, whenever possible, define explicit targets or thresholds that should be met for animal-based measures. Such target values should be based on relevant science and experience of experts.
- 4) In addition to animal-based measures, resource-based measures and management-based measures may be used and should be defined on the basis of science and expert experience showing that a welfare outcome is clearly linked to a resource or to a management procedure.
- 5) Users of the standard should select the most appropriate animal-based measures for their farming system or environment, from among those listed in the standard. Outcomes can be measured by an assessment of individuals or animal groups, or a representative sample of those, using data from *establishments*, transport or *slaughterhouses/abattoirs*.
- 6) Whatever the basis of the measure, if outcomes are unsatisfactory, users should consider what changes to resources or management are necessary to improve outcomes.

Article 7.1.5.

General principles for the welfare of animals in livestock production systems

- 1) Genetic selection should always take into account the health and welfare of *animals*.
- 2) *Animals* chosen for introduction into new environments should be suited to the local climate and able to adapt to local diseases, parasites and nutrition.
- 3) The physical environment, including the substrate (walking surface, resting surface, etc.), should be suited to the species so as to minimise risk of injury and transmission of diseases or parasites to *animals*.
- 4) The physical environment should allow comfortable resting, safe and comfortable movement including normal postural changes, and the opportunity to perform types of natural behaviour that *animals* are motivated to perform..
- 5) Social grouping of *animals* should be managed to allow positive social behaviour and minimise injury, distress and chronic fear.
- 6) For housed *animals*, air quality, temperature and humidity should support good animal health and not be aversive. Where extreme conditions occur, *animals* should not be prevented from using their natural methods of thermo-regulation.
- 7) *Animals* should have access to sufficient *feed* and water, suited to the *animals'* age and needs, to maintain normal health and productivity and to prevent prolonged hunger, thirst, malnutrition or dehydration.

- 8) Diseases and parasites should be prevented and controlled as much as possible through good management practices. *Animals* with serious health problems should be isolated and treated promptly or killed humanely if treatment is not feasible or recovery is unlikely.
- 9) Where painful procedures cannot be avoided, the resulting pain should be managed to the extent that available methods allow.
- 10) The handling of *animals* should foster a positive relationship between humans and *animals* and should not cause injury, panic, lasting fear or avoidable stress.
- 11) Owners and handlers should have sufficient skill and knowledge to ensure that *animals* are treated in accordance with these principles.

NB: FIRST ADOPTED IN 2004; MOST RECENT UPDATE ADOPTED IN 2018.

CHAPTER 7.2.

TRANSPORT OF ANIMALS BY SEA

Preamble : These recommendations apply to the following live domesticated animals: cattle, buffaloes, deer, camelids, sheep, goats, pigs and equines. They may also be applicable to other domesticated animals.

Article 7.2.1.

The amount of time animals spend on a *journey* should be kept to the minimum.

Article 7.2.2.

1. Animal behaviour

Animal handlers should be experienced and competent in handling and moving farm livestock and understand the behaviour patterns of animals and the underlying principles necessary to carry out their tasks.

The behaviour of individual animals or groups of animals will vary depending on their breed, sex, temperament and age and the way in which they have been reared and handled. Despite these differences, the following behaviour patterns, which are always present to some degree in domestic animals, should be taken into consideration in handling and moving the animals.

Most domestic livestock are kept in *herds* and follow a leader by instinct.

Animals which are likely to be hostile to others in a group situation should not be mixed.

The desire of some animals to control their personal space should be taken into account in designing *loading* and *unloading* facilities, transport *vessels* and *containers*.

Domestic animals will try to escape if any person approaches closer than a certain distance. This critical distance, which defines the flight zone, varies among species and individuals of the same species, and depends upon previous contact with humans. Animals reared in close proximity to humans (i.e. tame) have a smaller flight zone, whereas those kept in free range or extensive systems may have flight zones which may vary from one metre to many metres. *Animal handlers* should avoid sudden penetration of the flight zone which may cause a panic reaction which could lead to aggression or attempted escape and compromise the welfare of the animals.

Animal handlers should use the point of balance at the animal's shoulder to move animals, adopting a position behind the point of balance to move an animal forward and in front of the point of balance to move it backward.

Domestic animals have a wide-angle vision but only have a limited forward binocular vision and poor perception of depth. This means that they can detect objects and movements beside and behind them, but can only judge distances directly ahead.

Domestic animals can hear over a greater range of frequencies than humans and are more sensitive to higher frequencies. They tend to be alarmed by constant loud noises and by sudden noises, which may cause them to panic. Sensitivity to such noises should also be taken into account when handling animals.

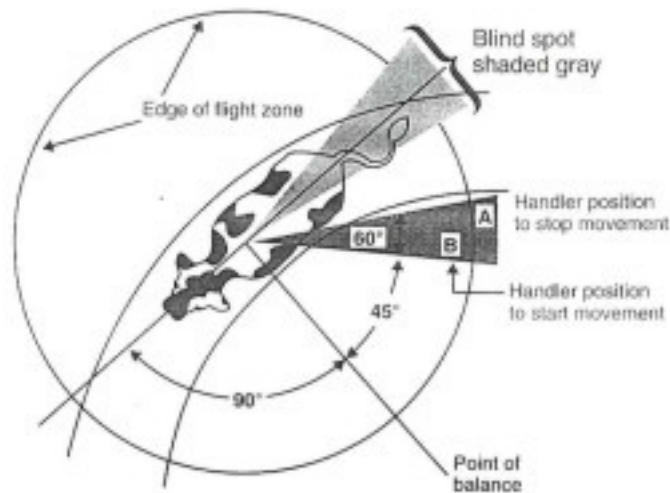
2. Distractions and their removal

Design of new *loading* and *unloading* facilities or modification of existing facilities should aim to minimise the potential for distractions that may cause approaching animals to stop, baulk or turn back. Below are examples of common distractions and methods for eliminating them:

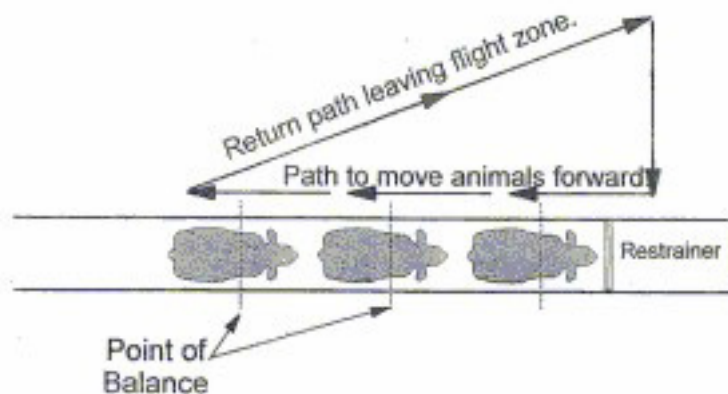
- a) reflections on shiny metal or wet floors – move a lamp or change lighting;
- b) dark entrances – illuminate with indirect lighting which does not shine directly into the eyes of approaching animals;
- c) animals seeing moving people or equipment up ahead – install solid sides on chutes and races or install shields;
- d) dead ends – avoid if possible by curving the passage, or make an illusory passage;
- e) chains or other loose objects hanging in chutes or on fences – remove them;
- f) uneven floors or a sudden drop in floor levels – avoid uneven floor surfaces or install a solid false floor to provide an illusion of a solid and continuous walking surface;

- g) sounds of air hissing from pneumatic equipment – install silencers or use hydraulic equipment or vent high pressure to the external environment using flexible hosing;
- h) clanging and banging of metal objects – install rubber stops on gates and other devices to reduce metal to metal contact;
- i) air currents from fans or air curtains blowing into the face of animals – redirect or reposition equipment.

An example of a flight zone (cattle)



Handler movement pattern to move cattle forward



Article 7.2.3.

Responsibilities

Once the decision to transport the animals by sea has been made, the welfare of the animals during their *journey* is the paramount consideration and is the joint responsibility of all people involved. The individual responsibilities of persons involved will be described in more detail in this article. These recommendations may also be applied to the transport of animals by water within a country.

The management of animals at post-discharge facilities is outside the scope of this chapter.

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 in accordance with 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 *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 3 e) 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 period1. 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.

Travel1. General considerations

- a) *Animal handler(s)* should check the consignment immediately before departure to ensure that the animals have been loaded in accordance with 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 in accordance with 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. 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.

NB: FIRST ADOPTED IN 1998; MOST RECENT UPDATE ADOPTED IN 2008.

CHAPTER 7.3.

TRANSPORT OF ANIMALS BY LAND

Preamble: These recommendations apply to the following live domesticated animals: cattle, buffaloes, camels, sheep, goats, pigs, *poultry* and equines. They will also be largely applicable to some other animals, e.g. deer, other camelids and ratites. *Wild animals* and *feral animals* may need different conditions.

Article 7.3.1.

The amount of time animals spend on a *journey* should be kept to the minimum.

Article 7.3.2.

1. Animal behaviour

Animal handlers should be experienced and competent in handling and moving farm livestock and understand the behaviour patterns of animals and the underlying principles necessary to carry out their tasks.

The behaviour of individual animals or groups of animals will vary depending on their breed, sex, temperament and age and the way in which they have been reared and handled. Despite these differences, the following behaviour patterns, which are always present to some degree in domestic animals, should be taken into consideration in handling and moving the animals.

Most domestic livestock are kept in groups and follow a leader by instinct.

Animals which are likely to harm each other in a group situation should not be mixed.

The desire of some animals to control their personal space should be taken into account in designing *loading* and *unloading* facilities, transport *vessels* and *containers*.

Domestic animals will try to escape if any person approaches closer than a certain distance. This critical distance, which defines the flight zone, varies among species and individuals of the same species, and depends upon previous contact with humans. Animals reared in close proximity to humans (i.e. tame) have a smaller flight zone, whereas those kept in free range or extensive systems may have flight zones which may vary from one metre to many metres. *Animal handlers* should avoid sudden penetration of the flight zone which may cause a panic reaction which could lead to aggression or attempted escape and compromise the welfare of the animals.

Animal handlers should use the point of balance at the animal's shoulder to move animals, adopting a position behind the point of balance to move an animal forward and in front of the point of balance to move it backward.

Domestic animals have a wide-angle vision but only have a limited forward binocular vision and poor perception of depth. This means that they can detect objects and movements beside and behind them, but can only judge distances directly ahead.

Although domestic animals have a highly sensitive sense of smell, they may react differently to the smells encountered during travel. Smells which cause negative responses should be taken into consideration when managing animals.

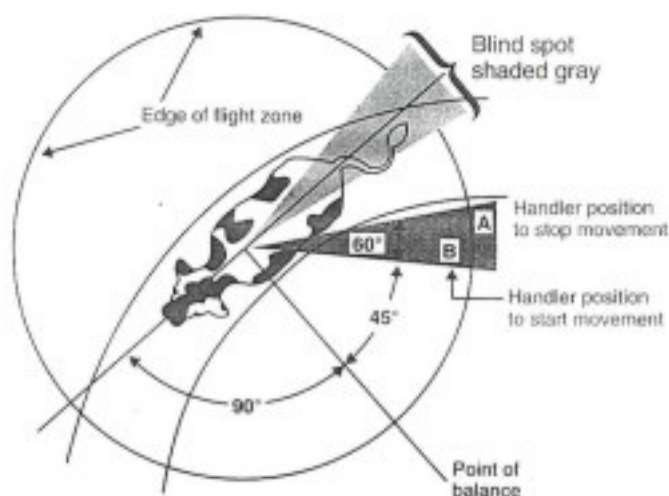
Domestic animals can hear over a greater range of frequencies than humans and are more sensitive to higher frequencies. They tend to be alarmed by constant loud noises and by sudden noises, which may cause them to panic. Sensitivity to such noises should also be taken into account when handling animals.

2. Distractions and their removal

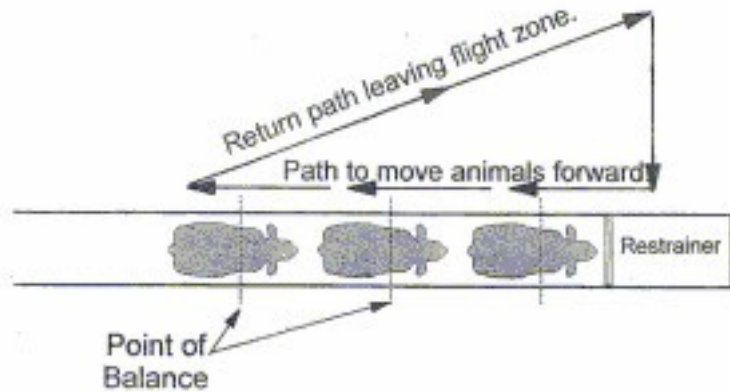
Design of new *loading* and *unloading* facilities or modification of existing facilities should aim to minimise the potential for distractions that may cause approaching animals to stop, baulk or turn back. Below are examples of common distractions and methods for eliminating them:

- a) reflections on shiny metal or wet floors – move a lamp or change lighting;
- b) dark entrances – illuminate with indirect lighting which does not shine directly into the eyes of approaching animals;
- c) animals seeing moving people or equipment up ahead – install solid sides on chutes and races or install shields;
- d) dead ends – avoid if possible by curving the passage, or make an illusory passage;
- e) chains or other loose objects hanging in chutes or on fences – remove them;
- f) uneven floors or a sudden drop in floor levels – avoid uneven floor surfaces or install a solid false floor to provide an illusion of a solid and continuous walking surface;
- g) sounds of air hissing from pneumatic equipment – install silencers or use hydraulic equipment or vent high pressure to the external environment using flexible hosing;
- h) clanging and banging of metal objects – install rubber stops on gates and other devices to reduce metal to metal contact;
- i) air currents from fans or air curtains blowing into the face of animals – redirect or reposition equipment.

An example of a flight zone (cattle)



Handler movement pattern to move cattle forward



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 3 a) of Article 7.3.7.;
 - g) welfare of the animals during the actual transport.
- 5) Managers of facilities at the start and at the end of the *journey* and at *resting points* are responsible for:
- a) providing suitable premises for *loading*, *unloading* and securely holding the animals, with water and *feed* when required, and with protection from adverse weather conditions until further transport, sale or other use (including rearing or slaughter);
 - b) providing an adequate number of *animal handlers* to load, unload, drive and hold animals in a manner that causes minimum stress and injury; in the absence of a separate *animal handler*, the driver is the *animal handler*;
 - c) minimising the opportunities for disease transmission;
 - d) providing appropriate facilities, with water and *feed* when required;
 - e) providing appropriate facilities for emergencies;
 - f) providing facilities for washing and disinfecting *vehicles* after *unloading*;
 - g) providing facilities and competent staff to allow the humane *killing* of animals when required;
 - h) ensuring proper rest times and minimal delay during stops.
- 6) The responsibilities of *Competent Authorities* include:
- a) establishing minimum standards for *animal welfare*, including requirements for inspection of animals before, during and after their travel, defining 'fitness to travel' and appropriate certification and record keeping;
 - 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 in accordance with 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 journey1. 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 in accordance with 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 in accordance with the rate at which problems arise in the species and under the conditions of transport.
9. Control of disease
- As animal transport is often a significant factor in the spread of infectious diseases, *journey* planning should take the following into account:
- a) mixing of animals from different sources in a single consignment should be minimised;
 - b) contact at *resting points* between animals from different sources should be avoided;
 - c) when possible, animals should be vaccinated against diseases to which they are likely to be exposed at their destination;
 - d) medications used prophylactically or therapeutically should be approved by the *Veterinary Authority* of the *exporting country* and the *importing country* and should only be administered by a *veterinarian* or other person who has been instructed in their use by a *veterinarian*.
10. Emergency response procedures
- There should be an emergency management plan that identifies the important adverse events that may be encountered during the *journey*, the procedures for managing each event and the action to be taken in an emergency. For each important event, the plan should document the actions to be undertaken and the responsibilities of all parties involved, including communications and record keeping.
11. Other considerations
- a) Extreme weather conditions are hazardous for animals undergoing transport and require appropriate *vehicle* design to minimise risks. Special precautions should be taken for animals that have not been acclimatised or which are unsuited to either hot or cold conditions. In some extreme conditions of heat or cold, animals should not be transported at all.
 - b) In some circumstances, transportation during the night may reduce thermal stress or the adverse effects of other external stimuli.

Article 7.3.6.

Documentation

- 1) Animals should not be loaded until the documentation required to that point is complete.
- 2) The documentation accompanying the consignment should include:
 - a) *journey* travel plan and emergency management plan;
 - b) date, time and place of *loading* and *unloading*;
 - c) veterinary certification, when required;

- d) *animal welfare* competencies of the driver (under study);
 - e) *animal identification* to allow *animal traceability* to the premises of departure and, where possible, to the premises of origin;
 - f) details of any animals considered at particular risk of suffering poor welfare during transport (point 3 e) of Article 7.3.7.);
 - g) documentation of the period of rest, and access to *feed* and water, prior to the *journey*;
 - h) *stocking density* estimate for each load in the consignment;
 - i) the *journey* log - daily record of inspection and important events, including records of morbidity and mortality and actions taken, climatic conditions, rest stops, travel time and distance, *feed* and water offered and estimates of consumption, medication provided, and mechanical defects.
- 3) When veterinary certification is required to accompany consignments of animals, it should address:
- a) fitness of animals to travel;
 - b) *animal identification* (description, number, etc.);
 - c) health status including any tests, treatments and *vaccinations* carried out;
 - d) when required, details of *disinfection* carried out.

At the time of certification, the *veterinarian* should notify the *animal handler* or the driver of any factors affecting the fitness of animals to travel for a particular *journey*.

Article 7.3.7.

Pre-journey period

1. General considerations

- a) *Pre-journey* rest is necessary if the welfare of animals has become poor during the collection period because of the physical environment or the social behaviour of the animals. The need for rest should be judged by a *veterinarian* or other competent person.
- b) *Pre-journey* assembly/holding areas should be designed to:
 - i) securely hold the animals;
 - ii) maintain a safe environment from hazards, including predators and disease;
 - iii) protect animals from exposure to severe weather conditions;
 - iv) allow for maintenance of social groups;
 - v) allow for rest, and appropriate water and *feed*.
- c) Consideration should be given to the previous transport experience, training and conditioning of the animals, if known, as these may reduce fear and stress in animals.
- d) *Feed* and water should be provided *pre-journey* if the *journey* duration is greater than the normal inter-feeding and drinking interval for the animal. Recommendations for specific species are described in detail in Article 7.3.12.
- e) When animals are to be provided with a novel diet or method of *feed* or water provision during the *journey*, an adequate period of adaptation should be allowed.
- f) Before each *journey*, *vehicles* and *containers* should be thoroughly cleaned and, if necessary, treated for animal health and public health purposes, using methods approved by the *Competent Authority*. When cleaning is necessary during a *journey*, this should be carried out with the minimum of stress and risks to the animals.
- g) Where an *animal handler* believes that there is a significant risk of disease among the animals to be loaded or significant doubt as to their fitness to travel, the animals should be examined by a *veterinarian*.

2. Selection of compatible groups

Compatible groups should be selected before transport to avoid adverse *animal welfare* consequences. The following recommendations should be applied when assembling groups of animals:

- a) Animals reared together should be maintained as a group; animals with a strong social bond, such as a dam and offspring, should be transported together.
- b) Animals of the same species can be mixed unless there is a significant likelihood of aggression; aggressive individuals should be segregated (recommendations for specific species are described in detail in Article 7.3.12.). For some species, animals from different groups should not be mixed because poor *welfare* occurs unless they have established a social structure.

- c) Young or small animals should be separated from older or larger animals, with the exception of nursing mothers with young at foot.
- d) Animals with horns or antlers should not be mixed with animals lacking horns or antlers unless judged to be compatible.
- e) Animals of different species should not be mixed unless they are judged to be compatible.

3. Fitness to travel

- a) Each animal should be inspected by a *veterinarian* or an *animal handler* to assess fitness to travel. If its fitness to travel is in doubt, the animal should be examined by a *veterinarian*. Animals found unfit to travel should not be loaded onto a *vehicle*, except for transport to receive veterinary attention.
- b) Humane and effective arrangements should be made by the owner and the agent for the handling and care of any animal rejected as unfit to travel.
- c) Animals that are unfit to travel include, but may not be limited to:
 - i) those that are sick, injured, weak, disabled or fatigued;
 - ii) those that are unable to stand unaided and bear weight on each leg;
 - iii) those that are blind in both eyes;
 - iv) those that cannot be moved without causing them additional suffering;
 - v) newborn with an unhealed navel;
 - vi) pregnant animals which would be in the final 10% of their gestation period at the planned time of *unloading*;
 - vii) females travelling without young which have given birth within the previous 48 hours;
 - viii) those whose body condition would result in poor welfare because of the expected climatic conditions.
- d) Risks during transport can be reduced by selecting animals best suited to the conditions of travel and those that are acclimatised to expected weather conditions.
- e) Animals at particular risk of suffering poor welfare during transport and which require special conditions (such as in the design of facilities and *vehicles*, and the length of the *journey*) and additional attention during transport, may include:
 - i) large or obese individuals;
 - ii) very young or old animals;
 - iii) excitable or aggressive animals;
 - iv) animals which have had little contact with humans;
 - v) animals subject to motion sickness;
 - vi) females in late pregnancy or heavy lactation, dam and offspring;
 - vii) animals with a history of exposure to stressors or pathogenic agents prior to transport;
 - viii) animals with unhealed wounds from recent surgical procedures such as dehorning.

4. Specific-species requirements

Transport procedures should be able to take account of variations in the behaviour of the species. Flight zones, social interactions and other behaviour vary significantly among species and even within species. Facilities and handling procedures that are successful with one species are often ineffective or dangerous with another.

Recommendations for specific species are described in detail in Article 7.3.12.

Article 7.3.8.

Loading

1. Competent supervision

- a) *Loading* should be carefully planned as it has the potential to be the cause of poor welfare in transported animals.
- b) *Loading* should be supervised and/or conducted by *animal handlers*. The animals are to be loaded quietly and without unnecessary noise, harassment or force. Untrained assistants or spectators should not impede the process.
- c) When *containers* are loaded onto a *vehicle*, this should be carried out in such a way to avoid poor *animal welfare*.

2. Facilities

- a) The facilities for *loading* including the collecting area, races and loading ramps should be designed and constructed to take into account the needs and abilities of the animals with regard to dimensions, slopes, surfaces, absence of sharp projections, flooring, etc.
- b) *Loading* facilities should be properly illuminated to allow the animals to be observed by *animal handler(s)*, and to allow the ease of movement of the animals at all times. Facilities should provide uniform light levels directly over approaches to sorting pens, chutes, loading ramps, with brighter light levels inside *vehicles/containers*, in order to minimise baulking. Dim light levels may be advantageous for the catching of *poultry* and some other animals. Artificial lighting may be required. Loading ramps and other facilities should have a non-slippery flooring.
- c) Ventilation during *loading* and the *journey* should provide for fresh air, the removal of excessive heat, humidity and noxious fumes (such as ammonia and carbon monoxide), and the prevention of accumulations of ammonia and carbon dioxide. Under warm and hot conditions, ventilation should allow for the adequate convective cooling of each animal. In some instances, adequate ventilation can be achieved by increasing the *space allowance* for animals.

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 in accordance with 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 in accordance with 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.

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/abattoir*, see Chapter 7.5.

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.). 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 pathogenic agents and increased susceptibility to infection related to stress and impaired defences against disease, including immunosuppression;
- c) exposure of animals to pathogenic agents 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/abattoirs*, 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.

NB: FIRST ADOPTED IN 1998; MOST RECENT UPDATE ADOPTED IN 2011.

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 health or welfare of animals;
- 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;
- 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 health or welfare of animals;
- 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% of the wall area; this may be reduced if the *container* has an open top;
- in the case of two-tiered *containers*, ventilation in the sides should be for cattle equivalent to not less than 20% of the floor area of each deck, and for pigs and sheep up to 40% of the floor area of each deck;
- have ventilation openings on all four sides of the crate except that two walls may have reduced ventilation space and the other walls have increased space where required by the positioning of the crates during transportation and/or the ventilation pattern of the aircraft;
- ensure that any internal supports or dividers do not block the cross ventilation;
- not have a solid wall above the height of the animal's head in normal resting position;
- in those species where the mouth is normally held near the floor, have at least 25 cm (10 in.) of ventilation space at the level of the animal's head; this opening should be divided in two with a maximum height for any opening of 13 cm; in all *containers*, there should be a sufficiently large ventilation opening at a height of 25 cm to 30 cm (10 to 11 in.) above floor level on all four sides to allow for circulation;
- have some physical means of ensuring the ventilation space is not blocked, such as the use of cleats (wedges) or allowing space between the outside of the *container* and the pallet.

2. Species requirements

In general, fractious animals or animals in late pregnancy should not be transported by air (see Article 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% 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
Deer (red deer and reindeer)	185
Ewes	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 IATA should continue to be accepted. However, the graphs giving the space requirements should be extended to take into account animals larger and smaller than those dealt with currently.

1. General considerations

When calculating stocking rates, the following should be taken into account:

- a) it is essential that accurate weights of animals are obtained in view of the limitations imposed by the load capabilities of the aircraft and the space required per animal;
- b) in narrow bodied aircraft, there is a loss of floor area in the upper tier of two-tier penning due to the contours of the aircraft;
- c) space available should be calculated on the inside measurements of the crates or penning system used, not on the floor space of the aircraft;
- d) multi-tiered crates, high outdoor temperatures at departure, arrival or stopover points, or extreme length of the trip will require an increase in the amount of space per animal; a 10% decrease in *stocking density* is

recommended for trips in excess of 24 hours;

- e) special attention should be paid to the transport of sheep in heavy wool which require an increase in space allotted per animal and to pigs which have limited ability to dissipate heat;
- f) animals confined in groups, especially in pens, should be stocked at a high enough density to prevent injuries at take-off, during turbulence and at landing, but not to the extent that individual animals cannot lie down and rise without risk of injury or crushing;
- g) in multi-tiered shipments, it should be recognized that the ventilation and cooling capacity of the aircraft is the limiting factor, especially in narrow bodied aircraft. Ventilation capacity varies on each individual aircraft and between aircraft of the same model.

2. 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/m ²	m ²	10 m ²	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% sodium carbonate and 0.1% sodium silicate;
 - v) 0.2% citric acid.
- c) All removeable equipment, penning and *containers* including loading ramps should be thoroughly cleaned and disinfected in accordance with the requirements of both the *exporting* and *importing countries*.
- d) After *disinfection*, all equipment to be replaced in the aircraft should be washed with clean water to remove any traces of disinfectant to avoid any damage to the aircraft structures.

2. 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:

- 1) incineration to an ash;
- 2) heating at an internal temperature of at least of 100°C for 30 minutes, then disposal in a land fill site;
- 3) controlled burial in a land fill site.

NB: FIRST ADOPTED IN 1982; MOST RECENT UPDATE ADOPTED IN 2011.

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/abattoirs* 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/abattoirs* 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 this 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 *slaughterhouses/abattoirs* and the *Veterinary Services* should ensure that *slaughterhouse/abattoir* 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/abattoirs*.

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/abattoirs*. Smells which cause fear or other negative responses should be taken into consideration when managing animals.

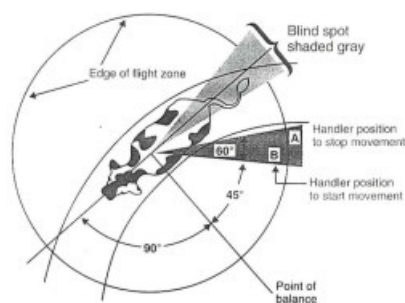
Domestic animals can hear over a greater range of frequencies than humans and are more sensitive to higher frequencies. They tend to be alarmed by constant loud noise and by sudden noises, which may cause them to panic. Sensitivity to such noises should also be taken into account when handling animals.

4. Distractions and their removal

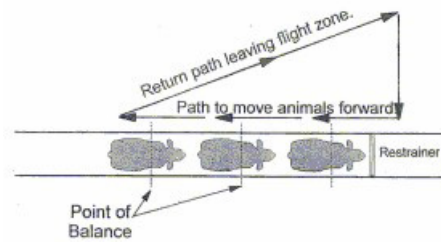
Distractions that may cause approaching animals to stop, baulk or turn back should be designed out from new facilities or removed from existing ones. Below are examples of common distractions and methods for eliminating them:

- a) reflections on shiny metal or wet floors – move a lamp or change lighting;
- b) dark entrances to chutes, races, stun boxes or conveyor restrainers – illuminate with indirect lighting which does not shine directly into the eyes of approaching animals or create areas of sharp contrast;
- c) animals seeing moving people or equipment up ahead – install solid sides on chutes and races or install shields;
- d) dead ends – avoid if possible by curving the passage, or make an illusory passage;
- e) chains or other loose objects hanging in chutes or on fences – remove them;
- f) uneven floors or a sudden drop in floor levels at the entrance to conveyor restrainers – avoid uneven floor surfaces or install a solid false floor under the restrainer to provide an illusion of a solid and continuous walking surface;
- g) sounds of air hissing from pneumatic equipment – install silencers or use hydraulic equipment or vent high pressure to the external environment using flexible hosing;
- h) clanging and banging of metal objects – install rubber stops on gates and other devices to reduce metal to metal contact;
- i) air currents from fans or air curtains blowing into the face of animals – redirect or reposition equipment.

An example of a flight zone (cattle)



Handler movement pattern to move cattle forward



Article 7.5.2.

Moving and handling animals

1. General considerations

Each *slaughterhouse/abattoir* should have a dedicated plan for *animal welfare*. The purpose of such a 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% 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/abattoir*. 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%, with less than 1% 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 construction1. 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/abattoir* 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/abattoirs*, 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/abattoir* 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/abattoirs* 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 buildup of temperature and humidity. Temperature and humidity should be monitored at appropriate intervals.

Recommendations for specific species are described in detail in Articles 7.5.5. to 7.5.9.

Article 7.5.5.

Management of foetuses during slaughter of pregnant animals

Under normal circumstances, pregnant animals that would be in the final 10% of their gestation period at the planned time of *unloading* at the *slaughterhouse/abattoir* 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
	Upright restraint	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
		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
		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

	Presentation of animals	Specific procedure	Specific purpose	Animal welfare concerns/ implications	Key animal welfare requirements	Applicable species
Restraining and /or conveying methods (contd)	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
		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
		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
Leg restraints		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 methods1. 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/abattoir*, 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.

Signs of correct *stunning* using a mechanical device 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.

Captive bolts powered by cartridges, compressed air or spring can be used for *poultry*. The optimum position for *poultry* species is at a right angle to the frontal surface. Firing of a captive bolt in accordance with the manufacturers' instructions should lead to immediate destruction of the skull and the brain and, as a result, immediate *death*.

3. Electrical stunning

a) General considerations

An electrical device should be applied to the animal in accordance with the following recommendations.

Electrodes should be designed, constructed, maintained and cleaned regularly to ensure that the flow of current is optimal and in accordance with manufacturing specifications. They should be placed so that they

span the brain. The application of electrical currents which bypass the brain is unacceptable unless the animal has been stunned. The use of a single current leg-to-leg is unacceptable as a *stunning* method.

If, in addition, it is intended to cause cardiac arrest, the electrodes should either span the brain and immediately thereafter the heart, on the condition that it has been ascertained that the animal is adequately stunned, or span brain and heart simultaneously.

Electrical *stunning* equipment should not be applied on animals as a means of guidance, movement, *restraint* or immobilisation, and shall not deliver any shock to the animal before the actual *stunning* or *killing*.

Electrical *stunning* apparatus should be tested prior to application on animals using appropriate resistors or dummy loads to ensure the power output is adequate to stun animals.

The electrical *stunning* apparatus should incorporate a device that monitors and displays voltage (true RMS) and the applied current (true RMS) and that such devices are regularly calibrated at least annually.

Appropriate measures, such as removing excess wool or wetting the skin only at the point of contact, can be taken to minimise impedance of the skin and facilitate effective *stunning*.

The *stunning* apparatus should be appropriate for the species. Apparatus for electrical *stunning* should be provided with adequate power to achieve continuously the minimum current level recommended for *stunning* as indicated in the table below.

In all cases, the correct current level shall be attained within one second of the initiation of stun and maintained at least for between one and three seconds and in accordance with the manufacturer's instructions. Minimum current levels for head-only *stunning* are shown in the following table.

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 waterbath. 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 waterbath, and the design of the entrance to the waterbath, 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 in accordance with the size of birds to ensure even the small birds are immersed in the waterbath 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:

Frequency (Hz)	Minimum current (milliamperes per bird)	
	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

4. Gas stunning (under study)

a) Stunning of pigs by exposure to carbon dioxide (CO₂)

The concentration of CO₂ for *stunning* should be preferably 90% by volume but in any case no less than 80% by volume. After entering the *stunning* chamber, the animals should be conveyed to the point of maximum concentration of the gas as rapidly as possible and be kept until they are dead or brought into a state of insensibility which lasts until *death* occur due to bleeding. Ideally, pigs should be exposed to this concentration of CO₂ for 3 minutes. Sticking should occur as soon as possible after exit from the gas chamber. In any case, the concentration of the gas should be such that it minimises as far as possible all stress of the animal prior to loss of consciousness.

The chamber in which animals are exposed to CO₂ and the equipment used for conveying them through it shall be designed, constructed and maintained in such a way as to avoid injury or unnecessary stress to the animals. The animal density within the chamber should be such to avoid stacking animals on top of each other.

The conveyor and the chamber shall be adequately lit to allow the animals to see their surroundings and, if possible, each other.

It should be possible to inspect the CO₂ chamber whilst it is in use, and to have access to the animals in emergency cases.

The chamber shall be equipped to continuously measure and display register at the point of *stunning* the CO₂ concentration and the time of exposure, and to give a clearly visible and audible warning if the concentration of CO₂ falls below the required level.

Emergency *stunning* equipment should be available at the point of exit from the *stunning* chamber and used on any pigs that do not appear to be completely stunned.

b) Inert gas mixtures for stunning pigs

Inhalation of high concentration of carbon dioxide is aversive and can be distressing to animals. Therefore, the use of non-aversive gas mixtures is being developed.

Such gas mixtures include:

- i) a maximum of 2% by volume of oxygen in argon, nitrogen or other inert gases, or
- ii) to a maximum of 30% by volume of carbon dioxide and a maximum of 2% by volume of oxygen in mixtures with carbon dioxide and argon, nitrogen or other inert gases.

Exposure time to the gas mixtures should be sufficient to ensure that no pigs regain consciousness before *death* supervenes through bleeding or cardiac arrest is induced.

c) Gas stunning of poultry

The main objective of gas *stunning* is to avoid the pain and suffering associated with shackling conscious *poultry* under waterbath *stunning* and *killing* systems. Therefore, gas *stunning* should be limited to birds contained in crates or on conveyors only. The gas mixture should be non-aversive to *poultry*.

Live *poultry* contained within transport modules or crates may be exposed to gradually increasing concentrations of CO₂ until the birds are properly stunned. No bird should recover consciousness during bleeding.

Gas *stunning* of *poultry* in their transport *containers* will eliminate the need for live birds' handling at the processing plant and all the problems associated with the electrical *stunning*. Gas *stunning* of *poultry* on a conveyor eliminates the problems associated with the electrical waterbath *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% carbon dioxide, 30% oxygen and 30% nitrogen, followed by a minimum of one minute exposure to 80% carbon dioxide in air; or
 - a minimum of 2 minutes exposure to any mixture of argon, nitrogen or other inert gases with atmospheric air and carbon dioxide, provided that the carbon dioxide concentration does not exceed 30% by volume and the residual oxygen concentration does not exceed 2% by volume; or
 - a minimum of 2 minutes exposure to argon, nitrogen, other inert gases or any mixture of these gases in atmospheric air with a maximum of 2% residual oxygen by volume; or
 - a minimum of 2 minutes exposure to a minimum of 55% carbon dioxide in air; or
 - a minimum of one minute exposure to 30% carbon dioxide in air, followed by a minimum of one minute exposure to at least 60% carbon dioxide in air.
- ii) Requirements for effective use are as follows:
- Compressed gases should be vaporised prior to administration into the chamber and should be at room temperature to prevent any thermal shock; under no circumstances, should solid gases with freezing temperatures enter the chamber.
 - Gas mixtures should be humidified.
 - Appropriate gas concentrations of oxygen and carbon dioxide should be monitored and displayed continuously at the level of the birds inside the chamber to ensure that anoxia ensues.

Under no circumstances, should birds exposed to gas mixtures be allowed to regain consciousness. If necessary, the exposure time should be extended.

5. Bleeding

From the point of view of *animal welfare*, animals which are stunned with a reversible method should be bled without delay. Maximum stun-stick interval depends on the parameters of the *stunning* method applied, the species concerned and the bleeding method used (full cut or chest stick when possible). As a consequence, depending on those factors, the *slaughterhouse/abattoir* 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	In accurate 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	
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	

Method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements applicable	Species	Comment
Gaseous (contd)	Inert gases	Recovery of consciousness	Concentration; duration of exposure; design, maintenance and operation of equipment; 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	
	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	

Slaughter methods	Specific method	Animal welfare concerns/ implications	Key requirements	Species	Comments
Bleeding with prior stunning (contd)	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.
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.

NB: FIRST ADOPTED IN 2005; MOST RECENT UPDATE ADOPTED IN 2016.

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 a *slaughterhouse/abattoir*, the recommendations in Chapter 7.5. 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	Article 7.6.6.
	all except neonates	penetrating captive bolt - followed by pithing or bleeding	yes	ineffective stunning, non-lethal wounding, regaining of consciousness before death	Article 7.6.7.
	adults only	non-penetrating captive bolt, followed by bleeding	yes	ineffective stunning, regaining of consciousness before death	Article 7.6.8.
	calves only	electrical, two-stage application	yes	pain associated with cardiac arrest after ineffective stunning	Article 7.6.10.
	calves only	electrical, single application (method 1)	yes	ineffective stunning	Article 7.6.11.
	all	injection with barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	Article 7.6.15.
Sheep and goats	all	free bullet	no	non-lethal wounding	Article 7.6.6.
	all except neonates	penetrating captive bolt, followed by pithing or bleeding	yes	ineffective stunning, non-lethal wounding, regaining of consciousness before death	Article 7.6.7.
	all except neonates	non-penetrating captive bolt, followed by bleeding	yes	ineffective stunning, regaining of consciousness before death	Article 7.6.8.
	neonates	non-penetrating captive bolt	yes	non-lethal wounding	Article 7.6.8.
	all	electrical, two-stage application	yes	pain associated with cardiac arrest after ineffective stunning	Article 7.6.10.
	all	electrical, single application (method 1)	yes	ineffective stunning	Article 7.6.11.

Species	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
Sheep and goats (contd)	neonates only	CO ₂ / air mixture	yes	slow induction of unconsciousness, aversiveness of induction	Article 7.6.12.
	neonates only	nitrogen or inert gas mixed with CO ₂	yes	slow induction of unconsciousness, aversiveness of induction	Article 7.6.13.
	neonates only	nitrogen or inert gases	yes	slow induction of unconsciousness	Article 7.6.14.
	all	injection of barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	Article 7.6.15.
Pigs	all	free bullet	no	non-lethal wounding	Article 7.6.6.
	all except neonates	penetrating captive bolt, followed by pithing or bleeding	yes	ineffective stunning, non-lethal wounding, regaining of consciousness before death	Article 7.6.7.
	neonates only	non-penetrating captive bolt	yes	non-lethal wounding	Article 7.6.8.
	all	electrical, two-stage application	yes	pain associated with cardiac arrest after ineffective stunning; design of the stunning tongs not appropriate for the small head or body of neonates	Article 7.6.10.
	all	electrical, single application (method 1)	yes	ineffective stunning	Article 7.6.11.
	neonates only	CO ₂ / air mixture	yes	slow induction of unconsciousness, aversiveness of induction	Article 7.6.12.
	neonates only	nitrogen or inert gas mixed with CO ₂	yes	slow induction of unconsciousness, aversiveness of induction	Article 7.6.13.
	neonates only	nitrogen or inert gases	yes	slow induction of unconsciousness	Article 7.6.14.
	all	injection with barbiturates and other	yes	non-lethal dose, pain associated with injection site	Article 7.6.15.
Poultry	adults only	penetrating and non-penetrating captive bolt	yes	ineffective stunning, non-lethal wounding, regaining of consciousness before death	Article 7.6.8.
	day-olds and eggs only	maceration	no	non-lethal wounding, non-immediacy	Article 7.6.9.
	adults only	electrical, single application (method 2)	yes	ineffective stunning	Article 7.6.11.
	adults only	electrical, single application, followed by killing (method 3)	yes	ineffective stunning; regaining of consciousness before death	Article 7.6.11.

Species	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
Poultry (contd)	all	CO ₂ / air mixture Method 1 Method 2	yes no	slow induction of unconsciousness, aversiveness of induction	Article 7.6.12.
	all	nitrogen or inert gas mixed with CO ₂	yes	slow induction of unconsciousness, aversiveness of induction	Article 7.6.13.
	all	nitrogen or inert gases	yes	slow induction of unconsciousness	Article 7.6.14.
	all	injection of barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	Article 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	Article 7.6.16.
Equids	all	free bullet	no	non-lethal wounding	Article 7.6.6.
	all, except neonates	penetrating captive bolt followed by pithing or bleeding	yes	ineffective stunning, non-lethal wounding, regaining of consciousness before death	Article 7.6.7
	all	injection of barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	Article 7.6.15.

Article 7.6.6.

Free bullet1. 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 used 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, pigs and equids, including large animals in open spaces.

Article 7.6.7.

Penetrating captive bolt

1. Introduction

A penetrating captive bolt is fired from a gun powered by either compressed air or a blank cartridge. There is no free projectile.

The captive bolt should be aimed on the skull in a position to penetrate the cortex and mid-brain of the animal. The impact of the bolt on the skull produces unconsciousness. Physical damage to the brain caused by penetration of the bolt may result in *death*; however, pithing or bleeding should be performed as soon as possible after the shot to ensure the *death* of the animal. Shooting *poultry* species with the captive bolts results in immediate destruction of the skull and brain, causing *death*. For a detailed description on the use of this method, see Chapter 7.5.

2. Requirements for effective use

- a) For cartridge powered and compressed air guns, the bolt velocity and the length of the bolt should be appropriate to the species and type of animal, in accordance with the recommendations of the manufacturer.
- b) Captive bolt guns should be frequently cleaned and maintained in good working condition.
- c) More than one gun may be necessary to avoid overheating, and a back-up gun should be available in the event of an ineffective shot.
- 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.
- 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, pigs and equids (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 a right angle to the skull in the optimal position.
- 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.

Maceration1. 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 application1. 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 (CO₂) induces respiratory and metabolic acidosis and hence reduces the pH of cerebrospinal fluid (CSF) and neurones thereby causing unconsciousness and, after prolonged exposure, *death*. Exposure to carbon dioxide does not induce immediate loss of consciousness, therefore the aversive nature of gas mixtures containing high concentrations of CO₂ and the respiratory distress occurring during the induction phase are important considerations for *animal welfare*.

2. Method 1

The animals are placed in a gas-filled *container* or apparatus.

a) Requirements for effective use in a *container* or apparatus

- i) *Containers* or apparatus should allow the required gas concentration to be maintained and accurately measured.
- ii) When animals are exposed to the gas individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the animals and allow them to be observed.
- iii) Animals can also be introduced to low concentrations (as low concentrations are not aversive) and the concentration could be increased afterwards and the animals then held in the higher concentration until *death* is confirmed.
- iv) Team members should ensure that there is sufficient time allowed for each batch of animals to die before subsequent ones are introduced into the *container* or apparatus.
- v) *Containers* or apparatus should not be overcrowded and measures are needed to avoid animals suffocating by climbing on top of each other.

b) Advantages

- i) CO₂ is readily available.
- ii) Application methods are simple.
- iii) The volume of gas required can be readily calculated.
- iv) As the units are operated outdoor, the gas is dispersed quickly at the end of each cycle by opening the door, improving operator's health and safety.
- v) The system uses skilled catching teams and equipment in daily use by the industry.
- vi) Metal *containers* can be readily cleansed and disinfected.

c) Disadvantages

- i) The need for properly designed *container* or apparatus.
- ii) The aversive nature of high CO₂ concentrations.
- iii) No immediate loss of consciousness.
- iv) The risk of suffocation due to overcrowding.
- v) Difficulty in verifying *death* while the animals are in the *container* or apparatus.

d) Conclusion

Method 1 is suitable for use in *poultry*, and neonatal sheep, goats and pigs.

3. Method 2

In this method, the crates or modules holding the birds are loaded into a chamber into which gas is introduced. As illustrated in the example below, a containerised gassing unit (CGU) typically comprises a gas-tight chamber designed to accommodate *poultry* transport crates or a single module. The chamber is fitted with gas lines and diffusers, with silencers that are connected via a system of manifolds and gas regulators to gas cylinders. There is a hole at the top to permit displaced air to escape when the *container* is filling with gas.

The procedures for the operation of CGU include (a) position the *container* on level, solid, open ground; (b) connect the gas cylinder to the *container* (c) load birds into the *container* (d) shut and secure the door, (e) deliver the gas until a concentration of 45% 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% 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% CO₂ and a longer period of exposure to die.

b) Advantages

- i) The gas is introduced quickly and quietly resulting in less turbulence and disturbance to the birds.
- ii) Gradual increase in the concentration of CO₂ minimises the aversive nature of this method for inducing unconsciousness.
- iii) The use of transport crates or modules to move birds minimises handling. Birds should be handled by trained, experienced catching teams at the time of depopulation of the poultry house.
- iv) The modules are loaded mechanically into the CGU and a lethal mixture of gas is rapidly introduced into the chamber immediately after sealing.
- v) CO₂ is readily available.
- vi) Birds are exposed to gas more uniformly and they do not smother each other when compared with Method 1.
- vii) The volume of gas required can be readily calculated.
- viii) As the units are operated outdoors, the gas is dispersed quickly at the end of each cycle by opening the door, improving operator's health and safety.
- ix) The system uses skilled catching teams and equipment in daily use by the industry.
- x) Metal *containers* can be readily cleansed and disinfected.

c) Disadvantages

- i) Requires trained operators, trained catchers, transport modules and fork lift. However, this equipment and suitable areas with hard surfaces are usually available.
- ii) The main limiting factors are speed of catching birds.
- iii) In the absence of a viewing window, visual confirmation of *death* while the birds are still in the *container* is difficult. However, cessation of vocalisation and convulsive wing flapping sounds can be used to determine onset of *death*.

d) Conclusion

- i) Method 2 is suitable for use in a wide range of *poultry* systems, providing there is access to *vehicles* to carry the *containers* and equipment.
- ii) Birds should be introduced into the *container* or apparatus, which is then sealed and filled as quickly as possible with the required gas concentrations, i.e. more than 40% CO₂. Birds are held in this atmosphere until *death* is confirmed.
- iii) Method 2 is suitable for use in *poultry*, and neonatal sheep, goats and pigs. However, CO₂ is likely to cause a period of distress in the animals before they lose consciousness.

4. Method 3

The gas is introduced into a poultry house.

a) Requirements for effective use in a poultry house

- i) Prior to introduction of the CO₂, the poultry house should be appropriately sealed to allow control over the gas concentration. The interval between sealing and gas administration should be kept to the minimum so as to avoid overheating.

Forced ventilation systems, where fitted, should only be switched off immediately prior to gas administration.

The main water supply to the poultry house may have to be turned off and water drained to avoid freezing and bursting of water pipes.

Feeders and water troughs should be lifted to avoid obstruction of the gas entry and prevent injury to birds.

- ii) Gas delivery pipes or lancets should be positioned appropriately such that birds are not hit directly by very cold gas delivered at high pressures. It may be necessary to exclude birds from the area in front of the delivery pipes, for a distance of about 20 meters, by partitioning the house with nets, wire mesh or similarly perforated materials.
- iii) The house should be gradually filled with CO₂ so that all birds are exposed to a concentration of >40% until they are dead; a vapouriser may be required to prevent freezing.
- iv) Devices should be used to accurately measure the gas concentration at the maximum height accommodation of birds.

b) Advantages

- i) Applying gas to birds *in situ* eliminates the need to manually remove live birds.
- ii) CO₂ is readily available.
- iii) Gradual raising of CO₂ concentration minimises the aversiveness of the induction of unconsciousness.

c) Disadvantages

- i) It is difficult to determine volume of gas required to achieve adequate concentrations of CO₂ in some poultry houses.
- ii) It is difficult to verify *death* while the birds are in the poultry house.

The extremely low temperature of liquid CO₂ entering the house and formation of solid CO₂ (dry ice) may cause concern for bird welfare.

d) Conclusion

Method 3 is suitable for use in *poultry* in closed-environment sheds. This method could be developed for killing pigs. However, CO₂ is likely to cause a period of distress in the birds before they lose consciousness.

Article 7.6.13.

Nitrogen or inert gas mixed with CO₂1. Introduction

CO₂ may be mixed in various proportions with nitrogen or an inert gas (e.g. argon), and the inhalation of such mixtures leads to hypercapnic-hypoxia and *death* when the oxygen concentration by volume is ≤2%, or ≤5% for chickens. Various mixtures of CO₂ and nitrogen or an inert gas can be administered to kill birds using Methods 1 and 2 described under Article 7.6.12. Whole house gassing with mixtures of CO₂ and nitrogen, or an inert gas, has not been tested owing to the complex issues presented by mixing gases in large quantities. Such mixtures however do not induce immediate loss of consciousness, therefore the aversiveness of various gas mixtures containing high concentrations of CO₂ and the respiratory distress occurring during the induction phase, are important *animal welfare* considerations.

Pigs and *poultry* appear not to find low concentrations of CO₂ strongly aversive, and a mixture of nitrogen or argon with ≤30% CO₂ by volume and ≤2% O₂ by volume can be used for *killing poultry*, neonatal sheep, goats and pigs.

2. Method 1

The animals are placed in a gas-filled *container* or apparatus.

a) Requirements for effective use

- i) *Containers* or apparatus should allow the required gas concentrations to be maintained, and the O₂ and CO₂ concentrations accurately measured during the *killing* procedure.
- ii) When animals are exposed to the gases individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the animals and allow them to be observed.
- iii) Animals should be introduced into the *container* or apparatus after it has been filled with the required gas concentrations (with $\leq 2\%$ O₂), and held in this atmosphere until *death* is confirmed.
- iv) Team members should ensure that there is sufficient time allowed for each batch of animals to die before subsequent ones are introduced into the *container* or apparatus.
- v) *Containers* or apparatus should not be overcrowded and measures are needed to avoid animals suffocating by climbing on top of each other.

b) Advantages

Low concentrations of CO₂ cause little aversiveness and, in combination with nitrogen or an inert gas, produces a fast induction of unconsciousness.

c) Disadvantages

- i) A properly designed *container* or apparatus is needed.
- ii) It is difficult to verify *death* while the animals are in the *container* or apparatus.
- iii) There is no immediate loss of consciousness.
- iv) Exposure times required to kill are considerable.

d) Conclusion

The method is suitable for *poultry*, and for neonatal sheep, goats and pigs.

3. Method 2

In this method, the crates or modules holding the birds are loaded into a *container* and gas is introduced into the *container*. 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% 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 $<2\%$ residual oxygen is achieved at the top of the crates.
- iv) An appropriate gas meter should be used to ensure a concentration of oxygen $<2\%$ 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% carbon dioxide and 80% 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% 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% should be achieved and maintained and birds should be held in this atmosphere until *death* is confirmed.

Article 7.6.14.

Nitrogen or inert gases

1. Introduction

This method involves the introduction of animals into a *container* or apparatus containing nitrogen or an inert gas such as argon. The controlled atmosphere produced leads to unconsciousness and *death* from hypoxia.

Research has shown that hypoxia is not aversive to pigs and *poultry*, and it does not induce any signs of respiratory distress prior to loss of consciousness.

2. Requirements for effective use

- a) *Containers* or apparatus should allow the required gas concentrations to be maintained, and the O₂ concentration accurately measured.
- b) When animals are exposed to the gases individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the animals and allow them to be observed.
- c) Animals should be introduced into the *container* or apparatus after it has been filled with the required gas concentrations (with $\leq 2\%$ O₂), and held in this atmosphere until *death* is confirmed.
- d) Team members should ensure that there is sufficient time allowed for each batch of animals to die before subsequent ones are introduced into the *container* or apparatus.
- e) *Containers* or apparatus should not be overcrowded, and measures are needed to avoid animals suffocating by climbing on top of each other.

3. Advantages

Animals are unable to detect nitrogen or inert gases, and the induction of hypoxia by this method is not aversive to animals.

4. Disadvantages

- a) A properly designed *container* or apparatus is needed.
- b) It is difficult to verify *death* while the animals are in the *container* or apparatus.
- c) There is no immediate loss of consciousness.
- d) Exposure times required to kill are considerable.

5. Conclusion

The method is suitable for *poultry* and neonatal sheep, goats and pigs.

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.
- f) Personnel performing this method should be trained and knowledgeable in anaesthetic techniques.

3. Advantages

- a) The method can be used in all species.

b) *Death* can be induced smoothly.

4. Disadvantages

- a) *Restraint* 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 and training required may restrict use to veterinarians.
- d) Contaminated carcasses may present a risk to other animals or domestic animals.

5. Conclusion

The method is suitable for *killing* small numbers of cattle, sheep, goats, pigs, equids 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 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 or ineffective bleeding due to convulsions may occur.
 - ii) The working area is contaminated with body fluids, which increases *biosecurity* risks.

NB: FIRST ADOPTED IN 2005; MOST RECENT UPDATE ADOPTED IN 2016.

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 *animal welfare* problems and have a socio-economic, environmental, political and religious impact in many countries. Human health, including the prevention of zoonotic diseases, notably rabies, is a priority. Dog population management is an integral part of rabies control programmes. Furthermore, the OIE recognises the importance of controlling dog populations without causing unnecessary animal suffering. *Veterinary Services* should play a lead role in preventing zoonotic diseases and ensuring *animal welfare* and should be involved in dog population control, coordinating their activities with other competent public institutions and/or agencies.

Article 7.7.1.

Guiding principles

The following recommendations are based on those laid down in Chapter 7.1. Some additional principles are relevant to these recommendations:

- 1) The promotion of *responsible dog ownership* can significantly reduce the numbers of *stray dogs* and the incidence of zoonotic diseases.
- 2) Because dog ecology is linked with human activities, control of dog populations has to be accompanied by changes in human behaviour to be effective.

Article 7.7.2.

Definitions

Carrying capacity means the upper limit of the dog population density that could be supported by the habitat based on the availability of resources (food, water, shelter), and human acceptance.

Dog population control programme means a programme with the aim of reducing a *stray dog* population to a particular level and/or maintaining it at that level and/or managing it in order to meet a predetermined objective (see Article 7.7.3.).

Person this can include more than one individual, and could comprise family/household members or an organisation.

Article 7.7.3.

Dog population control programme objectives

The objectives of a programme to control the dog population may include the following:

- 1) improve health and welfare of owned and *stray dog* population;
- 2) reduce numbers of *stray dogs* to an acceptable level;
- 3) promote responsible ownership;
- 4) assist in the creation and maintenance of a rabies immune or rabies free dog population;
- 5) reduce the *risk* of zoonotic diseases other than rabies;
- 6) manage other *risks* to human health (e.g. parasites);
- 7) prevent harm to the environment and other animals;
- 8) prevent illegal trade and trafficking.

Article 7.7.4.

Responsibilities and competencies1. 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. *slaughterhouses/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 in accordance with 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 in accordance with 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 *slaughterhouses/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 8.14. 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
- Electrocutation of conscious animal.

Because neonatal animals and adults with impaired breathing or low blood pressure are resistant to hypoxia, methods that depend upon achieving a hypoxic state (e.g. CO₂, CO, N₂, Ar) should not be used. These methods should not be used in animals aged less than two months, except to produce loss of consciousness and should be followed by another method to cause *death*. Concussion and cervical dislocation may be used in very small neonatal dogs and only in cases of emergency.

Operators should be well trained in the use of physical techniques to ensure that they are correctly and humanely carried out. The dog should be exsanguinated immediately after concussion or cervical dislocation.

d) Confirmation of death

For all methods of *euthanasia* used, *death* should be confirmed before animals are disposed of or left unattended. If an animal is not dead, another method of *euthanasia* should be performed.

e) Carcass disposal

Carcasses should be disposed of in a manner that complies with legislation. Attention should be paid to the risk of residues occurring in the carcass. Incineration is generally the safest way of carcass disposal.

Table 1. Summary analysis of methods for the euthanasia of dogs

Euthanasia method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements	Considerations relating to operator security	Advantages	Disadvantages
Chemical via injection	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 loss 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).
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.

Euthanasia method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements	Considerations relating to operator security	Advantages	Disadvantages
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 a 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.	Unconsciousness can occur in minutes, but death may take some time. Likelihood of suffering before unconsciousness.
	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.	Supplementation with air or O ₂ required to avoid hypoxemia during induction phase.	Some gases may be hazardous, especially for pregnant women. General recommendation: avoid human exposure to greater than or equal to 2 ppm to avoid narcosis.	Gas is not flammable or explosive. Valuable for use with small animals (<7 kgs) and animals that are already anaesthetised with gas.	High cost. Anaesthetic and euthanasia properties of the gas used should be known. Isoflurane has a pungent odour. Methoxyflurane's action is slow and dog may become agitated.

Euthanasia method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements	Considerations relating to operator security	Advantages	Disadvantages
Electrical	Electrocution	Cardiac fibrillation occurs before onset of unconsciousness, causing severe pain if dog is conscious. Pain can also be caused by violent extension of the limbs, head and neck. Method may not be effective if insufficient current applied.	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 in accordance with 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 be 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.

NB: FIRST ADOPTED IN 2009; MOST RECENT UPDATE ADOPTED IN 2011.

CHAPTER 7.8.

USE OF ANIMALS IN RESEARCH AND EDUCATION

Preamble: The purpose of this chapter is to provide advice and assistance for Member Countries to follow when formulating regulatory requirements, or other form of oversight, for the use of live animals in research and education. Wherever the term "research" is used, it includes basic and applied research, testing and the production of biological materials; "education" includes teaching and training. A system of animal use oversight should be implemented in each country. The system will, in practice, vary from country to country and in accordance with cultural, economic, religious and social factors. However, the OIE recommends that Member Countries address all the essential elements identified in this chapter in formulating a regulatory framework that is appropriate to their local conditions. This framework may be delivered through a combination of national, regional and institutional jurisdictions and both public sector and private sector responsibilities should be clearly defined.

The OIE recognises the vital role played by the use of live animals in research and education. The OIE Guiding Principles for Animal Welfare state that such a use makes a major contribution to the wellbeing of people and animals and emphasise the importance of the Three Rs (see Article 7.8.3.). Most scientists and members of the public agree that the animals should only be used when necessary; ethically justified (thereby avoiding unnecessary duplication of animal-based research); and when no other alternative methods, not using live animals, are available; that the minimum number of animals should be used to achieve the scientific or educational goals; and that such use of animals should cause as little pain and/or distress as possible. In addition, animal suffering is often recognised separately from pain and distress and should be considered alongside any lasting harm which is expected to be caused to animals.

The OIE emphasises the need for humane treatment of animals and that good quality science depends upon good *animal welfare*. It is the responsibility of all involved in the use of animals to ensure that they give due regard to these recommendations. In keeping with the overall approach to *animal welfare* detailed in the Guiding Principles, the OIE stresses the importance of standards based on outcomes for the animal.

The OIE recognises the significant role of *veterinarians* in animal-based research. Given their unique training and skills, they are essential members of a team including scientists and animal care technicians. This team approach is based on the concept that everyone involved in the use of animals has an ethical responsibility for the animals' welfare. The approach also ensures that animal use leads to high quality scientific and educational outcomes and optimum welfare for the animals used.

The OIE recognises that the use of live animals in research and education is a legitimate activity and, as a consequence, domestic and international transport of animals is essential to maintaining progress in advancing human and animal health. Such a transport should be conducted in a legal manner, ensuring the safety of the animal and applying humane principles.

The OIE recommends that records on animal use should be maintained at an institutional level, as appropriate to the institution and project proposals and species used. Key events and interventions should be recorded to aid decision making and promote good science and welfare. A summary of these records may be gathered on a national basis and be published to provide a degree of public transparency, without compromising personnel or animal safety, or releasing proprietary information.

Article 7.8.1.

Definitions

'Biocontainment': means the system and procedures designed to prevent the accidental release of biological material including allergens.

'Bioexclusion': means the prevention of the unintentional transfer of adventitious organisms with subsequent *infection* of animals, resulting in adverse effects on their health or suitability for research.

'Biosecurity': means a continuous process of *risk assessment* and *risk management* designed to minimise or eliminate microbiological *infection* with adventitious organisms that can cause clinical disease in the infected animals or humans, or make animals unsuitable for biomedical research.

'**Cloned animal**': means a genetic copy of another living or dead animal produced by somatic cell nuclear transfer or other reproductive technology.

'**Distress**': means the state of an animal, that has been unable to adapt to stressors, and that manifests as abnormal physiological or behavioural responses. It can be acute or chronic and may result in pathological conditions.

'**Endangered species**': means a population of organisms which is at risk of becoming extinct because it is either few in numbers, or threatened by changing environmental or predation parameters.

'**Environmental enrichment**': means increasing the complexity (e.g. with toys, cage furniture, foraging opportunities, social housing, etc.) in a captive animal's environment to foster the expression of non-injurious species-typical behaviours and reduce the expression of maladaptive behaviours, as provide cognitive stimulation.

'**Ethical review**': means consideration of the validity and justification for using animals including: an assessment and weighing of the potential harms for animals and likely benefits of the use and how these balance (see harm-benefit analysis below); and consideration of experimental design; implementation of the Three Rs; animal husbandry and care and other related issues such as personnel training. Ethical judgements are influenced by prevailing societal attitudes.

'**Harm-benefit analysis**': means the process of weighing the likely adverse effects (harms) to the animals against the benefits likely to accrue as a result of the proposed project.

'**Humane endpoint**': means the point in time at which an experimental animal's pain and/or distress is avoided, terminated, minimised or reduced, by taking actions such as giving treatment to relieve pain and/or distress, terminating a painful procedure, removing the animal from the study, or humanely killing the animal.

'**Laboratory animal**': means an animal that is intended for use in research. In most cases, such animals are purpose-bred to have a defined physiological, metabolic, genetic or pathogen free status.

'**Operant conditioning**': means the association that an animal makes between a particular response (such as pressing a bar) and a particular reinforcement that may be positive (for example, a food reward) or negative (e.g. a mild electric shock). As a result of this association, the occurrence of a specific behaviour of the animal can be modified (e.g. increased or decreased in frequency or intensity).

'**Pain**': means an unpleasant sensory and emotional experience associated with actual or potential tissue damage. It may elicit protective actions, result in learned avoidance and distress and may modify species-specific traits of behaviour, including social behaviour.

'**Project proposal (sometimes called protocol)**': means a written description of a study or experiment, programme of work, or other activities that includes the goals of the work, characterises the use of the animals, and includes ethical considerations.

'**Suffering**': means an unpleasant, undesired state of being that is the outcome of the impact on an animal of a variety of noxious stimuli and/or the absence of important positive stimuli. It is the opposite of good welfare.

Article 7.8.2.

Scope

This chapter applies to animals as defined in the *Terrestrial Code* (excluding bees) bred, supplied and/or used in research (including testing) and higher education. Animals to be used for production of biologicals and/or humanely killed for harvesting their cells, tissues and organs for scientific purposes are also covered. Member Countries should consider both the species and the developmental stage of the animal in implementing these standards.

Article 7.8.3.

The Three Rs

The internationally accepted tenet, the 'Three Rs', comprises the following alternatives:

- 1) replacement refers to the use of methods utilizing cells, tissues or organs of animals (relative replacement), as well as those that do not require the use of animals to achieve the scientific aims (absolute replacement);
- 2) reduction refers to the use of methods that enable researchers to obtain comparable levels of information from fewer animals or to obtain more information from the same number of animals;

- 3) refinement refers to the use of methods that prevent, alleviate or minimise pain, suffering, distress or lasting harm and/or enhance welfare for the animals used. Refinement includes the appropriate selection of relevant species with a lesser degree of structural and functional complexity in their nervous systems and a lesser apparent capacity for experiences that derive from this complexity. Opportunities for refinement should be considered and implemented throughout the lifetime of the animal and include, for example, housing and transportation as well as procedures and euthanasia.

Article 7.8.4.

The oversight framework

The role of a *Competent Authority* is to implement a system (governmental or other) for verification of compliance by institutions. This usually involves a system of authorisation (such as licensing or registering of institutions, scientists, and/or projects) and compliance which may be assessed at the institutional, regional and/or national level.

The oversight framework encompasses both ethical review of animal use and considerations related to animal care and welfare. This may be accomplished by a single body or distributed across different groups. Different systems of oversight may involve *animal welfare* officers, regional, national or local committees or bodies. An institution may utilise a local committee (often referred to as Animal Care and Use Committee, Animal Ethics Committee, Animal Welfare Body or Animal Care Committee) to deliver some or all of this oversight framework. It is important that the local committee reports to senior management within the institution to ensure it has appropriate authority, resources and support. Such a committee should undertake periodic review of its own policies, procedures and performance.

Ethical review of animal use may be undertaken by regional, national or local ethical review bodies or committees. Consideration should be given to ensuring the impartiality and independence of those serving on the committees.

In providing this oversight and ensuring the implementation of the Three Rs, the following expertise should be included as a minimum:

- 1) one scientist with experience in animal research, whose role is to ensure that protocols are designed and implemented in accordance with sound science;
- 2) one *veterinarian*, with the necessary expertise to work with research animals, whose specific role is to provide advice on the care, use and welfare of such animals;
- 3) one public member, where appropriate, to represent general community interests who is independent of the science and care of the animals and is not involved in the use of animals in research.

Additional expertise may be sought from the animal care staff, as these professional and technical staff are centrally involved in ensuring the welfare of animals used. Other participants, especially in relation to ethical review, may include statisticians, information scientists and ethicists and biosafety specialists, as appropriate to the studies conducted. It may be appropriate, in teaching institutions, to involve student representation.

Oversight responsibilities include three key elements:

1. Project proposal review

The purpose of the project proposal is to enable assessment of the quality of, and justification for, the study, work or activity.

Project proposals, or significant amendments to these, should be reviewed and approved prior to commencement of the work. The proposal should identify the person with primarily responsibility for the project and should include a description of the following elements, where relevant:

- a) the scientific or educational aims, including consideration of the relevance of the experiment to human or animal health or welfare, the environment, or the advancement of biological knowledge;
- b) an informative, non-technical (lay) summary may enhance understanding of the project and facilitate the ethical review of the proposal by allowing full and equitable participation of members of the oversight body or

committees who may be dealing with matters outside their specific field. Subject to safeguarding confidential information, such summaries may be made publicly available;

- c) the experimental design, including justification for choice of species, source and number of animals, including any proposed reuse;
- d) the experimental procedures;
- 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 actions to ensure compliance.

Article 7.8.5.

Assurance of training and competency

An essential component of the animal care and use programme is the assurance that the personnel working with the animals are appropriately trained and competent to work with the species used and the procedures to be performed, including ethical considerations. A system (institutional, regional or national) to assure competency should be in place, which includes supervision during the training period until competence has been demonstrated. Continuing professional and paraprofessional educational opportunities should be made available to relevant staff. Senior management, given their overarching responsibility for the animal care and use programme, should be knowledgeable about issues related to the competence of staff.

1. Scientific staff

Researchers using animals have a direct ethical and legal responsibility for all matters relating to the welfare of the animals in their care. Due to the specialised nature of animal research, focused training should be undertaken to supplement educational and experiential backgrounds of scientists (including visiting scientists) before initiating a study. Focused training may include such topics as the national and/or local regulatory framework and institutional policies. The laboratory animal *veterinarian* is often a resource for this and other training. Scientific staff should have demonstrated competency in procedures related to their research, e.g. surgery, anaesthesia, sampling and administration, etc.

2. Veterinarians

It is important that *veterinarians* working in an animal research environment have veterinary medical knowledge and experience in the species used. Furthermore, they should be educated and experienced in the normal behaviour, behavioural needs, stress responses and adaptability of the species, as well as research methodologies. Relevant approvals issued by the *veterinary statutory body* and appropriate national or regional schemes (where these exist) should be adopted as the reference for veterinary training.

3. Animal care staff

Animal care staff should receive training that is consistent with the scope of their work responsibilities and have demonstrated competency in the performance of these tasks.

4. Students

Students should learn scientific and ethical principles using non-animal methods (videos, computer models, etc.) when such methods can effectively reduce or replace the use of live animals and still meet learning objectives. Wherever it is necessary for students to participate in classroom or research activities involving live animals, they should receive appropriate supervision in the use of animals until such time that they have demonstrated competency in the related procedure(s).

5. Members of the local oversight committee or others involved with oversight

Continuing education about the use of animals in research and education, including associated ethics, regulatory requirements and their institutional responsibility, should be provided.

Occupational health and safety training for research animal related risks should be provided as part of the assurance of training and competency for personnel. This might include consideration of human infectious diseases which may infect research animals and thus compromise research results, as well as possible zoonoses. Personnel should understand that there are two categories of hazards, those that are intrinsic to working in an animal facility and those associated with the research. Specific training may be required for particular species, for specific procedures, and for the use of appropriate protective measures for personnel who may be exposed to animal allergens. Research materials, such as chemicals of unknown toxicity, biological agents and radiation sources, may present special hazards

Article 7.8.6.

Provision of veterinary care

Adequate veterinary care includes responsibility for promoting an animal's health and welfare before, during and after research procedures and providing advice and guidance based on best practice. Veterinary care includes attention to the physical and behavioural status of the animal. The *veterinarian* should have authority and responsibility for making judgements concerning *animal welfare*. Veterinary advice and care should be available at all times. In exceptional

circumstances, where species unfamiliar to the *veterinarian* are involved, a suitably qualified non-veterinary expert may provide advice.

1. Clinical responsibilities

Preventive medicine programmes that include *vaccinations*, ectoparasite and endoparasite treatments and other disease control measures should be initiated in accordance with 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 *disinfection* procedures, air pressure differentials in animal holding rooms, etc. Animals brought into the institution may carry diseases that require notification to government officials. It is important that the *veterinarian* be aware of, and comply with, these requirements.

5. Advice on surgery and postoperative care

A programme of adequate veterinary care includes input into the review and approval process of preoperative, surgical and postoperative procedures by an appropriately qualified *veterinarian*. A *veterinarian's* inherent responsibility includes providing advice concerning preoperative procedures, aseptic surgical techniques, the competence of staff to perform surgery and the provision of postoperative care. Veterinary oversight should include the detection and resolution of emerging patterns of surgical and post procedural complications.

6. Advice on analgesia, anaesthesia and euthanasia

Adequate veterinary care includes providing advice on the proper use of anaesthetics, analgesics, and methods of *euthanasia*.

7. Advice on humane endpoints

Humane endpoints should be established prior to commencement of a study in consultation with the *veterinarian* who also plays an important role in ensuring that approved humane endpoints are followed during the course of the study. It is essential that the *veterinarian* has the authority to ensure *euthanasia* or other measures are carried out as required to relieve pain and distress unless the project proposal approval specifically does not permit such an intervention on the basis of the scientific purpose and the ethical evaluation.

Ideal humane endpoints are those that can be used to end a study before the onset of pain and/or distress, without jeopardising the study's objectives. In consultation with the *veterinarian*, humane endpoints should be described in the project proposal and, thus, established prior to commencement of the study. They should form part of the ethical review. Endpoint criteria should be easy to assess over the course of the study. Except in rare cases, *death* (other than *euthanasia*) as a planned endpoint is considered ethically unacceptable.

Article 7.8.7.

Source of animals

Animals to be used for research should be of high quality to ensure the validity of the data.

1. Animal procurement

Animals should be acquired legally. It is preferable that animals are purchased from recognised sources producing or securing high quality animals. The use of wild caught nonhuman primates is strongly discouraged.

Purpose bred animals should be used whenever these are available and animals that are not bred for the intended use should be avoided unless there is compelling scientific justification or are the only available and suitable source. In the case of farm animals, non-traditional breeds and species, and animals captured in the wild, non-purpose bred animals are often used to achieve specific study goals.

2. Documentation

Relevant documentation related to the source of the animals, such as health and other veterinary certification, breeding records, genetic status and animal identification, should accompany the animals.

3. Animal health status

The health status of animals can have a significant impact on scientific outcomes. There also may be occupational health and safety concerns related to animal health status. Animals should have appropriate health profiles for their intended use. The health status of animals should be known before initiating research.

4. Genetically defined animals

A known genetic profile of the animals used in a study can reduce variability in the experimental data resulting from genetic drift and increase the reproducibility of the results. Genetically defined animals are used to answer specific research questions and are the product of sophisticated and controlled breeding schemes which should be validated by periodic genetic monitoring. Detailed and accurate documentation of the colony breeding records should be maintained.

5. Genetically altered (also genetically modified or genetically engineered) or cloned animals

A genetically altered animal is one that has had undergone genetic modification of its nuclear or mitochondrial genomes through a deliberate human intervention, or the progeny of such an animal(s), where they have inherited the modification. If genetically altered or cloned animals are used, such use should be conducted in accordance with relevant regulatory guidance. With such animals, as well as harmful mutant lines arising from spontaneous mutations and induced mutagenesis, consideration should be given to addressing and monitoring special husbandry and welfare needs associated with abnormal phenotypes. Records should be kept of biocontainment requirements, genetic and phenotypic information, and individual identification, and be communicated by the animal provider to the recipient. Archiving and sharing of genetically altered lines is recommended to facilitate the sourcing of these customised animals.

6. Animals captured in the wild

If *wild animals* are to be used, the capture technique should be humane and give due regard to human and animal health, welfare and safety. Field studies have the potential to cause disturbance to the habitat thus adversely affecting both target and non-target species. The potential for such disturbance should be assessed and minimised. The effects of a series of stressors, such as trapping, handling, transportation, sedation, anaesthesia, marking and sampling, can be cumulative, and may produce severe, possibly fatal, consequences. An assessment of the potential sources of stress and management plans to eliminate or minimise distress should form part of the project proposal.

7. Endangered species

Endangered species should only be used in exceptional circumstances where there is strong scientific justification that the desired outcomes cannot be achieved using any other species.

8. Transport, importation and exportation

Animals should be transported under conditions that are appropriate to their physiological and behavioural needs and pathogen free status, with care to ensure appropriate physical containment of the animals as well as exclusion of contaminants. The amount of time animals spend on a *journey* should be kept to a minimum. It is important to ensure that there is a well-constructed *journey* plan, with key staff identified who have responsibility for the animals

and that relevant documentation accompanies animals during transport to avoid unnecessary delays during the *journey* from the sender to the receiving institution.

9. Risks to biosecurity

In order to minimise the risk of contamination of animals with unwanted infectious microorganisms or parasites that may compromise the health of animals or make them unsuitable for use in research, the microbiological status of the animals should be determined and regularly assessed. Appropriate biocontainment and bioexclusion measures should be practised to maintain their health status and, if appropriate, measures taken to prevent their exposure to certain human or environmental commensals.

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

See Article 7.8.10.

2. Acclimatisation

Newly received animals should be given a period for physiological and behavioural stabilisation before their use. The length of time for stabilisation will depend on the type and duration of transportation, the age and species involved, place of origin, and the intended use of the animals. Facilities should be available to isolate animals showing signs of ill health.

3. Cages and pens

Cages and pens should be made out of material that can be readily cleaned and decontaminated. Their design should be such that the animals are unlikely to injure themselves. Space allocations should be reviewed and modified as necessary to address individual housing situations and animal needs (for example, for prenatal and postnatal care, obese animals, and group or individual housing). Both the quantity and quality of space provided is important. Whenever it is appropriate, social animals should be housed in pairs or groups, rather than individually, provided that such housing is not contraindicated by the protocol in question and does not pose an undue risk to the animals.

4. Enrichment

Animals should be housed with a goal of maximising species appropriate behaviours and avoiding or minimising stress induced behaviours. One way to achieve this is to enrich the structural and social environment of the animals and to provide opportunities for physical and cognitive activity. Such provision should not compromise the health and safety of the animals or people, nor interfere with the scientific goals.

5. Feeding

Provision should be made for each animal to have access to *feed* to satisfy its physiological needs. Precautions should be taken in packing, transporting, storing and preparing *feed* to avoid chemical, physical and microbiological contamination, deterioration or destruction. Utensils used for feeding should be regularly cleaned and, if necessary, sterilised.

6. Water

Untaminated 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.

Article 7.8.10.

Transportation

Transportation is a typically stressful experience for animals. Therefore, every precaution should be taken to avoid unnecessary stress caused by inadequate ventilation, exposure to extreme temperatures, lack of *feed* and water, long delays, etc. General recommendations are made in Chapters 7.3. and 7.4. There may be a justifiable reason to transport animals whose welfare is compromised as a consequence of scientific procedures which the animals are under-going or for which there are intended. In such cases, every precaution should be taken to avoid further stress. In addition, animals should be transported under conditions and in *containers* that are appropriate to their physiological and behavioural needs and pathogen free status, with care to ensure appropriate physical containment and safety of the animals. A contingency plan which addresses any possible delays should be in place and the name of an emergency contact person should be prominently displayed on the *container*.

- 1) The source of animals and therefore the mode and conditions of transport should be considered in the project proposal review described in point 1 c) of Article 7.8.4.
 - a) The consigner and consignee should coordinate the means, route and duration of transport with emphasis on the potential impact on the health and welfare of the animal(s).
 - b) The potential for delays in transportation should be anticipated and avoided.
- 2) The documentation required for international transport should be based on the OIE Model Veterinary Certificate for International Trade in Laboratory Animals (See Chapter 5.13.):
 - a) There should be assurance that complete, relevant and legible documentation accompanies animals during transport to avoid unnecessary delays during the *journey* from the sender to the receiving institution.
 - b) Electronic certificates should be implemented, wherever possible.
- 3) There should be a well-defined *journey* plan, commencing from the point when animals are placed in their *containers* until they are removed from the *containers* at their final destination:
 - a) The *journey* plan should be designed so that the time in transit is the shortest possible and most comfortable for the animal. Where *journeys* of some distance are involved, this is often best achieved through air transport, preferably by direct routes.
 - b) Key staff should be identified who have responsibility for the animals and have the authority for making decisions in unforeseen circumstances. Such staff should be contactable at all times.
 - c) The *journey* plan should be under the general oversight of a *veterinarian* or other competent person, knowledgeable and experienced in the biology and needs of the particular species. The following should specifically be addressed:
 - i) Some animals, such as genetically altered animals, may have special requirements.
 - ii) Issues of biosecurity and bioexclusion, e.g. through *container* design and handling.
- 4) In accordance with Chapters 7.3. and 7.4. and IATA regulations, an appropriate environment, such as *container* design and construction, temperature, food and water, should be provided to the animal throughout the planned *journey*. Adequate supplies of food, water and bedding should be provided to accommodate a delay of at least 24 hours.
- 5) Personnel handling animals throughout the planned *journey* should be trained in the basic needs of animals and in good handling practices for the species to facilitate the *loading* and *unloading* of animals.

- 6) Delivery
- a) Consignments of animals should be accepted into the facility without avoidable delay and, after inspection, should be removed from their *container* under conditions compatible with their pathogen free status.
 - b) They should then be transferred to clean cages or pens and be supplied with *feed* and water as appropriate.
 - c) Social animals transported in established pairs or groups should be maintained in these on arrival.

NB: FIRST ADOPTED IN 2010; MOST RECENT UPDATE ADOPTED IN 2013.

CHAPTER 7.9.

ANIMAL WELFARE AND BEEF CATTLE PRODUCTION SYSTEMS

Article 7.9.1.

Definition

Beef cattle production systems are defined as all commercial cattle production systems where the purpose of the operation includes some or all of the breeding, rearing and finishing of cattle intended for beef consumption.

Article 7.9.2.

Scope

This chapter addresses the welfare aspects of beef cattle production systems, from birth through to finishing. This scope does not include veal production.

Article 7.9.3.

Commercial beef cattle production systems

Commercial beef cattle production systems include:

1. Intensive
These are systems where cattle are in confinement and are fully dependent on humans to provide for basic animal needs such as food, shelter and water on a daily basis.
2. Extensive
These are systems where cattle have the freedom to roam outdoors, and where the cattle have some autonomy over diet selection (through grazing), water consumption and access to shelter.
3. Semi intensive
These are systems where cattle are exposed to any combination of both intensive and extensive husbandry methods, either simultaneously, or varied in accordance with changes in climatic conditions or physiological state of the cattle.

Article 7.9.4.

Criteria or measurables for the welfare of beef cattle

The following outcome-based measurables, specifically animal-based measurables, can be useful indicators of *animal welfare*. The use of these indicators and the appropriate thresholds should be adapted to the different situations where beef cattle are managed. Consideration should also be given to the design of the system.

1. Behaviour
Certain behaviours could indicate an *animal welfare* problem. These include decreased *feed* intake, increased respiratory rate or panting (assessed by panting score), and the demonstration of stereotypic, aggressive, depressive or other abnormal behaviours.

2. Morbidity rates

Morbidity rates, including disease, lameness, post-procedural complication and injury rates, above recognised thresholds may be direct or indirect indicators of the *animal welfare* status of the whole *herd*. Understanding the aetiology of the disease or syndrome is important for detecting potential *animal welfare* problems. Scoring systems, such as lameness scoring, can provide additional information.

Post-mortem examination is useful to establish causes of *death* in cattle. Both clinical and post-mortem pathology could be utilised as an indicator of disease, injuries and other problems that may compromise *animal welfare*.

3. Mortality rates

Mortality rates, like morbidity rates, may be direct or indirect indicators of the *animal welfare* status. Depending on the production system, estimates of mortality rates can be obtained by analysing causes of *death* and the rate and temporo-spatial pattern of mortality. Mortality rates should be recorded regularly, i.e. daily, monthly, annually or with reference to key husbandry activities within the production cycle.

4. Changes in weight and body condition

In growing animals, weight gain may be an indicator of animal health and *animal welfare*. Poor body condition and significant weight loss may be an indicator of compromised welfare.

5. Reproductive efficiency

Reproductive efficiency can be an indicator of animal health and *animal welfare* status. Poor reproductive performance can indicate *animal welfare* problems. Examples may include:

- anoestrus or extended post-partum interval,
- low conception rates,
- high abortion rates,
- high rates of dystocia.

6. Physical appearance

Physical appearance may be an indicator of animal health and *animal welfare*, as well as the conditions of management. Attributes of physical appearance that may indicate compromised welfare include:

- presence of ectoparasites,
- abnormal coat colour or texture or excessive soiling with faeces, mud or dirt,
- dehydration,
- emaciation.

7. Handling responses

Improper handling can result in fear and distress in cattle. Indicators could include:

- chute or race exit speed,
- chute or race behaviour score,
- percentage of animals slipping or falling,
- percentage of animals moved with an electric goad,
- percentage of animals striking fences or gates,
- percentage of animals injured during handling, such as broken horns, broken legs, and lacerations,
- percentage of animals vocalizing during restraint.

8. Complications due to routine procedure management

Surgical and non-surgical procedures are commonly performed in beef cattle for improving animal performance, facilitating management, and improving human safety and *animal welfare*. However, if these procedures are not performed properly, *animal welfare* can be compromised. Indicators of such problems could include:

- post procedure *infection* and swelling,
- myiasis,
- mortality.

Article 7.9.5.

Recommendations

Each recommendation includes a list of relevant outcome-based measurables derived from Article 7.9.4. This does not exclude other measures being used where appropriate.

1. Biosecurity and animal health

a) Biosecurity and disease prevention

Biosecurity means a set of measures designed to maintain a *herd* at a particular health status and to prevent the entry or spread of pathogenic agents.

Biosecurity plans should be designed and implemented, commensurate with the desired *herd* health status and current disease risk and, for OIE *listed diseases* in accordance with relevant recommendations found in the *Terrestrial Code*.

These *biosecurity plans* should address the control of the major sources and pathways for spread of pathogenic agents:

- i) cattle,
- ii) other animals,
- iii) people,
- iv) equipment,
- v) vehicles,
- vi) air,
- vii) water supply,
- viii) *feed*.

Outcome-based measurables: morbidity rate, mortality rate, reproductive efficiency, changes in weight and body condition.

b) Animal health management

Animal health management means a system designed to optimise the physical and behavioural health and welfare of the cattle *herd*. It includes the prevention, treatment and control of diseases and conditions affecting the *herd*, including the recording of illnesses, injuries, mortalities and medical treatments where appropriate.

There should be an effective programme for the prevention and treatment of diseases and conditions consistent with the programmes established by a qualified *veterinarian* as appropriate.

Those responsible for the care of cattle should be aware of the signs of ill-health or distress, such as reduced *feed* and water intake, changes in weight and body condition, changes in behaviour or abnormal physical appearance.

Cattle at higher risk of disease or distress will require more frequent inspection by *animal handlers*. If *animal handlers* are not able to correct the causes of ill-health or distress or if they suspect the presence of a listed reportable disease they should seek advice from those having training and experience, such as *veterinarians* or other qualified advisers.

Vaccinations and other treatments administered to cattle should be undertaken by people skilled in the procedures and on the basis of veterinary or other expert advice.

Animal handlers should have experience in recognising and dealing with non-ambulatory cattle. They should also have experience in managing chronically ill or injured cattle.

Non-ambulatory cattle should have access to water at all times and be provided with *feed* at least once daily. They should not be transported or moved unless absolutely necessary for treatment or diagnosis. Such movements should be done carefully using methods avoiding dragging or excessive lifting.

When treatment is attempted, cattle that are unable to stand up unaided and refuse to eat or drink should be killed humanely in accordance with Chapter 7.5. as soon as recovery is deemed unlikely.

Outcome-based measurables: morbidity rate, mortality rate, reproductive efficiency, behaviour, physical appearance, and changes in weight and body condition.

2. Environment

a) Thermal environment

Although cattle can adapt to a wide range of thermal environments particularly if appropriate breeds are used for the anticipated conditions, sudden fluctuations in weather can cause heat or cold stress.

i) Heat stress

The risk of heat stress for cattle is influenced by environmental factors including air temperature, relative humidity and wind speed, and animal factors including breed, age, body condition, metabolic rate and coat colour and density.

Animal handlers should be aware of the risk that heat stress poses to cattle. If conditions are expected to induce heat stress, routine daily activities that require moving cattle should cease. If the risk of heat stress reaches very high levels the *animal handlers* should institute an emergency action plan that could include reduction of stocking density, provision of shade, free access to drinking water, and cooling by the use of sprinkled water that penetrates the hair coat.

Outcome-based measurables: behaviour, including panting score and respiratory rate, morbidity rate, mortality rate.

ii) Cold stress

Protection from extreme weather conditions should be provided when these conditions are likely to create a serious risk to the welfare of cattle, particularly in neonates and young cattle and others that are physiologically compromised. This could be provided by natural or man-made shelter structures.

Animal handlers should also ensure that cattle have access to adequate *feed* and water during cold stress. During extreme cold weather conditions, *animal handlers* should institute an emergency action plan to provide cattle with shelter, appropriate *feed* and water.

Outcome-based measurables: mortality rates, physical appearance, behaviour including abnormal postures, shivering and huddling.

b) Lighting

Confined cattle that do not have access to natural light should be provided with supplementary lighting which follow natural periodicity sufficient for their health and welfare, to facilitate natural behaviour patterns and to allow adequate inspection of the cattle.

Outcome-based measurables: behaviour, morbidity, physical appearance.

c) Air quality

Good air quality is an important factor for the health and welfare of cattle. It is affected by air constituents such as gases, dust and micro-organisms, and is strongly influenced by management, particularly in intensive systems. The air composition is influenced by the stocking density, the size of the cattle, flooring, bedding, waste management, building design and ventilation system.

Proper ventilation is important for effective heat dissipation in cattle and preventing the buildup of NH₃ and effluent gases in the confinement unit. Poor air quality and ventilation are risk factors for respiratory discomfort and diseases. The ammonia level in enclosed housing should not exceed 25 ppm.

Outcome-based measurables: morbidity rate, behaviour, mortality rate, changes in weight and body condition.

d) Noise

Cattle are adaptable to different levels and types of noise. However, exposure of cattle to sudden or loud noises should be minimised where possible to prevent stress and fear reactions (e.g. stampede). Ventilation fans, feeding machinery or other indoor or outdoor equipment should be constructed, placed, operated and maintained in such a way that they cause the least possible amount of noise.

Outcome-based measurables: behaviour.

e) Nutrition

The nutrient requirements of beef cattle have been well defined. Energy, protein, mineral and vitamin contents of the diet are major factors determining the growth, feed efficiency, reproductive efficiency, and body composition.

Cattle should be provided with access to an appropriate quantity and quality of balanced nutrition that meets their physiological needs. Where cattle are maintained in extensive conditions, short term exposure to climatic extremes may prevent access to nutrition that meets their daily physiological needs. In such circumstances the *animal handler* should ensure that the period of reduced nutrition is not prolonged and that mitigation strategies are implemented if welfare is at risk of being compromised.

Animal handlers should have adequate knowledge of appropriate body condition for their cattle and should not allow body condition to fall outside an acceptable range. If supplementary *feed* is not available, steps should be taken to avoid starvation, including *slaughter*, sale or relocation of the cattle, or humane *killing*.

Feedstuffs and *feed ingredients* should be of satisfactory quality to meet nutritional needs. Where appropriate, *feed* and *feed ingredients* should be tested for the presence of substances that would adversely impact on animal health.

Cattle in intensive production systems typically consume diets that contain a high proportion of grain(s) (corn, milo, barley, grain by-products) and a smaller proportion of roughages (hay, straw, silage, hulls, etc.). Diets with insufficient roughage can contribute to abnormal oral behaviour in finishing cattle, such as tongue rolling. As the proportion of grain increases in the diet, the relative risk of digestive upset in cattle increases. *Animal handlers* should understand the impact of cattle size and age, weather patterns, diet composition and sudden dietary changes in respect to digestive upsets and their negative consequences (acidosis, bloat, liver abscess, laminitis). Where appropriate beef producers should consult a cattle nutritionist for advice on ration formulation and feeding programmes.

Beef producers should become familiar with potential micronutrient deficiencies or excesses for intensive and extensive production systems in their respective geographical areas and use appropriately formulated supplements where necessary.

All cattle need an adequate supply and access to palatable water that meets their physiological requirements and is free from contaminants hazardous to cattle health.

Outcome-based measurables: mortality rates, morbidity rates, behaviour, changes in weight and body condition, reproductive efficiency.

f) Flooring, bedding, resting surfaces and outdoor areas

In all production systems cattle need a well-drained and comfortable place to rest. All cattle in a group should have sufficient space to lie down and rest at the same time.

Pen floor management in intensive production systems can have a significant impact on cattle welfare. Where there are areas that are not suitable for resting such as excessive water and faecal accumulation, these areas should not be of a depth that would compromise welfare and should not comprise the whole of usable area available to the cattle.

Slopes of pens should be maintained to allow water to drain away from *feed* troughs and not pool excessively in the pens.

Pens should be cleaned as conditions warrant and, at a minimum, after each production cycle.

If cattle are kept on a slatted floor, the slat and gap widths should be appropriate to the hoof size of the cattle to prevent injuries. Wherever possible, cattle on slatted floor should have access to a bedded area.

In straw or other bedding systems, the bedding should be maintained to provide cattle with a dry and comfortable place in which to lie.

Surfaces of concrete alleys should be grooved or appropriately textured to provide adequate footing for cattle.

Outcome-based measurables: morbidity rates (e.g. lameness, pressure sores), behaviour, changes in weight and body condition, and physical appearance.

g) Social environment

Management of cattle should take into account the social environment as it relates to *animal welfare*, particularly in intensive systems. Problem areas include: agonistic and mounting activity, mixing of heifers and

steers, feeding cattle of different size and age in the same pens, high stocking density, insufficient space at the feeder, insufficient water access and mixing of bulls.

Management of cattle in all systems should take into account the social interactions of cattle within groups. The *animal handler* should understand the dominance hierarchies that develop within different groups and focus on high risk animals, such as very young, very old, small or large size for cohort group, for evidence of bullying and excessive mounting behaviour. The *animal handler* should understand the risks of increased agonistic interactions between animals, particularly after mixing groups. Cattle that are suffering from excessive agonistic activity or mounting behaviour should be removed from the group.

Horned and non-horned cattle should not be mixed because of the risk of injury.

Adequate fencing should be provided to minimise any *animal welfare* problems that may be caused by mixing of inappropriate groups of cattle.

Outcome-based measurables: behaviour, physical appearance, changes in weight and body condition, morbidity and mortality rate.

h) Stocking density

High stocking densities may increase the occurrence of injuries and have an adverse effect on growth rate, feed efficiency and behaviour, such as locomotion, resting, feeding and drinking.

Stocking density should be managed such that crowding does not adversely affect normal behaviour of cattle. This includes the ability to lie down freely without the risk of injuries, move freely around the pen and access *feed* and water. Stocking density should also be managed such that weight gain and duration of time spent lying is not adversely affected by crowding. If abnormal behaviour is seen, measures should be taken such as reducing stocking density.

In extensive systems, stocking density should be matched to the available *feed* supply.

Outcome-based measurables: behaviour, morbidity rate, mortality rate, changes in weight and body condition, physical appearance.

i) Protection from predators

Cattle should be protected as much as possible from predators.

Outcome-based measurables: mortality rate, morbidity rate (injury rate), behaviour, physical appearance.

3. Management

a) Genetic selection

Welfare and health considerations, in addition to productivity, should be taken into account when choosing a breed or subspecies for a particular location or production system. Examples of these include nutritional maintenance requirement, ectoparasite resistance and heat tolerance.

Individual animals within a breed can be genetically selected to propagate offspring that exhibit traits beneficial to animal health and welfare. These include maternal instincts, ease of calving, birth weight, milking ability, body conformation and temperament.

Outcome-based measurables: morbidity rate, mortality rate, behaviour, physical appearance, reproductive efficiency.

b) Reproductive management

Dystocia can be a welfare risk to beef cattle. Heifers should not be bred before they are physically mature enough to ensure the health and welfare of both dam and calf at birth. The sire has a highly heritable effect on final calf size and as such can have a significant impact on ease of calving. Sire selection should therefore account for the maturity and size of the female. Heifers and cows should not be implanted, inseminated or mated in such a way that the progeny results in increased risk to dam and calf welfare.

Pregnant cows and heifers should be managed during pregnancy so as not to become too fat or too thin. Excessive fatness increases the risk of dystocia, and both excessive condition gain and loss increase the risk of metabolic disorders during late pregnancy or after parturition.

Where possible, cows and heifers should be monitored when they are close to calving. Animals observed to be having difficulty in calving should be assisted by a competent handler as soon as possible after they are detected.

Outcome-based measurables: morbidity rate (rate of dystocia), mortality rate (cow and calf), reproductive efficiency.

c) Colostrum

Receiving adequate immunity from colostrum generally depends on the volume and quality of colostrum ingested, and how soon after birth the calf receives it.

Where possible, *animal handlers* should ensure that calves receive sufficient colostrum within 24 hours of birth.

Outcome-based measurables: mortality rate, morbidity rate, changes in weight.

d) Weaning

For the purposes of this chapter, weaning means the transfer of the calf from a milk-based diet to a fibrous diet. In beef cattle production systems, weaning can be a stressful time in the calf's life.

Calves should be weaned only when their ruminant digestive system has developed sufficiently to enable them to maintain growth and welfare.

There are different weaning strategies utilised in the beef cattle production systems. These include abrupt separation, fence line separation and the use of devices placed in the nose of the calf to discourage suckling.

Special care should be taken if abrupt weaning is immediately followed by additional stressors such as transportation, as calves are at risk of increased morbidity under these circumstances.

If necessary, beef cattle producers should seek expert advice on the most appropriate time and method of weaning for their type of cattle and production system.

Outcome-based measurables: morbidity rate, mortality rate, behaviour, physical appearance, changes in weight and body condition.

e) Painful husbandry procedures

Husbandry practices that have the potential to cause pain are routinely practiced on cattle for reasons of production efficiency, animal health and welfare and human safety. These procedures should be performed in such a way as to minimise any pain and stress to the animal. These procedures should be performed at as early an age as possible or using anaesthesia or analgesia under the recommendation or supervision of a *veterinarian*.

Future options for enhancing *animal welfare* in relation to these procedures include: ceasing the procedure and addressing the current need for the operation through management strategies; breeding cattle that do not require the procedure; or replacing the current procedure with a non-surgical alternative that has been shown to enhance *animal welfare*.

Example of such interventions include: castration, dehorning, ovariectomy (spaying), tail docking, identification.

i) Castration

Castration of beef cattle is performed in many production systems to reduce inter-animal aggression, improve human safety, avoid the risk of unwanted pregnancies in the *herd*, and enhance production efficiency.

Where it is necessary to castrate beef cattle, producers should seek guidance from *veterinarians* as to the optimum method and timing for their type of cattle and production system.

Methods of castration used in beef cattle include surgical removal of the testes, ischaemic methods, and crushing and disruption of the spermatic cord.

Where practical, cattle should be castrated before the age of three months, or at the first available handling opportunity beyond this age using the method available that causes least pain or suffering to the animal.

Producers should seek guidance from *veterinarians* on the availability and advisability of analgesia or anaesthesia for castration of beef cattle, particularly in older animals.

Operators performing castration of beef cattle should be trained and competent in the procedure used, and be able to recognise the signs of complications.

ii) Dehorning (including disbudding)

Beef cattle are commonly dehorned in order to reduce animal injuries and hide damage, improve human safety, reduce damage to facilities and facilitate transport and handling. Where practical and appropriate for the production system, the selection of polled cattle is preferable to dehorning.

Where it is necessary to dehorn beef cattle, producers should seek guidance from veterinary advisers as to the optimum method and timing for their type of cattle and production system.

Where practical, cattle should be dehorned while horn development is still at the horn bud stage, or at the first available handling opportunity beyond this age. This is because the procedure involves less tissue trauma when horn development is still at the horn bud stage, and there is no attachment of horn to the skull of the animal.

Methods of dehorning (disbudding) at the horn bud stage include removal of the horn buds with a knife, thermal cautery of the horn buds, or the application of chemical paste to cauterise the horn buds.

Methods of dehorning when horn development has commenced involve the removal of the horn by cutting or sawing through the base of the horn close to the skull.

Producers should seek guidance from *veterinarians* on the availability and advisability of analgesia or anaesthesia for dehorning of beef cattle, particularly in older animals, where horn development is more advanced.

Operators performing dehorning of beef cattle should be trained and competent in the procedure used, and be able to recognise the signs of complications.

iii) Ovariectomy (spaying)

Ovariectomy of heifers is sometimes required to prevent unwanted pregnancies under extensive rangeland conditions. Surgical spaying should be performed by *veterinarians* or by highly trained operators. Producers should seek guidance from *veterinarians* on the availability and advisability of analgesia or anaesthesia for spaying of beef cattle. The use of analgesia or anaesthesia should be encouraged.

iv) Tail docking

Tail docking has been performed in beef cattle to prevent tail tip necrosis in confinement operations. Research shows that increasing space per animal and proper bedding are effective in preventing tail tip necrosis. Therefore it is not recommended for producers to dock the tails of beef cattle.

v) Identification

Ear-tagging, ear-notching, tattooing, freeze branding and radio frequency identification devices (RFID) are preferred methods of permanently identifying beef cattle from an *animal welfare* standpoint. In some situations however hot iron branding may be required or be the only practical method of permanent identifying beef cattle. If cattle are branded, it should be accomplished quickly, expertly and with the proper equipment. Identification systems should be established also in accordance with Chapter 4.1.

Outcome-based measurables: postprocedural complication rate, morbidity rate, behaviour, physical appearance, changes in weight and body condition.

f) Handling and inspection

Beef cattle should be inspected at intervals appropriate to the production systems and the risks to the health and welfare of the cattle. In intensive farming systems, cattle should be inspected at least once a day.

Some animals may benefit from more frequent inspection for example: neonatal calves, cows in late gestation, newly weaned calves, and cattle experiencing environmental stress and those that have undergone painful husbandry or veterinary surgical procedures.

Animal handlers need to be competent in recognising the clinical signs of health, disease and welfare of beef cattle. There should be a sufficient number of *animal handlers* to adequately ensure the health and welfare of the cattle.

Beef cattle identified as sick or injured should be given appropriate treatment at the first available opportunity by competent and trained *animal handlers*. If *animal handlers* are unable to provide appropriate treatment, the services of a *veterinarian* should be sought.

If the animal's condition suggests the prognosis is poor with little chance of recovery, the animal should be humanely killed as soon as possible. For a description of methods for the humane *killing* of beef cattle see Article 7.6.5.

Recommendations on the handling of cattle are also found in Chapter 7.5.

Where beef cattle are herded into a handling facility from extensive conditions, they should be moved quietly and calmly at the pace of the slowest animal. Weather conditions should be taken into account and cattle should not be herded in excessively hot or cold conditions. Cattle should not be driven to the point of distress. In situations where the gathering and handling of the cattle is likely to be stressful, consideration should be given to the avoidance of multiple handling events by combining necessary management procedures within the one handling event. Where handling itself is not stressful, management procedures should be staged over time to avoid additive stress of multiple procedures.

Properly trained dogs can be effective aids for cattle herding. Cattle are adaptable to different visual environments. However, exposure of cattle to sudden or persistent movement or visual contrasts should be minimised where possible to prevent stress and fear reactions.

Electroimmobilisation should not be used.

Outcome-based measurables: handling response, morbidity rate, mortality rate, behaviour, reproductive efficiency, changes in weight and body condition.

g) Personnel training

All people responsible for beef cattle should be competent in accordance with their responsibilities and should understand cattle husbandry, behaviour, *biosecurity*, general signs of disease, and indicators of poor *animal welfare* such as stress, pain and discomfort, and their alleviation.

Competence may be gained through formal training or practical experience.

Outcome-based measurables: handling response, morbidity rate, mortality rate, behaviour, reproductive efficiency, changes in weight and body condition.

h) Emergency plans

Where the failure of power, water and *feed* supply systems could compromise *animal welfare*, beef producers should have contingency plans to cover the failure of these systems. These plans may include the provision of fail-safe alarms to detect malfunctions, backup generators, access to maintenance providers, ability to store water on farm, access to water cartage services, adequate on-farm storage of *feed* and alternative *feed* supply.

Plans should be in place to minimise and mitigate the effects of natural disasters or extreme climatic conditions, such as heat stress, drought, blizzard, fire and flooding. Humane *killing* procedures for sick or injured cattle should be part of the emergency action plan. In times of drought, animal management decisions should be made as early as possible and these should include a consideration of reducing cattle numbers. Emergency plans should also cover the management of the farm in the face of an emergency disease *outbreak*, consistent with national programmes and recommendations of *Veterinary Services* as appropriate.

i) Location, construction and equipment

Farms for beef cattle should be situated in an appropriate geographical location for the health, welfare and productivity of the cattle.

All facilities for beef cattle should be constructed, maintained and operated to minimise the risk to the welfare of the cattle.

Equipment for handling and restraining beef cattle should only be used in a way that minimises the risk of injury, pain or distress.

Cattle in intensive or extensive production systems should be offered adequate space for comfort and socialisation.

Cattle that are kept tethered should, as a minimum, be able to lie down, and if tethered outdoors, turn around and walk.

In intensive production systems the feeder should be sufficiently large so that cattle have adequate access to *feed* and they should be clean and free of spoiled, mouldy, sour, packed or unpalatable *feed*. Also cattle should have access to water at all times.

Floors in housing facilities should be properly drained, and barns and races and chutes should provide traction to prevent injuries to cattle.

Races, chutes and pens should be free from sharp edges and protrusions to prevent injury to cattle.

Alleys and gates should be designed and operated to avoid impeding cattle movement. Slippery surfaces should be avoided. Grooved concrete, metal grating (not sharp), rubber mats or deep sand can be used to minimise slipping and falling. Quiet handling is essential to minimise slipping. When gates and catches are operated, excessive noise should be minimised, because it may cause distress to the cattle.

Hydraulic, pneumatic and manual restraining equipment should be adjusted, as appropriate, to the size of cattle to be handled. Hydraulic and pneumatic operated restraining equipment should have pressure limiting devices to prevent injuries. Regular cleaning and maintenance of working parts is imperative to ensure the system functions properly and is safe for the cattle.

Mechanical and electrical devices used in housing facilities should be safe for cattle.

Dipping baths are sometimes used in beef cattle production for ectoparasite control. Where these are used, they should be designed and operated to minimise the risk of crowding to prevent injury and drowning.

The loading of the cattle at the farms should be conducted accordingly to Chapters 7.2., 7.3. and 7.4.

Outcome-based measurables: handling response, morbidity rate, mortality rate, behaviour, changes in weight and body condition, physical appearance, lameness.

j) Humane killing

For sick and injured cattle a prompt diagnosis should be made to determine whether the animal should be humanely killed or receive additional care.

The decision to humanely kill an animal and the procedure itself should be undertaken by a competent person.

Reasons for humane *killing* may include:

- i) severe emaciation, weak cattle that are non-ambulatory or at risk of becoming downers;
- ii) non-ambulatory cattle that will not stand up, refuse to eat or drink, have not responded to therapy;
- iii) rapid deterioration of a medical condition for which therapies have been unsuccessful;
- iv) severe, debilitating pain;
- v) compound (open) fracture;
- vi) spinal injury;
- vii) central nervous system disease; and
- viii) multiple joint *infections* with chronic weight loss.

For a description of methods for the humane *killing* of beef cattle see Article 7.6.5.

NB: FIRST ADOPTED IN 2012; MOST RECENT UPDATE ADOPTED IN 2013.

CHAPTER 7.10.

ANIMAL WELFARE AND BROILER CHICKEN PRODUCTION SYSTEMS

Article 7.10.1.

Definitions

For the purpose of this chapter:

Broiler: means a bird of the species *Gallus gallus* kept for commercial *meat* production. *Poultry* kept in village or backyard *flocks* are not included.

Harvesting: means the catching and *loading* of birds on farm for transportation to the *slaughterhouse/abattoir*.

Article 7.10.2.

Scope

This chapter covers the production period from arrival of *day-old birds* on the farm to harvesting the broilers in commercial production systems. Such systems involve confinement of the birds, the application of biosecurity measures, and trade in the products of those birds, regardless of scale of production. These recommendations cover broilers kept in cages, on slatted floors, litter or dirt and indoors or outdoors.

Broiler production systems include:

1. Completely housed system

Broilers are completely confined in a poultry house, with or without environmental control.

2. Partially housed system

Broilers are kept in a poultry house with access to a restricted outdoor area.

3. Completely outdoors system

Broilers are not confined inside a poultry house at any time during the production period but are confined in a designated outdoor area.

This chapter should be read in conjunction with Chapters 7.2., 7.3. and 7.4. on the welfare of broilers during transport to the *slaughterhouse/abattoir*.

Article 7.10.3.

Criteria or measurables for the welfare of broilers

The welfare of broilers should be assessed using outcome-based measurables. Consideration should also be given to the resources provided and the design of the system. The following outcome-based measurables, specifically animal-based measurables, can be useful indicators of *animal welfare*. The use of these indicators and the appropriate thresholds should be adapted to the different situations where broilers are managed, also taking into account the strain of bird concerned.

Some criteria can be measured in the farm setting, such as gait, mortality and morbidity rates, while others are best measured at the *slaughterhouse/abattoir*. For example, at *slaughter flocks* can be assessed for presence of bruising, broken limbs and other injuries. The age of these lesions can help to determine the source. Back scratching and contact dermatitis and breast blisters are also easily observed at the *slaughterhouse/abattoir*. Other conditions such as ascites,

leg deformities, dehydration and disease conditions can also be assessed at *slaughter*. It is recommended that values for welfare measurables be determined with reference to appropriate national, sectoral or perhaps regional norms for commercial broiler production.

The following outcome-based criteria and measurables are useful indicators of broiler welfare:

1. Mortality, culling and morbidity

Daily, weekly and cumulative mortality, culling and morbidity rates should be within expected ranges. Any unforeseen increase in these rates could reflect an *animal welfare* problem.

2. Gait

Broilers are susceptible to developing a variety of infectious and non-infectious musculoskeletal disorders. These disorders may lead to lameness and to gait abnormalities. Broilers that are lame or have gait abnormalities may have difficulty reaching the food and water, may be trampled by other broilers, and may experience pain. Musculoskeletal problems have many causes, including genetics, nutrition, sanitation, lighting, litter quality, and other environmental and management factors. There are several gait scoring systems available.

3. Contact dermatitis

Contact dermatitis affects skin surfaces that have prolonged contact with wet litter or other wet flooring surfaces. The condition is manifested as blackened skin progressing to erosions and fibrosis on the lower surface of the foot pad, at the back of the hocks, and sometimes in the breast area. If severe, the foot and hock lesions may contribute to lameness and lead to secondary *infections*. Validated scoring systems for contact dermatitis have been developed for use in *slaughterhouse/abattoir*.

4. Feather condition

Evaluation of the feather condition of broilers provides useful information about aspects of welfare. Plumage dirtiness is correlated with contact dermatitis and lameness for individual birds or may be associated with the environment and production system. Plumage dirtiness can be assessed as part of on-farm inspections, at the time of harvesting or prior to plucking. A scoring system has been developed for this purpose.

5. Incidence of diseases, metabolic disorders and parasitic infestations

Ill-health, regardless of the cause, is a welfare concern, and may be exacerbated by poor environmental or husbandry management.

6. Behaviour

a) Fear behaviour

Fearful broilers show avoidance of humans, and this behaviour is seen in *flocks* where *animal handlers* walk through the poultry house quickly when performing their tasks rather than moving more slowly while interacting with the broilers. Fearfulness (e.g. of sudden loud noises) can also lead to the broilers piling on top of, and even suffocating, one another. Fearful broilers may be less productive. Validated methods have been developed for evaluating fearfulness.

b) Spatial distribution

Changes in the spatial distribution (e.g. huddling) of the birds may indicate thermal discomfort or the existence of areas of wet litter or uneven provision of light, food or water.

c) Panting and wing spreading

Excessive panting and wing spreading indicates heat stress or poor air quality, such as high levels of ammonia.

d) Dust bathing

Dust bathing is an intricate body maintenance behaviour performed by many birds, including broilers. During dust bathing, broilers work loose material, such as litter, through their feathers. Dust bathing helps to keep the feathers in good condition, which in turns helps to maintain body temperature and protect against skin injury. Reduced dust bathing behaviour in the *flock* may indicate problems with litter or range quality, such as litter or ground being wet or not friable.

e) Feeding, drinking and foraging

Reduced feeding or drinking behaviour can indicate management problems, including inadequate feeder or drinker space or placement, dietary imbalance, poor water quality, or *feed* contamination. Feeding and drinking behaviour are often depressed when broilers are ill, and intake may be also reduced during periods of heat stress and increased during cold stress. Foraging is the act of searching for food, typically by walking and pecking or scratching the litter substrate; reduced foraging activity could suggest problems with litter quality or presence of conditions that decrease bird movement.

f) Feather pecking and cannibalism

Feather pecking can result in significant feather loss and may lead to cannibalism. Cannibalism is the tearing of the flesh of another bird, and can result in severe injury. These abnormal behaviours have multi-factorial causes.

7. Water and feed consumption

Monitoring daily water consumption is a useful tool to indicate disease and other welfare conditions, taking into consideration ambient temperature, relative humidity, *feed* consumption and other related factors. Problems with the water supply can result in wet litter, diarrhoea, dermatitis or dehydration.

Changes in *feed* consumption can indicate unsuitability of *feed*, the presence of disease or other welfare problems.

8. Performance

- a) Growth rate (gr) - an index that indicates the average daily gain of weight per average broiler of a *flock*.
- b) Feed conversion - an index that measures the quantity of *feed* consumed by a *flock* relative to the total live weight harvested, expressed as the weight of *feed* required to produce one kg of broiler body weight.
- c) Liveability - an index that indicates the percentage of broilers present at the end of the production period. More commonly this indicator is measured as its opposite, mortality.

9. Injury rate

The rate of these injuries can indicate welfare problems in the *flock* during production or harvesting. Injuries include those due to other broilers (scratches, feather loss or wounding due to feather pecking and cannibalism) and those due to environmental conditions, such as skin lesions (e.g. contact dermatitis) and those due to human intervention, such as catching. The most prevalent injuries seen during catching are bruises, broken limbs, dislocated hips, and damaged wings.

10. Eye conditions

Conjunctivitis can indicate the presence of irritants such as dust and ammonia. High ammonia levels can also cause corneal burns and eventual blindness. Abnormal eye development can be associated with low light intensity.

11. Vocalisation

Vocalisation can indicate emotional states, both positive and negative. Interpretation of *flock* vocalisations is possible by experienced *animal handlers*.

Article 7.10.4.

Recommendations

1. Biosecurity and animal health

a) Biosecurity and disease prevention

Biosecurity programmes should be designed and implemented, commensurate with the best possible *flock* health status and current disease risk (endemic and exotic or transboundary) that is specific to each epidemiological group of broilers and in accordance with relevant recommendations in the *Terrestrial Code*. These programmes should address the control of the major routes for transmission of diseases and pathogenic agents:

- i) direct transmission from other *poultry*, domesticated and wild animals and humans,
- ii) fomites, such as equipment, facilities and *vehicles*,
- iii) *vectors* (e.g. arthropods and rodents),
- iv) aerosols,
- v) water supply,
- vi) *feed*.

Outcome-based measurables: incidence of diseases, metabolic disorders and parasitic *infestations*, mortality, performance.

b) Animal health management, preventive medicine and veterinary treatment

Those responsible for the care of broilers should be aware of the signs of ill-health or distress, such as a change in *feed* and water intake, reduced growth, changes in behaviour, abnormal appearance of feathers, faeces, or other physical features.

If persons in charge are not able to identify the causes of diseases, ill-health or distress, or to correct these, or if they suspect the presence of a reportable disease, they should seek advice from *veterinarians* or other qualified advisers. Veterinary treatments should be prescribed by a *veterinarian*.

There should be an effective programme for the prevention and treatment of diseases consistent with the programmes established by *Veterinary Services* as appropriate.

Vaccinations and treatments should be administered, on the basis of veterinary or other expert advice, by personnel skilled in the procedures and with consideration for the welfare of the broilers.

Sick or injured broilers should be humanely killed as soon as possible. Similarly, killing broilers for diagnostic purposes should be done in a humane manner in accordance with Chapter 7.6.

Outcome-based measurables: incidence of diseases, metabolic disorders and parasitic *infestations*, mortality, performance, gait.

2. Environment and management

a) Thermal environment

Thermal conditions for broilers should be appropriate for their stage of development, and extremes of heat, humidity and cold should be avoided. For the growing stage, a heat index can assist in identifying the comfort zones for the broilers at varying temperature and relative humidity levels.

When environmental conditions move outside these zones, strategies should be used to mitigate the adverse effects on the broilers. These may include adjusting air speed, provision of heat, evaporative cooling and adjusting stocking density.

Management of the thermal environment should be checked frequently enough so that failure of the system would be noticed before it caused a welfare problem.

Outcome-based measurables: behaviour, mortality, contact dermatitis, water and *feed* consumption, performance, feather condition.

b) Lighting

There should be an adequate period of continuous light.

The light intensity during the light period should be sufficient and homogeneously distributed to allow the broilers to find *feed* and water after they are placed in the poultry house, to stimulate activity, and allow adequate inspection.

There should also be an adequate period of continuous darkness during each 24-hour period to allow the broilers to rest, to reduce stress and to promote normal behaviour, gait and good leg health.

There should be a period for gradual adjustment to lighting changes.

Outcome-based measurables: gait, metabolic disorders, performance, behaviour, eye condition, injury rate.

c) Air quality

Adequate ventilation is required at all times to provide fresh air, to remove waste gases such as carbon dioxide and ammonia, dust and excess moisture content from the environment.

Ammonia concentration should not routinely exceed 25 ppm at broiler level.

Dust levels should be kept to a minimum. Where the health and welfare of broilers depend on an artificial ventilation system, provision should be made for an appropriate back-up power and alarm system.

Outcome-based measurables: incidence of respiratory diseases, metabolic disorders, eye conditions, performance, contact dermatitis and behaviour.

d) Noise

Broilers are adaptable to different levels and types of noise. However, exposure of broilers to sudden or loud noises should be minimised where possible to prevent stress and fear reactions, such as piling. Ventilation fans, feeding machinery or other indoor or outdoor equipment should be constructed, placed, operated and maintained in such a way that they cause the least possible amount of noise.

Location of farms should, where possible, take into account existing local sources of noise.

Outcome-based measurables: daily mortality rate, morbidity, performance, injury rate, fear behaviour.

e) Nutrition

Broilers should always be fed a diet appropriate to their age and genetics, which contains adequate nutrients to meet their requirements for good health and welfare.

Feed and water should be acceptable to the broilers and free from contaminants at a concentration hazardous to broiler health.

The water system should be cleaned regularly to prevent growth of hazardous microorganisms.

Broilers should be provided with adequate access to *feed* on a daily basis. Water should be available continuously. Special provision should be made to enable young chicks access to appropriate *feed* and water.

Broilers that are physically unable to access *feed* or water should be humanely killed as soon as possible.

Outcome-based measurables: *feed* and water consumption, performance, behaviour, gait, incidence of diseases, metabolic disorders and parasitic *infestations*, mortality, injury rate.

f) Flooring, bedding, resting surfaces and litter quality

The floor of a poultry house should preferably be easy to clean and disinfect.

The provision of loose and dry bedding material is desirable in order to insulate the chicks from the ground and to encourage dust bathing and foraging.

Litter should be managed to minimise any detrimental effects on welfare and health. Poor litter quality can lead to contact dermatitis and breast blisters. Litter should be replaced or adequately treated when required to prevent diseases in the next *flock*.

Litter quality is partly related to the type of substrate used and partly to different management practices. The type of substrate should be chosen carefully. Litter should be maintained so that it is dry and friable and not dusty, caked or wet. Poor litter quality can result from a range of factors including water spillage, inappropriate *feed* composition, enteric *infections*, poor ventilation and overcrowding.

If broilers are kept on slatted floors, where a very humid climate precludes the use of other flooring substrates, the floors should be designed, constructed and maintained to adequately support the broilers, prevent injuries and ensure that manure can fall through or be adequately removed.

To prevent injury and keep them warm, *day-old birds* should be placed on an appropriate type of flooring suitable for their size.

If *day-old birds* are housed on litter, before they enter the poultry house, a layer of uncontaminated substrate, such as wood shavings, straw, rice husk, shredded paper, treated used litter should be added to a sufficient depth to allow normal behaviour and to separate them from the floor.

Outcome-based measurables: contact dermatitis, feather condition, gait, behaviour (dust bathing and foraging), eye conditions, incidence of diseases, metabolic disorders and parasitic *infestations*, performance.

g) Prevention of feather pecking and cannibalism

Feather pecking and cannibalism are rarely seen in broilers because of their young age. However, management methods, such as reducing light intensity, providing foraging materials, nutritional modifications, reducing stocking density, selecting the appropriate genetic stock should be implemented where feather pecking and cannibalism are a potential problem.

If these management strategies fail, therapeutic beak trimming is the last resort.

Outcome-based measurables: injury rate, behaviour, feather condition, mortality.

h) Stocking density

Broilers should be housed at a stocking density that allows them to access *feed* and water and to move and adjust their posture normally. The following factors should be taken into account: management capabilities,

ambient conditions, housing system, production system, litter quality, ventilation, *biosecurity* strategy, genetic stock, and market age and weight.

Outcome-based measurables: injury rate, contact dermatitis, mortality, behaviour, gait, incidence of diseases, metabolic disorders and parasitic *infestations*, performance, feather condition.

i) Outdoor areas

Broilers can be given access to outdoor areas as soon as they have sufficient feather cover and are old enough to range safely. There should be sufficient exit areas to allow them to leave and re-enter the poultry house freely.

Management of outdoor areas is important in partially housed and completely outdoors production systems. Land and pasture management measures should be taken to reduce the risk of broilers being infected by pathogenic agents or infested by parasites. This might include limiting the stocking density or using several pieces of land consecutively in rotation.

Outdoor areas should be placed on well drained ground and managed to minimise swampy conditions and mud.

Outdoor areas should provide shelter for broilers and be free from poisonous plants and contaminants.

Protection from adverse climatic conditions should be provided in completely outdoors systems.

Outcome-based measurables: behaviour, incidence of disease, metabolic disorders and parasitic *infestations*, performance, contact dermatitis, feather condition, injury rate, mortality, morbidity.

j) Protection from predators

Broilers should be protected from predators.

Outcome-based measurables: fear behaviour, mortality, injury rate.

k) Choice of broiler strain

Welfare and health considerations should balance any decisions on productivity and growth rate when choosing a broiler strain for a particular location or production system.

Outcome-based measurables: gait, metabolic disorders, contact dermatitis, mortality, behaviour, performance.

l) Painful interventions

Painful interventions, such as beak trimming, toe trimming and dubbing, should not be routinely practised on broilers.

If therapeutic beak trimming is required, it should be carried out by trained and skilled personnel at as early an age as possible and care should be taken to remove the minimum amount of beak necessary using a method which minimises pain and controls bleeding.

Surgical castration should not be performed without adequate pain and *infection* control methods and should only be performed by *veterinarians* or trained and skilled personnel under veterinary supervision.

Outcome-based measurables: mortality, culling and morbidity, behaviour.

m) Handling and inspection

Broilers should be inspected at least daily. Inspection should have three main objectives: to identify sick or injured broilers to treat or cull them, to detect and correct any welfare or health problem in the *flock*, and to pick up dead broilers.

Inspection should be done in such a way that broilers are not unnecessarily disturbed, for example *animal handlers* should move quietly and slowly through the *flock*.

When broilers are handled, they should not be injured or unnecessarily frightened or stressed.

Broilers which have an incurable illness, significant deformity or injury should be removed from the *flock* and killed humanely as soon as possible as described in Chapter 7.6.

Cervical dislocation is an accepted method for killing individual broilers if carried out competently as described in Article 7.6.17.

Outcome-based measurables: behaviour, performance, injury rate, mortality, vocalisation, morbidity.

n) Personnel training

All people responsible for the broilers should have received appropriate training or be able to demonstrate that they are competent to carry out their responsibilities and should have sufficient knowledge of broiler behaviour, handling techniques, emergency killing procedures, *biosecurity*, general signs of diseases, and indicators of poor *animal welfare* and procedures for their alleviation.

Outcome-based measurables: all measurables could apply.

o) Emergency plans

Broiler producers should have emergency plans to minimise and mitigate the consequences of natural disasters, disease *outbreaks* and the failure of mechanical equipment. Planning may include the provision of fail-safe alarm devices to detect malfunctions, backup generators, access to maintenance providers, alternative heating or cooling arrangements, ability to store water on farm, access to water cartage services, adequate on farm storage of *feed* and alternative *feed* supply and a plan for managing ventilation emergencies.

The emergency plans should be consistent with national programmes established or recommended by *Veterinary Services*. Humane *killing* procedures should be part of the emergency plan.

p) Location, construction and equipment of farms

The location of broiler farms should be chosen to be safe from the effects of fires and floods and other natural disasters to the extent practical. In addition farms should be sited to avoid or minimise *biosecurity* risks, exposure of broilers to chemical and physical contaminants, noise and adverse climatic conditions.

Broiler houses, outdoor areas and equipment to which broilers have access should be designed and maintained to avoid injury or pain to the broilers.

Broiler houses should be constructed and electrical and fuel installations should be fitted to minimise the risk of fire and other hazards.

Broiler producers should have a maintenance programme in place for all equipment the failure of which can jeopardise broiler welfare.

q) On farm harvesting

Broilers should not be subject to an excessive period of *feed* withdrawal prior to the expected *slaughter* time. Water should be available up to the time of harvesting.

Broilers that are not fit for *loading* or transport because they are sick or injured should be killed humanely.

Catching should be carried out by skilled *animal handlers* and every attempt should be made to minimise stress and fear reactions, and injury. If a broiler is injured during catching, it should be killed humanely.

Broilers should not be picked up by their neck or wings.

Broilers should be carefully placed in the transport *container*.

Mechanical catchers, where used, should be designed, operated and maintained to minimise injury, stress and fear to the broilers. A contingency plan is advisable in case of mechanical failure.

Catching should preferably be carried out under dim or blue light to calm the broilers.

Catching should be scheduled to minimise the time to *slaughter* as well as climatic stress during catching, transport and holding.

Stocking density in transport *containers* should suit climatic conditions and maintain comfort.

Containers should be designed and maintained to avoid injury, and they should be cleaned and, if necessary, disinfected regularly.

Outcome-based measurables: behaviour, vocalisation, injury rate, mortality rate at harvesting and on arrival at the *slaughterhouse/abattoir*.

NB: FIRST ADOPTED IN 2013; MOST RECENT UPDATE ADOPTED IN 2016.

CHAPTER 7.11.

ANIMAL WELFARE AND DAIRY CATTLE PRODUCTION SYSTEMS

Article 7.11.1.

Definition

Dairy cattle production systems are defined as all commercial cattle production systems where the purpose of the operation includes some or all of the breeding, rearing and management of cattle intended for production of milk.

Article 7.11.2.

Scope

This chapter addresses the welfare aspects of dairy cattle production systems.

Article 7.11.3.

Commercial dairy cattle production systems

Dairy cattle in commercial production may be kept in housed or pastured systems, or a combination of both:

1. Housed

These are systems where cattle are kept on a formed surface, indoors or outdoors, and are fully dependent on humans to provide for basic animal needs such as food, shelter and water. The type of housing will depend on the environment, climatic conditions and management system. The animals may be housed unrestrained or tethered, within this housing system.

2. Pastured

These are systems where cattle live outdoors, and have some autonomy over diet selection, water consumption and access to shelter. Pastured systems do not involve any housing except that required for milking.

3. Combination systems

These are systems where cattle are managed in any combination of housed and pasture production systems, either simultaneously, or varied in accordance with weather or physiological state of the cattle.

Article 7.11.4.

Criteria (or measurables) for the welfare of dairy cattle

The following outcome-based criteria, specifically animal-based criteria, can be useful indicators of *animal welfare*. Consideration should also be given to the design of the system and animal management practices. The use of these indicators and their appropriate thresholds should be adapted to the different situations where dairy cattle are managed. These criteria can be considered as a tool to monitor the impact of design and management, given that both of these can affect *animal welfare*.

1. Behaviour

Certain behaviours could indicate an *animal welfare* problem. These include decreased *feed* intake, altered locomotory behaviour and posture, altered lying time, altered respiratory rate and panting, coughing, shivering and huddling, excessive grooming and the demonstration of stereotypic, agonistic, depressive or other abnormal behaviours.

2. Morbidity rate

Morbidity rates, including for infectious and metabolic diseases, lameness, peri-partum and post-procedural complications and injury rates, above recognised thresholds, may be direct or indirect indicators of the *animal welfare* status of the whole *herd*. Understanding the aetiology of the disease or syndrome is important for detecting potential *animal welfare* problems. Mastitis, and hoof, reproductive and metabolic diseases are also particularly important animal health problems for adult dairy cows. Scoring systems, such as for body condition, lameness and milk quality, can provide additional information.

Both clinical examination and pathology should be utilised as an indicator of disease, injuries and other problems that may compromise *animal welfare*.

3. Mortality and culling rates

Mortality and culling rates affect the length of productive life and, like morbidity rates, may be direct or indirect indicators of the *animal welfare* status. Depending on the production system, estimates of mortality and culling rates can be obtained by analysing *death* and culling and their temporal and spatial patterns of occurrence. Mortality and culling, and their causes, should be recorded regularly, e.g. daily, monthly, annually or with reference to key husbandry activities within the production cycle.

Necropsy is useful in establishing the cause of *death*.

4. Changes in body weight, body condition and milk yield

In growing animals, body weight changes outside the expected growth rate, especially excessive sudden loss, are indicators of poor animal health or *animal welfare*. Future performance, including milk yield and fertility, of replacement heifers can be affected by under- or over-nutrition at different stages of rearing.

In lactating animals, body condition outside an acceptable range, significant body weight change and significant decrease in milk yield may be indicators of compromised welfare.

In non-lactating animals and bulls, body condition outside an acceptable range and significant body weight change may be indicators of compromised welfare.

5. Reproductive efficiency

Reproductive efficiency can be an indicator of animal health and *animal welfare* status. Poor reproductive performance, compared with the targets expected for a particular breed, can indicate *animal welfare* problems.

Examples may include:

- anoestrus or extended post-partum interval,
- low conception rates,
- high abortion rates,
- high rates of dystocia,
- retained placenta,
- metritis,
- loss of fertility in breeding bulls.

6. Physical appearance

Physical appearance may be an indicator of animal health and *animal welfare*, as well as the conditions of management. Attributes of physical appearance that may indicate compromised welfare include:

- presence of ectoparasites,
- abnormal coat colour, texture or hair loss,
- excessive soiling with faeces, mud or dirt (cleanliness),
- swellings, injuries or lesions,
- discharges (e.g. from nose, eyes, reproductive tract),
- feet abnormalities,
- abnormal posture (e.g. rounded back, head low),
- emaciation or dehydration.

7. Handling responses

Improper handling can result in fear and distress in cattle. Indicators include:

- evidence of poor human-animal relationship, such as excessive flight distance,
- negative behaviour at milking time, such as reluctance to enter the milking parlour, kicking, vocalisation,

- animals striking restraints or gates,
- injuries sustained during handling, such as bruising, lacerations, broken horns or tails and fractured legs,
- animals vocalising abnormally or excessively during restraint and handling,
- disturbed behaviour in the chute or race such as repeated reluctance to enter,
- animals slipping or falling.

8. Complications from common procedures

Surgical and non-surgical procedures may be performed in dairy cattle for facilitating management, improving human safety and *animal welfare* (e.g. disbudding, hoof trimming), and treatment of certain conditions (e.g. displaced abomasum). However, if these procedures are not performed properly, *animal welfare* can be compromised. Indicators of such problems could include:

- post procedure infection, swelling and pain behaviour,
- reduced *feed* and water intake,
- post procedure body condition and weight loss,
- morbidity and mortality.

Article 7.11.5.

Recommendations

Ensuring good welfare of dairy cattle is contingent on several management factors, including system design, environmental management, and animal management practices which include responsible husbandry and provision of appropriate care. Serious problems can arise in any system if one or more of these elements are lacking.

Articles 7.11.6. and 7.11.7. provide recommendations for measures applied to dairy cattle.

Each recommendation includes a list of outcome-based measurables derived from Article 7.11.4. This does not exclude other measures being used where appropriate.

Article 7.11.6.

Recommendations on system design and management including physical environment

When new facilities are planned or existing facilities are modified, professional advice on design in regards to animal welfare and health should be sought.

Many aspects of the environment can impact the welfare and health of dairy cattle. These include thermal environment, air quality, lighting, noise, etc.

1. Thermal environment

Although cattle can adapt to a wide range of thermal environments particularly if appropriate breeds are used for the anticipated conditions, sudden fluctuations in weather can cause heat or cold stress.

a) Heat stress

The risk of heat stress for cattle is influenced by environmental factors including air temperature, relative humidity, wind speed, animal density (area and volume available per animal), shade availability, animal factors including breed, age, body condition, metabolic rate and stage of lactation, and coat colour and density.

Animal handlers should be aware of the risk that heat stress poses to cattle and of the thresholds in relation to heat and humidity that may require action. As conditions change, routine daily activities that require moving cattle should be amended appropriately. If the risk of heat stress reaches very high levels the *animal handlers* should institute an emergency action plan that gives priority to access to additional water and could include

provision of shade, fans, reduction of animal density, and provision of cooling systems as appropriate for the local conditions.

Outcome-based measurables: *feed* and water intake; behaviour, especially respiratory rate and panting; physical appearance, especially dehydration; morbidity rate; mortality rate; changes in milk yield.

b) Cold stress

Protection from extreme weather conditions should be provided when these conditions are likely to create a serious risk to the welfare of cattle, particularly in neonates and young cattle and others that are physiologically compromised. This could be provided by extra bedding and natural or man-made shelters.

During extreme cold weather conditions, *animal handlers* should institute an emergency action plan to provide cattle with shelter, adequate *feed* and water.

Outcome-based measurables: mortality and morbidity rates; physical appearance; behaviour, especially abnormal postures, shivering and huddling; growth rate; body condition; weight loss.

2. Lighting

Housed cattle that do not have sufficient access to natural light should be provided with supplementary lighting which follows natural periodicity sufficient for their health and welfare, to facilitate natural behaviour patterns and to allow adequate and safe inspection of the cattle. The lighting should not cause discomfort to the animals. Housed dairy cows should be provided with subdued night time lighting. Entrance to and exit from restraint facilities and their surrounding area should be well lit.

Outcome-based measurables: behaviour, especially altered locomotory behaviour; morbidity; physical appearance.

3. Air quality

Good air quality and ventilation are important for the health and welfare of cattle and reduce the risk of respiratory discomfort and diseases. Air quality is affected by air constituents such as gases, dust and micro-organisms, and is influenced strongly by management and building design in housed systems. Air composition is influenced by animal density, the size of the cattle, flooring, bedding, waste management, building design and ventilation system.

Proper ventilation is important for effective heat dissipation in cattle and to prevent the build-up of effluent gases (e.g. ammonia and hydrogen sulphide), including those from manure and dust in the housing unit. The ammonia level in enclosed housing should not exceed 25 ppm. A useful indicator is that if air quality is unpleasant for humans it is also likely to be a problem for cattle.

Outcome-based measurables: morbidity rate; mortality rate; behaviour, especially respiratory rate or panting; coughing; changes in weight and body condition; growth rate; physical appearance, especially wet coat.

4. Noise

Cattle are adaptable to different levels and types of noise. However, exposure of cattle to sudden and unexpected noises, including from personnel, should be minimised where possible to prevent stress and fear reactions. Ventilation fans, alarms, feeding machinery or other indoor or outdoor equipment should be constructed, placed, operated and maintained in a manner that minimises noise.

Outcome-based measurables: behaviour especially agitation and nervousness; changes in milk yield.

5. Flooring, bedding, resting surfaces and outdoor areas

In all production systems cattle need a well-drained and comfortable place to rest. All cattle in a group should have sufficient space to lie down and rest at the same time.

Particular attention should be given to the provisions for areas used for calving. The environment in such areas (e.g. floors, bedding, temperature, calving pen and hygiene) should be appropriate to ensure the welfare of calving cows and new born calves.

In housed systems calving areas should be thoroughly cleaned and provided with fresh bedding between each calving. Group pens for calving should be managed based on the principle 'all in - all out'. The group calving pen

should be thoroughly cleaned and provided with fresh bedding between each animal group. The time interval between first and last calving of cows kept in the same group calving pen should be minimised.

Outdoor calving pens and fields should be selected to provide the cow with a clean and comfortable environment.

Floor management in housed production systems can have a significant impact on cattle welfare. Areas that compromise welfare and are not suitable for resting (e.g. places with excessive faecal accumulation, or wet bedding) should not be included in the determination of the area available for cattle to lie down.

Slopes of the pens should allow water to drain away from *feed* troughs and not pool the pens.

Flooring, bedding, resting surfaces and outdoor yards should be cleaned as conditions warrant, to ensure good hygiene, comfort and minimise risk of diseases and injuries.

In pasture systems, stock should be rotated between fields to ensure good hygiene and minimise risk of diseases and injuries.

Bedding should be provided to all animals housed on concrete. In straw, sand or other bedding systems such as rubber mats, crumbled-rubber-filled mattresses and waterbeds, the bedding should be suitable (e.g. hygienic, non-toxic) and maintained to provide cattle with a clean, dry and comfortable place on which to lie.

The design of a standing, or cubicle, or free stall, should be such that the animals can stand and lie comfortably on a solid surface (e.g. length, width and height should be appropriate for the size of the largest animal). There should be sufficient room for the animal to rest and to rise adopting normal postures, to move its head freely as it stands up, and to groom itself without difficulty. Where housing design provides only individual spaces for cows to rest, there should be at least one space per cow.

Alleys and gates should be designed and operated to allow free movement of cattle. Floors should be designed to minimise slipping and falling, promote foot health, and reduce the risk of claw injuries.

If a housing system includes areas of slatted floor, cattle, including replacement stock, should have access to a solid lying area. The slat and gap widths should be appropriate to the hoof size of the cattle to prevent injuries.

If cattle have to be tethered whether indoors or outdoors, they should, as a minimum, be able to lie down, stand up, maintain normal body posture and groom themselves unimpeded. Cows kept in tie stall housing should be allowed sufficient untethered exercise to prevent welfare problems. When tethered outdoors they should be able to walk. *Animal handlers* should be aware of the higher risks of welfare problems where cattle are tethered.

Where breeding bulls are in housing systems, care should be taken to ensure that they have sight of other cattle with sufficient space for resting and exercise. If used for natural mating, the floor should not be slatted or slippery.

Outcome-based measurables: morbidity rates, especially lameness and injuries (e.g. hock and knee injuries and skin lesions); behaviour (e.g. altered locomotion and posture, altered lying time, grooming and not using the intended lying areas); changes in weight and body condition; physical appearance (e.g. hair loss, cleanliness score); growth rate.

6. Location, construction and equipment

The impacts of climate and geographical factors on dairy cattle should be evaluated when farms are established. Efforts should be made to mitigate any negative impacts of those factors, including matching dairy breed to location and consideration of alternate sites.

All facilities for dairy cattle should be constructed, maintained and operated to minimise the risk to the welfare of the cattle.

In pasture and combination systems tracks and races between the milking area and fields should be laid out and managed so as to minimise the overall distances walked. Construction and maintenance of tracks and races, including their surface, should minimise any risk to the welfare of the cattle, especially from foot health problems.

Equipment for milking, handling and restraining dairy cattle should be constructed and used in a way that minimises the risk of injury, pain or distress. Manufacturers of such equipment should consider *animal welfare* when designing it and when preparing operating instructions.

Electrified equipment designed to control animal behaviour (e.g. cow trainer) may cause welfare problems if not designed, used and maintained properly.

Electrified fences and gates should be well-designed and maintained to avoid welfare problems, and used only in accordance with manufacturer's instructions.

Where access to an outdoor area, including pasture, is possible, there may be additional benefits to dairy cattle from the opportunity to graze and exercise, especially a decreased risk of lameness.

In all production systems, *feed* and water provision should allow all cattle to have access to *feed* and water. Feeding systems should be designed to minimise agonistic behaviour. Feeders and water providers should be easy to clean and properly maintained.

Milking parlours, free stalls, standings, cubicles, races, chutes and pens should be properly maintained and be free from sharp edges and protrusions to prevent injury to cattle.

There should be a separated area where individual animals can be examined closely and which has restraining facilities.

When relevant, sick and injured animals should be treated away from healthy animals. When a dedicated space is provided this should accommodate all the needs of the animal e.g. recumbent animals may require additional bedding or an alternative floors surface.

Hydraulic, pneumatic and manual equipment should be adjusted, as appropriate, to the size of cattle to be handled. Hydraulic and pneumatic operated restraining equipment should have pressure limiting devices to prevent injuries. Regular cleaning and maintenance of working parts is essential to ensure the system functions properly and is safe for the cattle.

Mechanical and electrical devices used in facilities should be safe for cattle.

Dipping baths and spray races used for ectoparasite control should be designed and operated to minimise the risk of crowding and to prevent injury and drowning.

Collecting yards (e.g. entry to the milking parlour) should be designed and operated to minimise stress and prevent injuries and lameness.

The loading areas and ramps, including the slope of the ramp, should be designed to minimise stress and injuries for the animals and ensure the safety of the *animal handlers*, in accordance with Chapters 7.2., 7.3. and 7.4.

Outcome-based measurables: handling response; morbidity rate, especially lameness; mortality rate; behaviour, especially altered locomotory behaviour; injury rate; changes in weight and body condition; physical appearance; growth rate.

7. Emergency plans

The failure of power, water and *feed* supply systems could compromise *animal welfare*. Dairy producers should have contingency plans to cover the failure of these systems. These plans may include the provision of fail-safe alarms to detect malfunctions, back-up generators, contact information for key service providers, ability to store water on farm, access to water cartage services, adequate on-farm storage of *feed*, alternative *feed* supply, and emergency *killing* of animals according to Chapter 7.6.

Preventive measures for emergencies should be input-based rather than outcome based. Contingency plans should include an evacuation plan and be documented and communicated to all responsible parties. Alarms and back-up systems should be checked regularly.

Article 7.11.7.

Recommendations on animal management practices

Good animal management practices are critical to providing an acceptable level of *animal welfare*. Personnel involved in handling and caring for dairy cattle should be competent with relevant experience or training to equip them with the necessary practical skills and knowledge of dairy cattle behaviour, handling, health, *biosecurity*, physiological needs and welfare. There should be a sufficient number of *animal handlers* to ensure the health and welfare of the cattle.

1. Biosecurity and animal health

a) Biosecurity and disease prevention

Biosecurity plans should be designed, implemented and maintained, commensurate with the best possible *herd* health status, available resources and infrastructure, and current disease risk and, for *listed diseases* in accordance with relevant recommendations in the *Terrestrial Code*.

These *biosecurity plans* should address the control of the major sources and pathways for spread of pathogenic agents:

- cattle, including introductions to the *herd*,
- calves coming from different sources,
- other domestic animals, *wildlife*, and pests,
- people including sanitation practices,
- equipment, tools and facilities,
- *vehicles*,
- air,
- water supply, *feed* and bedding,
- manure, waste and dead stock disposal,
- semen and embryos.

Outcome-based measurables: morbidity rate; mortality rate; reproductive efficiency; changes in weight and body condition; changes in milk yield.

b) Animal health management

Animal health management should optimise the physical and behavioural health and welfare of the dairy *herd*. It includes the prevention, treatment and control of diseases and conditions affecting the *herd* (in particular mastitis, lameness, reproductive and metabolic diseases).

There should be an effective programme for the prevention and treatment of diseases and conditions, formulated in consultation with a *veterinarian*, where appropriate. This programme should include the recording of production data (e.g. number of lactating cows, births, animal movements in and out of the *herd*, milk yield), morbidities, mortalities, culling rate and medical treatments. It should be kept up to date by the *animal handler*. Regular monitoring of records aids management and quickly reveals problem areas for intervention.

For parasitic burdens (e.g. endoparasites, ectoparasites and protozoa), a programme should be implemented to monitor, control and treat, as appropriate.

Lameness can be a problem in dairy cattle. *Animal handlers* should monitor the state of feet and take measures to prevent lameness and maintain foot health.

Those responsible for the care of cattle should be aware of early specific signs of disease or distress (e.g. coughing, ocular discharge, changes in milk appearance, changes in locomotory behaviour), and non-specific

signs such as reduced *feed* and water intake, reduction of milk production, changes in weight and body condition, changes in behaviour or abnormal physical appearance.

Cattle at higher risk of disease or distress will require more frequent inspection by *animal handlers*. If *animal handlers* suspect the presence of a disease or are not able to correct the causes of disease or distress, they should seek advice from those having training and experience, such as *veterinarians* or other qualified advisers, as appropriate.

Vaccinations and other treatments administered to cattle should be carried out by *veterinarians* or other people skilled in the procedures and on the basis of veterinary or other expert advice and with consideration for the welfare of the dairy cattle.

Animal handlers should be competent in identifying and appropriately managing chronically ill or injured cattle, for instance in recognising and dealing with non-ambulatory cattle, especially those that have recently calved. Veterinary advice should be sought as appropriate.

Non-ambulatory cattle should have access to water at all times and be provided with *feed* at least once daily and milked as necessary. They should be provided shade and protected from predators. They should not be transported or moved unless absolutely necessary for treatment or diagnosis. Such movements should be done carefully using methods that avoid dragging the animal or lifting it in a way that might exacerbate injuries.

Animal handlers should also be competent in assessing fitness to transport, as described in Chapter 7.3.

In case of disease or injury, when treatment has failed or recovery is unlikely (e.g. cattle that are unable to stand up, unaided or refuse to eat or drink), the animal should be humanely killed as soon as possible in accordance with Chapter 7.6.

Animals suffering from photosensitisation should be provided with shade and where possible the cause should be identified.

Outcome-based measurables: morbidity rate; mortality rate; reproductive efficiency; depressive behaviour; altered locomotory behaviour; physical appearance; changes in weight and body condition; changes in milk yield.

c) Emergency plans for disease outbreaks

Emergency plans should cover the management of the farm in the face of an emergency disease *outbreak*, consistent with national programmes and recommendations of *Veterinary Services* as appropriate.

2. Nutrition

The nutrient requirements of dairy cattle have been well defined. Energy, protein, mineral and vitamin content of the diet are major factors determining milk production and growth, feed efficiency, reproductive efficiency, and body condition.

Cattle should be provided with access to an appropriate quantity and quality of balanced nutrition that meets their physiological needs.

Where cattle are maintained in outdoor conditions, short term exposure to climatic extremes may prevent access to nutrition that meets their daily physiological needs. In such circumstances the *animal handler* should ensure that the period of reduced nutrition is not prolonged and that extra food and water supply are provided if welfare would otherwise be compromised.

Animal handlers should have adequate knowledge of appropriate body condition scoring systems for their cattle and should not allow body condition to go outside an acceptable range in accordance with breed and physiological status.

Feedstuffs and *feed ingredients* should be of satisfactory quality to meet nutritional needs and stored to minimise contamination and deterioration. Where appropriate, *feed* and *feed ingredients* should be tested for the presence of substances that would adversely impact on animal health. Control and monitoring of animal *feed* should be implemented in accordance with relevant recommendations in Chapter 6.4.

The relative risk of digestive upset in cattle increases as the proportion of grain increases in the diet or if quality of silage is poor. Grain or new diets should be introduced slowly and palatable fibrous *feed* such as silage, grass and hay, should be available *ad libitum* to meet metabolic requirements in a way that promotes digestion and ensures normal rumen function.

Animal handlers should understand the impact of cattle size and age, weather patterns, diet composition and sudden dietary changes in respect to digestive upsets and their negative consequences (displaced abomasum,

sub-acute ruminal acidosis, bloat, liver abscess, laminitis). Where appropriate, dairy producers should consult a cattle nutritionist for advice on ration formulation and feeding programmes.

Particular attention should be paid to nutrition in the last month of pregnancy, with regards to energy balance, roughage and micronutrients, in order to minimise calving and post-calving diseases and body condition loss.

Liquid milk (or milk replacer) is essential for healthy growth and welfare of calves. However, feeding calves all-liquid diets as the sole source of nutrition after 4-6 weeks of age limits the physiological development of the rumen. Calves over two weeks old should have a sufficient daily ration of fibrous *feed* and starter ration (concentrate) to promote rumen development and to reduce abnormal oral behaviours.

Dairy producers should become familiar with potential micronutrient deficiencies or excesses for production systems in their respective geographical areas and use appropriately formulated supplements where necessary.

All cattle, including unweaned calves, need an adequate supply and access to palatable water that meets their physiological requirements and is free from contaminants hazardous to cattle health.

Outcome-based measurables: mortality rates; morbidity rates; behaviour, especially agonistic behaviour (at the feeding area); changes in weight and body condition; reproductive efficiency; changes in milk yield; growth rate; vocalisation.

3. Social environment

Management of cattle should take into account their social environment as it relates to *animal welfare*, particularly in housed systems. Problem areas include: agonistic and oestrus activity, mixing of heifers and cows, feeding cattle of different size and age in the same pens, decreased space allowance, insufficient space at the feeder, insufficient water access and mixing of bulls.

Management of cattle in all systems should take into account the social interactions of cattle within groups. The *animal handler* should understand the dominance hierarchies that develop within different groups and focus on high risk animals, such as sick or injured, very young, very old, small or large size for cohort group, for evidence of agonistic behaviour and excessive mounting behaviour. The *animal handler* should understand the risks of increased agonistic interactions between animals, particularly after mixing groups.

When other measures have failed, cattle that are expressing excessive agonistic activity or excessive mounting behaviour should be removed from the group.

Animal handlers should be aware of the *animal welfare* problems that may be caused by mixing of inappropriate groups of cattle and provide adequate measures to minimise them (e.g. introduction of heifers in a new group, mixing of animals at different production stages that have different dietary needs).

Horned and non-horned cattle should not be mixed because of the risk of injury.

Outcome-based measurables: behaviour, especially lying times, physical injuries and lesions; changes in weight and body condition; physical appearance (e.g. cleanliness); lameness scores; changes in milk yield; morbidity rate; mortality rate; growth rate; vocalisation.

4. Space allowance

Cattle in all production systems should be offered adequate space for comfort and socialisation.

Insufficient and inadequate space allowance may increase the occurrence of injuries and have an adverse effect on growth rate, feed efficiency, and behaviour such as locomotion, resting, feeding and drinking.

Space allowance should be managed taking into account different areas for lying, standing and feeding. Crowding should not adversely affect normal behaviour of cattle and durations of time spent lying.

All cattle should be able to rest simultaneously, and each animal lie down, stand up and move freely. In growing animals, space allowance should also be managed such that weight gain is not adversely affected. If abnormal behaviour is seen, corrective measures should be taken, such as increasing space allowance, redefining the areas available for lying, standing and feeding.

In pastured systems, stocking density should depend on the available *feed* and water supply and pasture quality.

Outcome-based measurables: behaviour, especially agonistic or depressive behaviour; morbidity rate; mortality rate; changes in weight and body condition; physical appearance; changes in milk yield; parasite burden; growth rate.

5. Protection from predators

Cattle should be protected from predators.

Outcome-based measurables: mortality rate; morbidity rate (injury rate); behaviour; physical appearance.

6. Genetic selection

Welfare and health considerations, in addition to productivity, should be taken into account when choosing a breed or subspecies for a particular location or production system.

In breeding programmes, attention should be paid to criteria conducive to the improvement of cattle welfare, including health. The conservation and development of genetic lines of dairy cattle, which limit or reduce animal welfare problems, should be encouraged. Examples of such criteria include nutritional maintenance requirement, disease resistance and heat tolerance.

Individual animals within a breed should be selected to propagate offspring that exhibit traits beneficial to animal health and welfare by promoting robustness and longevity. These include resistance to infectious and production related diseases, ease of calving, fertility, body conformation and mobility, and temperament.

Outcome-based measurables: morbidity rate; mortality rate; length of productive life; behaviour; physical appearance; reproductive efficiency; lameness; human-animal relationship; growth rate; body condition outside an acceptable range.

7. Artificial insemination, pregnancy diagnosis and embryo transfer

Semen collection should be carried out by a trained operator in a manner that does not cause pain or distress to the bull and any teaser animal used during collection and in accordance with Chapter 4.6.

Artificial insemination and pregnancy diagnosis should be performed by a competent operator in a manner that does not cause pain or distress.

Embryo transfer should be performed under an epidural or other anaesthesia by a trained operator, preferably a *veterinarian* or a *veterinary paraprofessional* and in accordance with the provisions of Chapter 4.7. and Chapter 4.8.

Outcome-based measurables: behaviour; morbidity rate; reproductive efficiency.

8. Dam and sire selection and calving management

Dystocia is a welfare risk to dairy cattle. Heifers should not be bred before they reach the stage of physical maturity sufficient to ensure the health and welfare of both dam and calf at birth. The sire has a highly heritable effect on final calf size and as such can have a significant impact on ease of calving. Sire selection for embryo implantation, insemination or natural mating, should take into account the maturity and size of the female.

Pregnant cows and heifers should be managed during pregnancy so as to achieve an appropriate body condition range for the breed. Excessive fatness increases the risk of dystocia and metabolic disorders during late pregnancy or after parturition.

Cows and heifers should be monitored when they are close to calving. Animals observed to be having difficulty in calving should be assisted by a competent handler as soon as possible after they are detected. When a caesarean section is required, it must be carried out by a *veterinarian*.

Outcome-based measurables: morbidity rate; mortality rate (cow and calf); reproductive efficiency, especially rate of dystocia, retained placenta and metritis; body condition.

9. Newborn calves

Calving aids should not be used to speed the birthing process, only to assist in cases of dystocia, and should not cause undue pain, distress, or further medical problems.

Newborn calves are susceptible to hypothermia. The temperature and ventilation of the birthing area should consider the needs of the newborn calf. Soft, dry bedding and supplemental heat can help prevent cold stress.

Receiving adequate immunity from colostrum generally depends on the volume and quality of colostrum ingested, and how soon after birth the calf receives it.

Animal handlers should ensure that calves receive colostrum of a satisfactory quality, within 24 hours of birth, and in sufficient quantity, to provide passive immunity. Colostrum is most beneficial if received during the first six hours after birth. When there is risk of disease transfer from the dam, colostrum from a healthy cow should be used.

Recently born calves should not be transported until the navel is dry, and after which time any transport required should be carried out in accordance with Chapter 7.3.

Calves should be handled and moved in a manner which minimises distress and avoids pain and injury.

Outcome-based measurables: physical appearance; mortality rate; morbidity rate; growth rate.

10. Cow-calf separation and weaning

Different strategies to separate the calf from the cow are utilised in dairy cattle production systems. These include early separation (usually within 48 hours of birth) or a more gradual separation (leaving the calf with the cow for a longer period so it can continue to be suckled). Separation is stressful for both cow and calf.

For the purposes of this chapter, weaning means the change from a milk-based diet to a fibrous diet and the weaned calf no longer receives milk in its diet. This change should be made gradually and calves should be weaned only when their ruminant digestive system has developed sufficiently to enable them to maintain growth, health and good welfare.

Dairy cattle producers should seek expert advice on the most appropriate time and method of weaning for their type of cattle and production system.

Outcome-based measurables: morbidity rate; mortality rate; behaviour after separation (vocalisation, activity of the cow and calf); physical appearance; changes in weight and body condition; growth rate.

11. Rearing of replacement stock

Young calves are at particular risk of thermal stress. Special attention should be paid to management of the thermal environment (e.g. provision of additional bedding, nutrition or protection to maintain warmth and appropriate growth).

Individual calf-housing may facilitate monitoring of health of very young calves and minimise the risk of disease spread, but replacement stock should then be reared in groups. Animals in groups should be of similar age and physical size.

Whether reared individually or in group pens, each calf should have enough space to be able to turn around, rest, stand up and groom comfortably and see other animals.

Replacement stock should be monitored for cross-sucking and appropriate measures taken to prevent this occurring (e.g. provide sucking devices, revise or modify feeding practices, provide other environmental enrichments).

Particular attention should be paid to the nutrition, including trace elements, of growing replacement stock to ensure good health and that they achieve an appropriate growth curve for the breed and farming objectives.

Outcome-based measurables: morbidity rate; mortality rate; behaviour, especially cross-sucking, altered grooming and lying behaviours; injuries; physical appearance; changes in weight and body condition; growth rate.

12. Milking management

Milking, whether by hand or machine, should be carried out in a calm and considerate manner in order to avoid pain and distress. Special attention should be paid to the hygiene of personnel, the udder and milking equipment. All cows should be checked for abnormal milk at every milking.

Milking machines, especially automated milking systems, should be used and maintained in a manner which minimises injury to teats and udders. Manufacturers of such equipment should provide operating instructions that consider *animal welfare*.

A regular milking routine should be established relevant to the stage of lactation and the capacity of the system.

Animal handlers should regularly check the information provided by the milking system and act accordingly to protect the welfare of the cows.

Special care should be paid to animals being milked for the first time. They should be familiarised with the milking facility prior to giving birth.

Long waiting times before and after milking can lead to health and welfare problems (e.g. lameness, reduced time to eat). Management should ensure that waiting times are minimised.

Outcome-based measurables: morbidity rate (e.g. udder health, milk quality); behaviour; changes in milk yield; physical appearance (e.g. lesions).

13. Painful husbandry procedures

Husbandry practices are routinely carried out in cattle for reasons of management, *animal welfare* and human safety. Those practices that have the potential to cause pain should be performed in such a way as to minimise any pain and stress to the animal. Such procedures should be performed at as early an age as possible or using anaesthesia or analgesia under the recommendation or supervision of a *veterinarian*.

Options for enhancing *animal welfare* in relation to these procedures include: ceasing the procedure and addressing the need for the operation through management strategies; breeding cattle that do not require the

procedure; or replacing the current procedure with a non-surgical alternative that has been shown to enhance *animal welfare*.

a) Disbudding and dehorning

Horned dairy cattle are commonly disbudded or dehorned in order to reduce animal injuries and hide damage, improve human safety, reduce damage to facilities and facilitate transport and handling. The selection of polled cattle is preferable to dehorning.

Performing disbudding at an early age is preferred, rather than dehorning older cattle.

Thermal cautery of the horn bud by a trained operator with proper equipment is the recommended method in order to minimise post-operative pain. This should be done at an appropriate age before the horn bud has attached to the skull.

Guidance from a *veterinarian* or *veterinary paraprofessional* as to the optimum method and timing for the type of cattle and production system should be sought. The use of anaesthesia and analgesia are strongly recommended when performing disbudding, and should always be used when dehorning. Appropriate restraint systems and procedures are required when disbudding or dehorning.

Other methods of disbudding include: removal of the horn buds with a knife and the application of chemical paste to cauterise the horn buds. Where chemical paste is used, special attention should be paid to avoid chemical burns to other parts of the calf or to other calves. This method is not recommended for calves older than two weeks.

Operators should be trained and competent in the procedure used, and be able to recognise the signs of pain and complications that may include excessive bleeding or sinus infection.

Methods of dehorning when horn development has commenced involve the removal of the horn by cutting or sawing through the base of the horn close to the skull.

b) Tail docking

Tail docking does not improve the health and welfare of dairy cattle and therefore it is not recommended. As an alternative, trimming of tail hair should be considered where maintenance of hygiene is a problem.

c) Identification

Ear-tagging, ear-notching, tattooing, branding and radio frequency identification devices (RFID) are methods of permanently identifying dairy cattle. The least invasive approach should be adopted whichever method is chosen (e.g. the least number of ear tags per ear and the smallest notch practical). It should be accomplished quickly, expertly and with proper equipment.

Freeze branding and branding with a hot iron should be avoided where alternative identification methods exist (e.g. electronic identification or ear-tags). When branding is used, the operator should be competent in procedures used and be able to recognise signs of complications.

Identification systems should be established also in accordance with Chapter 4.1.

Outcome-based measurables: morbidity rate (post-procedural complications); abnormal behaviour; vocalisation; physical appearance.

14. Inspection and handling

Dairy cattle should be inspected at intervals appropriate to the production system and the risks to the health and welfare of the cattle. Lactating cows should be inspected at least once a day. Some animals should be inspected more frequently, for example, neonatal calves, cows in late gestation, newly weaned calves, cattle experiencing environmental stress and those that have undergone painful husbandry procedures or veterinary treatment.

Dairy cattle identified as sick or injured should be given appropriate treatment at the first available opportunity by competent *animal handlers*. If *animal handlers* are unable to provide appropriate treatment, the services of a *veterinarian* should be sought.

Recommendations on the handling of cattle are also found in Chapter 7.5. In particular handling aids that may cause pain and distress (e.g. electric goads) should be used only in extreme circumstances and provided that the animal can move freely. Dairy cattle should not be prodded in sensitive areas including the udder, face, eyes, nose or ano-genital region. Electric prods should not be used on calves (see also point 3) of Article 7.3.8.).

Where dogs are used as an aid for cattle herding they should be properly trained. *Animal handlers* should be aware that presence of dogs can stress the cattle and cause fear and should keep them under control at all times. The use of dogs is not appropriate in housed systems, collection yards or other small enclosures where the cattle cannot move freely away.

Cattle are adaptable to different visual environments. However, exposure of cattle to sudden movement or changes in visual contrasts should be minimised where possible to prevent stress and fear reactions.

Electroimmobilisation should not be used.

Outcome-based measurables: handling responses; morbidity rate; mortality rate; behaviour, especially altered locomotory behaviour and vocalisation.

15. Personnel training

All people responsible for dairy cattle should be competent in accordance with their responsibilities and should understand cattle husbandry, animal handling, milking routines, reproductive management techniques, behaviour, *biosecurity*, signs of disease, and indicators of poor *animal welfare* such as stress, pain and discomfort, and their alleviation.

Competence may be gained through formal training or practical experience.

Outcome-based measurables: handling responses; morbidity rate; mortality rate; behaviour; reproductive efficiency; changes in weight and body condition; changes in milk yield.

16. Disaster management

Plans should be in place to minimise and mitigate the effect of disasters (e.g. earthquake, fire, drought, flooding, blizzard, hurricane). Such plans may include evacuation procedures, identifying high ground, maintaining emergency *feed* and water stores, destocking and humane *killing* when necessary.

In times of drought, animal management decisions should be made as early as possible and these should include a consideration of reducing cattle numbers.

Humane *killing* procedures for sick or injured cattle should be part of the disaster management plan.

Reference to emergency plans can also be found in point 7) of Article 7.11.6. and point 1 c) of Article 7.11.7.

17. Humane killing

For sick and injured cattle a prompt diagnosis should be made to determine whether the animal should be treated or humanely killed.

The decision to kill an animal humanely and the procedure itself should be undertaken by a competent person.

Reasons for humane *killing* may include:

- severe emaciation, weak cattle that are non-ambulatory or at risk of becoming non ambulatory;
- non-ambulatory cattle that will not stand up, refuse to eat or drink, have not responded to therapy;
- rapid deterioration of a medical condition for which therapies have been unsuccessful;
- severe, debilitating pain;
- compound (open) fracture;
- spinal injury;
- central nervous system disease;
- multiple joint *infections* with chronic weight loss;
- calves that are premature and unlikely to survive, have a debilitating congenital defect, or otherwise unwanted; and
- as part of disaster management response.

For a description of acceptable methods for humane *killing* of dairy cattle see Chapter 7.6.

NB: FIRST ADOPTED IN 2015; MOST RECENT UPDATE ADOPTED IN 2017.

CHAPTER 7.12.

WELFARE OF WORKING EQUIDS

Article 7.12.1.

Introduction

In many countries, working equids, used for transport and traction, contribute directly and indirectly to households' livelihoods and benefit communities as a whole. Working equids may be of direct or indirect use in production and commercial activities.

Specifically, they contribute to agricultural production and food security by transporting, for instance, water and fodder for other livestock, firewood and other daily needs to the homestead and agricultural products to the market. They provide draught power for agricultural work and transport. They may supply manure, *milk*, *meat* and hides for household use or income.

The welfare of these working equids is often poor because their owners lack sufficient resources to meet their needs or have insufficient knowledge of the appropriate care of equids. Certain working contexts, such as working in construction industries or in harsh environments, may present a particular risk to their welfare.

Article 7.12.2.

Scope

This chapter applies to horses, donkeys and mules that are destined, used for or retired from traction, transport and generation of income. Equids used in sports or competitions, leisure activities, research or kept solely for the production of *meat* or biopharmaceuticals, are excluded.

For the purposes of this chapter, harness means all parts of the driving harness, saddle, bridle and bit that are used to control the working equid, act as a braking system when pulling a cart, hold loads in place and transfer power to attached carts or agricultural implements.

Article 7.12.3.

Responsibilities

All organisations with defined responsibilities as outlined below should have personnel with the requisite knowledge and skill to perform their duties.

1. Veterinary Authority

The *Veterinary Authority* is responsible for implementation of animal health and welfare policies, legislation and programmes. However, in the case of working equids, the responsibility may be shared with other government agencies, institutions and relevant stakeholders.

2. Other government agencies

The responsibilities of other government agencies depend on the range of working equid uses and contexts.

For example those agencies responsible for regulating industrial and construction activities, whether for environmental or labour compliance, may also have a responsibility for the working equids involved in the industry.

Particularly in urban areas, the transport or other responsible agency may have legislative authority in dealing with traffic circulation and have a role to play in ensuring a safe environment for working equids as well as other road users.

Environmental protection agencies may regulate and enforce measures to prevent working equids from accessing sources of contamination.

The agency responsible for public health may have legislative authority in dealing with zoonoses.

Education authorities have a responsibility in schools and agricultural, *veterinary paraprofessional* and veterinary training institutions. A component on welfare of working equids should be included in animal health and production curricula.

3. 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 with regard to aspects of transport, agriculture, public health, environmental health and inspection, and compliance activities including those in relation to animal health measures and responsibility for abandoned and stray animals.

In many countries local government agencies are responsible for the development and enforcement of legislation relating to equine drawn carts and carried loads in traffic, *animal identification* (registration), licensing and disposal of dead animals.

4. Private veterinarians

Private *veterinarians* are responsible for providing services and advice to working equid owners or handlers and play an important role in disease *surveillance* because they may be the first to see an equid suffering from a *notifiable disease*. They may also play a role (often in liaison with the police or other local authorities) in dealing with cases of neglect that lead to welfare problems.

Two-way communication between the private *veterinarians* and *Veterinary Authority*, often via the medium of a veterinary professional organisation, is important and the *Veterinary Authority* is responsible for setting up appropriate mechanisms for this interaction.

Private *veterinarians* may also have a responsibility in supervising and coordination of *veterinary paraprofessionals* involved in delivering animal health services.

5. Non-governmental organisations

Relevant non-governmental organisations (NGOs) and intergovernmental organisations should understand the role of working equids and may help to collect and provide information to support policy formulation, to advocate and promote health and welfare of working equids.

Local NGOs are potential partners of the *Veterinary Services* in the development and implementation of working equid health and welfare programmes.

NGOs may also contribute, together with *veterinarians* and *Competent Authorities*, in educating the public in the importance of the welfare of working equids.

6. Working equid owners and users

Owners and users are ultimately responsible for the welfare of their working equids by ensuring their animals' "five freedoms" (Article 7.1.2.).

Article 7.12.4.

Criteria or measurables for the welfare of working equids

The following outcome-based measurables can be useful indicators of *animal welfare*. The use of these indicators and the appropriate thresholds should be adapted to the different situations where working equids are used.

1. Behaviour

Presence or absence of certain equine behaviours could indicate an *animal welfare* problem, including fear, depression or pain. Behaviours differ between horses, donkeys and mules and a good understanding of normal behaviour of each species is required.

Some behaviours may not be uniquely indicative of one type of problem; they may be exhibited for a variety of causes. Depression, apathy, dullness and lethargy in equids that are normally active and alert are indicative of a welfare problem. Changes in eating or drinking patterns may indicate a welfare problem, especially a decreased *feed* intake. This might also be an indicator of dental problems, poor *feed* quality or even *feed* contamination.

Behaviours indicating discomfort or pain:

- head pressing, teeth grinding, grunting, food dropping, and inability to eat normally. Such behaviours may indicate disease or pain;
- depression, circling, foot pawing, flank watching, inability to stand up, and rolling. Such behaviours may indicate abdominal or other discomfort;
- disturbance of ground or bedding. Such behaviours may indicate disease, abdominal pain or malnutrition;
- weight shifting, foot pawing, reluctance to move or abnormal movement. Such behaviours may indicate leg, foot, spinal or abdominal pain;
- head shaking or avoidance of head contact. Such behaviours may indicate head, ear or ocular discomfort;
- itching, rubbing, self-inflicted abrasions. Such behaviours may indicate skin problems or parasites;
- restlessness, agitation and anxiety, rigid stance and reluctance to move, lowered head carriage, fixed stare and dilated nostrils, clenched jaw, aggression and reluctance to be handled, may indicate non-specific pain in horses. In donkeys, these behaviours are more subtle and may not be recognised;
- vocalisation, rolling, kicking at abdomen, flank watching and stretching may indicate abdominal pain in horses. In donkeys, dullness and depression;
- weight-shifting, limb guarding, abnormal weight distribution, pointing, hanging and rotating limbs, abnormal movement and reluctance to move may indicate limb and foot pain in horses. These signs are more subtle in donkeys, although repeated episodes of lying down are reportedly more indicative;
- headshaking, abnormal bit behaviour, altered eating, anorexia and quidding may indicate head and dental pain.

Behaviours indicating fear or anxiety:

- unusual avoidance of humans, especially when handlers or objects associated with their handling come close;
- a reluctance by the working equids to engage in their use for traction or transport or even a cessation and aggressive behaviour, especially when fitting equipment or loading is undertaken.

Behaviours indicating stress:

- oral stereotypies: crib biting, aerophagia ("wind sucking");
- locomotive stereotypies: stable walking, weaving;
- abnormal vocalisation, agitation or defecation.

2. Morbidity

Morbidity, including incidence of disease, lameness, injuries or post-procedural complications, may be a direct or indirect indicator of the *animal welfare* status.

Understanding the aetiology of the disease or syndrome is important for detecting potential *animal welfare* problems. Scoring systems, such as those used to score lameness and body condition, provide additional information.

3. Mortality

Mortality, like morbidity, may be a direct or indirect indicator of the *animal welfare* status. Depending on the context, causes of mortality should be investigated as well as temporal and spatial patterns of mortality and possible relationship with husbandry and handling practices. Necropsy is useful in establishing the cause of death.

4. Body condition and physical appearance

Poor or changing body condition or physical appearance may be an indicator of compromised animal welfare and health and scoring systems help to provide objectivity.

Observation of physical appearance often provides an indication of animal welfare and health. Attributes of physical appearance that may indicate compromised welfare include:

- feet or limb abnormalities;

- wounds or injuries;
- dehydration or signs of heat stress;
- abnormal discharges;
- presence of parasites;
- abnormal coat or hair loss;
- excessive soiling with faeces, mud or dirt;
- emaciation.

5. Handling responses

Poor human-animal interactions can lead to or be caused by improper handling. This may include bad driving and inappropriate restraint methods, or the misuse of whips and sticks, and can result in fear and distress.

Indicators include:

- aversive or apathetic responses to fitting of equipment and loads,
- defensive responses from the equid to the owner or user such as threatening facial expressions, kicking, biting and avoiding human contact.

6. Complications due to management practices

Some management practices, such as castration and hoof care, are commonly performed in working equids to facilitate handling and improve human safety and *animal welfare*.

Working equids are shod for two main reasons; to prevent hoof wear and to improve performance. Many equids cope well without shoes and, if they are coping well, are best unshod. However, poor hoof care and farriery predispose the working equid to injury and infection, and can result in changes to the size, shape and function of the hoof. Untreated abnormalities of the foot can create long-term problems in other parts of the leg and body due to change in gait and weight bearing.

If management practices such as these are not performed properly, *animal welfare* may be compromised.

Indicators of such problems include:

- post-procedure *infection* and swelling;
- post-procedure lameness;
- myiasis;
- behaviour indicating pain or fear;
- mortality.

It is important to note that some practices are not based on evidence and are inherently bad for welfare. Evidence of firing, nasal slitting, lampas cutting and harmful substances applied to wounds should be identified as indicators of poor welfare.

7. Lameness

Traditionally, lameness has been defined as any alteration of the horse's gait. In addition, lameness can manifest in such ways as a change in attitude or performance. These abnormalities can be caused by pain in the neck, withers, shoulders, back, loin, hips, legs or feet. Identifying the source of the problem is essential for proper treatment. Lameness or gait abnormalities are the most common signs of working equids seen by *veterinarians*. Various scoring systems are available to assess the degree of lameness.

Indicators of such problems include:

- hoof conformation abnormalities;
- unequal weight bearing;
- hoof and pastern axis and angles.

8. Fitness to work

Fitness to work is the state or condition of being physically sound and healthy, especially as a result of exercise and proper nutrition, to perform work well. Various factors such as the animal's age, breed or physiological state (e.g. pregnancy) may influence its fitness to work.

Indicators of an equid's inability to carry out the work demanded of it include the presence of heat stress, lameness, poor body condition or weight loss, harness related wounds and aversive behavioural responses to, for example, harness or equipment fitting.

Article 7.12.5.

Recommendations

Articles 7.12.6. to 7.12.13. provide recommendations for measures applied to working equids.

Each recommendation includes a list of relevant outcome-based measurables derived from Article 7.12.4. This does not exclude other measures being used when appropriate.

Article 7.12.6.

Feeding and provision of water1. Feeding

Equids are natural grazers that eat small quantities but eat often. Their natural diet is mainly grasses, which have a high roughage content. Horses in particular should be fed frequently with a predominantly fibre-based diet: grass, hay or a suitable and safe alternative in order to mimic their natural feeding pattern as closely as possible.

Energy, fibre, protein, mineral (including trace minerals) and vitamin contents in the diet of working equids, their balance, safety, digestibility and availability are major factors determining the power of the animals, their growth and overall productivity and their health and welfare.

Working equids should be provided with access to an appropriate quantity of balanced and safe *feed*, of adequate quality to meet their specific physiological and working needs. In case of *feed* shortages, the *animal handler* should ensure that the period of reduced feeding is as short as possible and that mitigation strategies are implemented if welfare and health are at risk of being compromised.

If supplementary *feed* is not available, steps should be taken to avoid starvation, including *slaughter*, sale or relocation of the animals, or humane *killing*.

Owners and handlers should allow working equids to forage whenever possible and allow for an adequate number of working breaks to allow the animals to eat. Long fibre forage is important for digestion. Cut green forage should be provided when grazing is not possible. Dry long fibre forage should be provided when adequate green forage is not available.

Inadequate diets and feeding systems may contribute to disease, stress, discomfort or to abnormal behaviour in working equids and should be avoided. *Animal handlers* should be aware of the animals' nutritional needs and consult an expert for advice on ration formulation and feeding programmes when needed.

2. Provision of water

The most important nutrient for the welfare of working equids is water. Working equids need regular and adequate access to palatable, safe water that meets their physiological and work requirements which may vary.

Outcome-based measurables: behaviour, morbidity, mortality, body condition and physical appearance, and fitness to work.

Article 7.12.7.

Shelter

Effective shelter should be provided for working equids both in the resting and working environments. Shelter should provide protection against adverse weather conditions and against predators and injury as well as good ventilation and the ability to rest comfortably. Resting space should be dry, clean and large enough for the equid to lie down, get up and turn around easily.

1. Heat stress

Heat stress is a common condition in working equids in hot, humid environments and *animal handlers* should be aware of the risk that heat stress poses. Equid owners and handlers should be aware of how to prevent it through provision of appropriate shade or shelter along with sufficient drinking water and avoiding work at extreme high

temperatures. Owners may also be trained in effective treatment of hyperthermia as timely veterinary assistance may not be available.

Behaviours which indicate heat stress include increased respiratory rate and effort; flared nostrils; increased head movement and lack of response to the environment; excessive sweating.

Outcome-based measurables: behaviour, morbidity, mortality, body condition and physical appearance and fitness to work.

2. Cold

Protection from extreme cold weather conditions should be provided when these are likely to create a serious risk to the welfare of equids, particularly of neonates and young animals and others that are physiologically compromised. Such a protection could be provided by extra bedding, blankets or shelter. Care should be taken that, in an attempt to protect against the cold, ventilation and air quality are not compromised.

Behaviour which indicates suffering from cold stress includes shivering and huddling together.

Outcome-based measurables: behaviour, mortality and body condition and physical appearance.

3. Protection from predators and injury

Working equids should be kept safe from predators and from road accidents, which are common occurrences if equids are left free to roam. If working equids are housed alongside horned cattle, care should be taken to protect them from injury. Enclosures used should be structurally sound and free of sharp edges, protrusions and other features that could cause injury.

Outcome-based measurables: behaviour, morbidity, mortality, body condition and physical appearance and lameness.

Article 7.12.8.

Management of disease and injuries

1. Biosecurity

Biosecurity plans should be designed, commensurate with the desired health status of the equid population or *herd* and current disease risk. These *biosecurity plans* should be promoted with stakeholders for effective implementation and should address the control of the major sources and pathways for spread of pathogens by:

- a) equids;
- b) other *animals* and *vectors*;
- c) people;
- d) equipment;
- e) *vehicles*;
- f) air;
- g) water supply;
- h) *feed*.

Outcome-based measurables: morbidity, mortality, changes in body condition and physical appearance.

2. Animal health management

Effective national programmes for the prevention and treatment of working equid diseases and conditions require clear roles and responsibilities to be defined for official and private animal health service personnel as well as for owners.

Owners and handlers of working equids should be aware of signs of ill-health, disease, distress and injuries. If they suspect the presence of disease and are not able to manage it, they should seek advice from *veterinarians* or other qualified persons.

Non-ambulatory working equids should have access to *feed* and water at all times. They should not be transported or moved unless absolutely necessary for treatment or diagnosis. Such movements should be done carefully using methods that avoid dragging or excessive lifting.

When treatment is attempted, equids that are unable to stand unaided and refuse to eat or drink should be euthanised in accordance with Chapter 7.6., as soon as recovery is deemed unlikely.

Outcome-based measurables: morbidity, mortality, behaviour, body condition and physical appearance.

Article 7.12.9.

Handling and management practices

Management practices should be accomplished expertly and with the proper equipment and pain relief if appropriate. Painful husbandry procedures should be performed under the recommendation or supervision of a *veterinarian*.

Drivers and handlers should be trained to acquire good management skills.

Poor management practices include bad handling, inappropriate restraint such as too tight tethering or hobbling, the working of animals that are unfit or immature, poor housing that does not protect the equids from adverse weather conditions, inadequate handling equipment, excessive number of working hours, underfeeding, lack of access to water, lack of resting periods, working under heat stress, overloading, beating or whipping and some traditional practices.

Competent Authorities and *veterinarians* should educate owners and handlers of working equids to cease unsafe, ineffective and inhumane practices and also encourage good management and handling skills.

Working equids should not be kept confined indoors for long periods.

Working equids should not be tethered or hobbled continuously. In situations where temporary hobbling is necessary, the *animal handlers* should ensure sufficient distance between the two hobbled legs to allow the equid to stand naturally and move without risk of injury.

When temporary tethering is necessary working equids should be able to lie down, and if tethered outdoors, turn around and walk. The tethering site should be free from obstructions that may entangle the tether. Adequate water, *feed* and supervision should be provided; if necessary, action should be taken by moving the animals to areas providing shade or shelter.

Mares in season should not be tethered near stallions; mares about to foal or with a foal should not be tethered.

Equipment used to hobble should be designed for that purpose. The parts of the hobbles which are in contact with the skin should not be made from material that causes pain or injury.

Owners and users of working equids should be discouraged from using whips and harmful goads such as sticks. Instead humane training practices for equids should be promoted which focus on developing good driving practices.

Outcome-based measurables: behaviour, morbidity, mortality, body condition and physical appearance, lameness and fitness to work.

Article 7.12.10.

Behaviour

Animal handlers should be familiar with normal and abnormal behaviour of each type of working equid in order to interpret the welfare implications of what is being observed.

Human-animal interaction should be positive in order not to compromise the welfare of the working equid.

Different natural behaviours and social interactions between horses, mules and donkeys should be taken into account.

Outcome-based measurables: behaviour, body condition and physical appearance, and fitness to work.

Article 7.12.11.

End of working life

Consideration should be given to end of life issues.

Abandonment of equids should be discouraged. The *Competent Authorities* should develop and implement guidance or legislation to prevent abandonment while taking steps to make provision for abandoned animals to ensure their welfare.

When working equids need to be slaughtered or killed, recommendations in Chapters 7.5. and 7.6. should be followed to avoid the equids suffering a prolonged and painful death by abandonment, neglect or disease or acute, painful death such as being eaten by *wild animals*, or hit by a road vehicle.

Article 7.12.12.

Appropriate workloads

Equids continue to develop until over the age of five years so consideration should be given, according to workload, as to when working life commences. In general this should be three years of age or more but never less than two years of age. Animals that are subjected to excessive work too young in life will usually suffer from leg and back injuries in later life, resulting in a much-reduced working life.

Consideration should be given to the animal's overall condition, and other factors such as climate, and the work load should be adjusted accordingly. In particular, special considerations should be given to old animals and to mares three months before and after foaling, in order to not jeopardise pregnancy and allow the foal sufficient suckling access and resting time.

In general, animals should work a maximum of six hours per day and should be given at least one, preferably two, full day's rest in every seven-day period.

Consideration should be given to the weather conditions (work should be reduced in very hot weather). Breaks should be given at least every two hours and drinkable water should be provided.

All animals should receive sufficient good quality *feed* corresponding to their individual requirements. Drinkable water and roughage should be available to aid digestion.

Sick or injured animals should not be worked. Any animal that has been under veterinary treatment should not be returned to work until advised by the *veterinarian*.

Outcome-based measurables: behaviour, body condition and physical appearance, handling response, lameness and fitness to work.

Article 7.12.13.

Farriery and harnessing

1. Farriery

Owners and handlers should routinely clean and check the hooves of the working equid before and after work.

Hoof trimming and shoeing of working equids should only be performed by persons with the necessary knowledge and skills.

Outcome-based measurables: behaviour, body condition and physical appearance, lameness and fitness to work.

2. Harnessing

A properly designed, well-fitted and comfortable harness allows the working equid to pull the equipment to the best of its ability, efficiently and without risk of pain or injuries. Harness injury should be prevented by using properly fitted and adjusted harness which is checked daily for damage and repaired promptly as necessary. Equids should

be appropriately groomed before harnessing and checked after work for signs of rubbing and hair loss and the source of any problems should be removed through maintenance and padding where required.

Harnesses should not have sharp edges which could cause injury; should fit well so that it does not cause wounds or chafing caused by excess movement; should be smoothly shaped or padded so that loads imposed on the working equids' bodies are spread over a large area; and should not impede the animal's movement or normal breathing or restrict blood supply.

Carts should be maintained to ensure accurate balancing and appropriate tyre pressure. For draught equids the use of swingletrees is recommended so as to balance the pull and thus as a result reduce the risk of sores from the harness.

Owners should ensure effective harnessing and good riding and driving practices.

Bits should be of a simple type (such as a straight bar snaffle), depending on work, but should always be smooth, appropriately sized for the equid and kept clean. Inappropriate materials such as thin cord or wire should never be used as bits or to repair bits.

Outcome-based measurables: behaviour, body condition and physical appearance, lameness and fitness to work.

NB: FIRST ADOPTED IN 2016; MOST RECENT UPDATE ADOPTED IN 2017.

CHAPTER 7.13.

ANIMAL WELFARE AND PIG PRODUCTION SYSTEMS

Article 7.13.1.

Definitions

'Commercial pig production systems' means those systems in which the purpose of the operation includes some or all of the following: breeding, rearing and management of pigs (*Sus scrofa*) for the production and sale of pigs or pig *meat*.

For the purposes of this chapter, 'management' is defined at the farm management level and at the *animal handler* level. At the level of farm management, human resources management practices, including selection and training of handlers, and animal management practices, such as best practice in housing and husbandry and implementation of welfare protocols and audits, all have an impact on *animal welfare*. At the *animal handler* level this requires a range of well-developed husbandry skills and knowledge of how to care for animals.

For the purposes of this chapter, 'environmental enrichment' means increasing the complexity (e.g. foraging opportunities, social housing) of the animal's environment to foster the expression of normal behaviour, provide cognitive stimulation and reduce the expression of abnormal behaviour. The aim of providing enrichment should be to improve the physical and mental state of the animal.

For the purposes of this chapter 'stereotypy' is a repetitive behaviour induced by frustration, repeated attempts to cope or central nervous system dysfunction. It is expressed as a sequence of abnormal behaviours which appear to have no obvious purpose or function. Permanent dysfunction of the central nervous system in response to stressful conditions may mean that developed stereotypies may not resolve despite later changes to the environment or other treatments such as those relating to feeding levels or diet composition. Some stereotypies commonly observed in pigs include sham chewing, stone chewing, tongue rolling, teeth grinding, bar biting and floor licking.

For the purposes of this chapter 'apathy' means that the animal ceases to respond to stimuli that would normally elicit a response. Furthermore, apathetic behaviour has been described as an abnormal or maladaptive behaviour, indicated by reduced activity, lack of interest or concern (i.e. indifference) and lack of feeling or emotion (impassiveness).

For the purposes of this chapter 'agonistic behaviour' is a continuum of behaviours expressed in conflict situations, and includes offence, defence and submissive or escape components. The behaviours involved may include contact, such as biting and pushing, or non-contact, such as threats in the form of body postures and gestures. Aggressive behaviour (i.e. fighting) is a component of agonistic behaviour.

For the purposes of this chapter, 'play behaviour' is characterised by specific neuroendocrinological responses and the appearance of having fun. It is often prompted by novel or unpredictable stimuli, and is related to exploration. It functions to prepare animals for unexpected situations by increasing the versatility of movements and enhancing their ability to cope with unexpected stressful situations. Animals actively seek and create unexpected situations in play, deliberately relaxing their movements or putting themselves into disadvantageous positions.

Article 7.13.2.

Scope

This chapter addresses the welfare aspects of commercial domestic pig production systems. *Captive wild* pigs are not considered.

Article 7.13.3.

Commercial pig production systems

Commercial pig production systems include:

1. Indoor systems

These are systems in which pigs are kept indoors and are fully dependent on humans to provide for basic animal needs such as *feed* and water. The type of housing depends on the environment, climatic conditions and management system. The animals may be kept in groups or individually.

2. Outdoor systems

These are systems in which pigs live outdoors with shelter or shade, have some autonomy over access to shelter or shade, but may be fully dependent on humans to provide for basic animal needs such as *feed* and water. Pigs are typically kept in paddocks or pastures according to their production stage. The animals may be kept in groups or individually.

3. Combination systems

These are systems in which pigs are managed in any combination of indoor and outdoor production systems.

Article 7.13.4.

Criteria (or measurables) for the welfare of pigs

The following outcome-based criteria (or measurables), specifically animal-based criteria, can be useful indicators of *animal welfare*. The use of these indicators and their appropriate thresholds should be adapted to the different situations in which pigs are managed such as regional differences, *herd* health, pig breed or crossbreed, and climate. Consideration should also be given to the resources provided and the design of the system. These criteria can be considered as tools to monitor the efficiency of design and management, given that they can affect *animal welfare*.

1. Behaviour

Certain behaviours appear to be indicators of good animal welfare and health in pigs such as play and specific vocalisations.

Certain behaviours could indicate an *animal welfare* and health problem. These include sudden immobility, escape attempts, changes in *feed* and water intake, altered locomotory behaviour or posture, altered lying time, postures and patterns, altered respiratory rate and panting, coughing, shivering and huddling, high-pitched vocalisations and increased call rate, increased agonistic (including aggression), stereotypic, apathetic or other abnormal behaviours.

Environments that induce stereotypies typically also reduce animal welfare. Although stereotypies are generally held to indicate poor welfare, there are some instances where there is a poor association between stereotypies and stress. For example, frustration-induced stress may be somewhat rectified if the behaviour itself reduces the underlying motivation. Within a group, individuals that perform stereotypies may thus be coping more successfully than those that do not. Nevertheless, stereotypies indicate either a present problem for the animal or a past problem that has resolved. As with other indicators, caution should be used when using stereotypies as a welfare measure in isolation from other indicators.

2. Morbidity rates

Rates of infectious and metabolic diseases, lameness, peripartum and post-procedural complications, injury and other forms of morbidity, above recognised thresholds, may be direct or indirect indicators of *animal welfare* at the *herd* level. Understanding the aetiology of the disease or syndrome is important for detecting potential *animal welfare* problems. Mastitis and metritis, leg and hoof problems, shoulder ulcers in sows, skin lesions, respiratory and digestive diseases, and reproductive diseases are also particularly important animal health problems for pigs. Scoring systems, such as for body condition, lameness and injuries, and information gathered at the *slaughterhouse/abattoir*, can provide additional information.

Both clinical and *post mortem* pathologic examination should be utilised as indicators of disease, injuries and other problems that may compromise *animal welfare*.

3. Mortality and culling rates

Mortality and culling rates affect the length of productive life and, like morbidity rates, may be direct or indirect indicators of *animal welfare* at the *herd* level. Depending on the production system, estimates of mortality and culling rates can be obtained by analysing the causes of *death* and culling and their temporal and spatial patterns of occurrence. Mortality and culling rates, and their causes, when known, should be recorded regularly, e.g. daily, and used for monitoring e.g. monthly, annually.

Necropsy is useful in establishing the cause of *death*.

4. Changes in body weight and body condition

In growing animals, body weight changes outside the expected growth rate, especially excessive sudden weight loss, are indicators of poor *animal welfare* and health.

Body condition outside an acceptable range or large variation amongst individual animals in the group may be an indicator of compromised *animal welfare* and health, and reproductive efficiency in mature animals.

5. Reproductive efficiency

Reproductive efficiency can be an indicator of *animal welfare* and health status. Poor reproductive efficiency, compared with the targets expected for a particular breed or crossbreed, can indicate *animal welfare* problems.

Examples may include:

- low conception rates,
- high abortion rates,
- metritis and mastitis,
- small litter size (total born),
- low numbers born alive,
- high numbers of stillborns or mummies.

6. Physical appearance

Physical appearance may be an indicator of *animal welfare* and health. Attributes of physical appearance that may indicate compromised *animal welfare* include:

- body condition outside an acceptable range,
- presence of ectoparasites,
- abnormal texture or hair loss,
- excessive soiling with faeces,
- skin discolouration, including sunburn,
- swellings, injuries or lesions,
- discharges (e.g. from nose or eyes, including tear staining),
- feet and leg abnormalities,
- abnormal posture (e.g. rounded back, head low),
- emaciation or dehydration.

7. Handling response

Improper handling or lack of human contact can result in fear and distress in pigs. Fear of humans may be an indicator of poor *animal welfare*. Indicators may include:

- evidence of poor human-animal relationship, such as marked avoidance of handlers and abnormal or excessive vocalisation when being moved or when *animal handlers* interact with pigs,
- animals slipping or falling during handling,
- injuries sustained during handling, such as bruising, lacerations and fractures.

8. Lameness

Pigs are susceptible to a variety of infectious and non-infectious musculoskeletal disorders. These disorders may cause lameness and gait abnormalities. Pigs that are lame or have gait abnormalities may have difficulty reaching *feed* and water and may experience pain and distress. Musculoskeletal problems have many causes, including genetic, nutrition, sanitation, floor quality, and other environmental and management factors. There are several gait scoring systems available.

9. Complications from common procedures

Some painful or potentially painful procedures such as surgical castration, tail docking, teeth clipping or grinding, tusk trimming, identification, nose ringing and hoof care are performed on pigs to facilitate management, meet market or environmental requirements and improve human safety or safeguard *animal welfare*.

However, if these procedures are not performed properly, *animal welfare* and health can be unnecessarily compromised.

Indicators of problems associated with these procedures could include:

- post-procedure *infection* and swelling,
- post-procedure lameness,
- behaviour indicating pain, fear, distress or suffering,
- increased morbidity, mortality and culling rates,
- reduced *feed* and water intake,
- post procedure body condition and weight loss.

Article 7.13.5.

Recommendations

Ensuring good welfare of pigs is contingent on several management factors, including system design, environmental management, and animal management practices which include responsible husbandry and provision of appropriate care. Serious problems can arise in any system if one or more of these elements are lacking.

Articles 7.13.6. to 7.13.27. provide recommendations for measures applied to pigs.

Each recommendation in Article 7.13.6. to 7.13.24. includes a list of relevant animal-based criteria (or measurables) derived from Article 7.13.4. This does not exclude other criteria (or measurables) being used where or when appropriate.

Article 7.13.6.

Training of personnel

Pigs should be cared for by a sufficient number of personnel, who collectively possess the ability, knowledge and competence necessary to maintain the welfare and health of the animals.

All people responsible for pigs should be competent through formal training or practical experience in accordance with their responsibilities. This includes understanding of and skill in animal handling, nutrition, reproductive management techniques, behaviour, *biosecurity*, signs of disease, and indicators of poor *animal welfare* such as stress, pain and discomfort, and their alleviation.

Animal-based criteria (or measurables): handling response, physical appearance, behaviour, changes in body weight, body condition, reproductive efficiency, lameness and morbidity, mortality and culling rates and complications from common procedures.

Article 7.13.7.

Handling and inspection

Animal handlers with positive attitudes to handling and caring for pigs can lead to positive welfare outcomes. This may be shown by the length of time taken for the animals to approach a human, a short flight distance, or a willingness to interact with humans.

Pigs should be inspected at least once a day when fully dependent on humans to provide for basic needs such as *feed* and water and to identify welfare and health problems.

Some animals should be inspected more frequently, for example, farrowing sows, new born piglets, newly weaned pigs, newly-mixed gilts and sows, sick or injured pigs and those showing abnormal behaviours such as tail biting.

Pigs identified as sick or injured should be given appropriate treatment as soon as possible by competent *animal handlers*. If *animal handlers* are unable to provide appropriate treatment, the services of a *veterinarian* should be sought.

Recommendations on the handling of pigs are also found in Chapter 7.3. In particular handling aids that may cause pain and distress (e.g. electric goads) should be used only when other methods fail and provided that the animal can move freely and is able to move away from the handling aid. The use of electric goads should be avoided (see also point 3 of Article 7.3.8.), and should not be repeatedly used on the same animal, and not be used in sensitive areas including the udder, face, eyes, nose, ears or anogenital region. *Animal handlers* should be alert for signs of stress in pigs and know when to release handling pressure (by giving pigs more time and space) to reduce the level of threat.

Exposure of pigs to sudden movement, loud noises or changes in visual contrasts should be minimised where possible to prevent stress and fear reactions. Pigs should not be improperly or aggressively handled (e.g. kicked, thrown, dropped, walked on top of, held or pulled by one front leg, ears or tail). Pigs that become distressed during handling should be attended to immediately.

Pigs should be restrained only for as long as necessary and only appropriate, well-maintained restraint devices should be used.

Well designed and maintained handling facilities assists proper handling.

Animal-based criteria (or measurables): physical appearance, behaviour, changes in body weight and body condition, handling response, reproductive efficiency, lameness and morbidity, mortality and culling rates.

Article 7.13.8.

Painful procedures

Some procedures such as surgical castration, tail docking, teeth clipping or grinding, tusk trimming, identification, and nose ringing may be performed on pigs. These procedures should only be performed by trained personnel, when necessary to facilitate management, meet market or environmental requirements, improve human safety or safeguard *animal welfare*.

These procedures are painful or have the potential to cause pain. They should be performed in such a way as to minimise any pain, distress or suffering to the animal.

Options for enhancing *animal welfare* in relation to these procedures include the internationally recognised 'three Rs': replacement (e.g. using entire males or immunocastrated males rather than surgically castrated males), reduction (e.g. tail docking and teeth clipping only when necessary) and refinement (e.g. providing analgesia or anaesthesia under the recommendation or supervision of a *veterinarian*).

Ovariectomy should not be performed without anaesthesia and prolonged analgesia. An immunological product that reversibly and effectively suppresses ovarian function in pigs is available. Immunological prevention of oestrus should be encouraged to avoid ovariectomy.

Animal-based criteria (or measurables): complications from common procedures, morbidity rates, mortality and culling rates, abnormal behaviour, physical appearance and changes in weight and body condition.

Article 7.13.9.

Provision of feed and water

The amount of *feed* and nutrients pigs require in any management system is affected by factors such as climate, the nutritional composition and quality of the diet, the age, gender, genetics, size and physiological state of the pigs (e.g. pregnancy, lactation, growth), and their state of health, growth rate, previous feeding levels and level of activity and exercise.

All pigs should receive adequate quantity and quality of *feed* and nutrients each day to enable each pig to:

- maintain good health;
- meet its physiological requirements; and
- meet its requirements for foraging and feeding behaviour.

Feed and water should be provided in such a way as to prevent excessive or injurious competition.

Pigs should be fed a diet with the intention of minimising the occurrence of gastric ulcers (e.g. increasing dietary fiber or reducing crude protein).

All pigs should have access to an adequate supply of drinkable water that meets their physiological requirements and is free from contaminants hazardous to pig health. Water flow rates in drinkers should be set according to the age of the animal, stage of production and environmental conditions.

In outdoor systems where pigs have some autonomy over diet selection, stocking density should be matched to the available natural *feed* supply.

Animal-based criteria (or measurables): changes in body weight and body condition, physical appearance (emaciation, dehydration), behaviour (agonistic behaviour at feeding and watering places and abnormal behaviour such as tail biting), mortality and culling rates, and morbidity rates.

Article 7.13.10.

Environmental enrichment

Animals should be provided with an environment that provides complexity, manipulability and cognitive stimulation to foster normal behaviour (e.g. exploration, foraging such as rooting, biting and chewing materials other than feedstuffs, and social interaction), reduce abnormal behaviour (e.g. tail, ear, leg and flank biting, sham chewing, bar biting and apathetic behaviour) and improve their physical and mental state.

Pigs should be provided with enrichments that aim to improve their welfare through the enhancement of their physical and social environments, such as:

- sufficient quantity of suitable materials to enable pigs to fulfil their needs to explore and look for *feed* (edible materials), bite (chewable materials), root (investigable materials) and manipulate materials. Novelty is another aspect that is important in maintaining interest in the provided materials;
- social enrichment that involves either keeping pigs in groups or individually with visual, olfactory and auditory contact with other pigs;
- positive human contact (such as regular direct physical contact associated with positive events, which may include *feed*, pats, rubs, scratching and talking when the opportunity arises).

Animal-based criteria (or measurables): physical appearance (injuries), behaviour (stereotypies, tail biting), changes in body weight and body condition, handling response, reproductive efficiency, lameness and morbidity, mortality and culling rates.

Article 7.13.11.

Prevention of abnormal behaviour

In pig production there is a number of abnormal behaviours that can be prevented or minimised with appropriate management procedures.

Many of these problems are multifactorial and minimising their occurrence requires an examination of the whole environment and of several management factors. Management procedures that may reduce the occurrence of some of these behavioural problems include:

- 1) Oral stereotypies (e.g. bar biting, sham chewing, excessive drinking) may be minimised by providing environmental enrichment and increasing feeding time and satiety by increasing fibre content in the diet or foraging roughage.
- 2) Tail biting may be reduced by providing an adequate enrichment material and an adequate diet (avoiding deficiencies of minerals or essential amino acids), and avoiding high stocking densities and competition for resources, such as *feed* and water. Other factors to consider include animal characteristics (breed, genetics, gender) and social environment (*herd* size, mixing animals), general health, thermal comfort and air quality.
- 3) Belly nosing and ear sucking may be reduced by increasing the weaning age, and providing *feed* to piglets prior to weaning to avoid the abrupt change of *feed*.
- 4) Vulva biting may be reduced by minimising competition for resources, including *feed* and water, and reducing group size.

Animal-based criteria (or measurables): physical appearance (injuries), behaviour (abnormal behaviour), morbidity rates, mortality and culling rates, reproductive efficiency and changes in body weight and body condition.

Article 7.13.12.

Housing (including outdoor production systems)

When new facilities to accommodate pigs are planned or existing facilities are modified, professional advice on design in regards to welfare and health of animals should be sought.

Housing systems and their components should be designed, constructed and regularly inspected and maintained in a manner that reduces the risk of injury, disease and stress for pigs. Facilities should allow for the safe, efficient and humane management and movement of pigs. In systems where pigs could be exposed to adverse weather conditions they should have access to shelter to avoid thermal stress and sunburn.

There should be a separate pen or area where sick and injured animals or animals that exhibit abnormal behaviour can be isolated, treated and monitored. Certain animals may need to be kept individually. When a separated space is provided, this should accommodate all the needs of the animal e.g. recumbent or lame animals or animals with severe wounds may require additional bedding or an alternative floor surface, and water and *feed* should be within reach.

Pigs should not be tethered as part of their normal housing systems.

Good outcomes in the welfare and health of animals can be achieved in a range of housing systems. The design and management of the system are critical for achieving these outcomes.

Sows and gilts, like other pigs, are social animals and prefer living in groups, therefore pregnant sows and gilts should preferably be housed in groups. Boars may need to be housed in individual pens.

Animal-based criteria (or measurables): physical appearance (injuries), behaviour, changes in body weight and body condition, handling response, reproductive efficiency, lameness and morbidity, mortality and culling rates.

Article 7.13.13.

Space allowance

Space allowance should be managed taking into account different areas for lying, standing, feeding and elimination. Stocking density should not adversely affect normal behaviour of pigs and duration of time spent lying.

Insufficient and inadequate space allowance may increase stress, the occurrence of injuries and have an adverse effect on growth rate, *feed* efficiency, reproduction and behaviour such as locomotion, resting, feeding and drinking, agonistic and abnormal behaviour.

1. Group housing

Floor space may interact with a number of factors such as temperature, humidity, floor type and feeding systems to affect pig welfare. All pigs should be able to lie down simultaneously and to stand up and move freely. Sufficient space should be provided to enable animals to have access to *feed*, water, to separate lying and elimination areas and to avoid aggressive animals.

Group housing systems should provide sufficient space and opportunities to avoid or escape from potential aggressors.

If abnormally aggressive behaviour is seen, corrective measures should be taken, such as increasing space allowance and providing barriers where possible or individually housing the aggressive pig.

Animal-based criteria (or measurables): reduction or variation in body weight and body condition, increasing agonistic and abnormal behaviour such as tail biting, injuries, morbidity, mortality and culling rates, and physical appearance (e.g. excessive presence of faeces on the skin).

2. Individual pens

Pigs should only be housed in individual pens if necessary. In individual pens, pigs should be provided with sufficient space so that they can stand up, turn around and lie comfortably in a natural position, and that provides separate areas for elimination, lying and eating.

Animal-based criteria (or measurables): increasing abnormal behaviour (stereotypies), morbidity, mortality and culling rates, and physical appearance (e.g. excessive presence of faeces on the skin, injuries).

3. Stalles et cages

Feeding, insemination and gestation stalls and farrowing crates should be sized appropriately to allow pigs to:

- stand up in their natural stance without contact with either side of the stall or crate,
- stand up in their natural stance without contact with the top bars,
- stand without simultaneously touching both ends of the stall or crate,
- lie comfortably on their sides without disturbing neighbouring pigs or being injured by another pig, except in the case of stalls used only for feeding.

Animal-based criteria (or measurables): physical appearance (e.g. injuries), increasing abnormal behaviour (stereotypies), reproductive efficiency, lameness and morbidity, mortality and culling rates (e.g. piglets).

Article 7.13.14.

Flooring, bedding, resting surfaces

In all production systems, pigs need a well-drained, dry and comfortable place to rest, except in situations where sprinklers or misters may be used to prevent heat stress.

Floor management in indoor production systems can have a significant impact on pig welfare. Flooring, bedding, resting surfaces and outdoor yards should be cleaned as conditions warrant, to ensure good hygiene, comfort and minimise risk of diseases and injuries. Areas with excessive faecal accumulation are not suitable for resting.

Floors should be designed to minimise slipping and falling, promote foot health, and reduce the risk of claw injuries.

If a housing system includes areas of slatted floor, the slat and gap widths should be appropriate to the claw size of the pigs to prevent injuries.

Slope of the floor should allow water to drain and not pool.

In outdoor systems, pigs should be rotated between paddocks or pastures to ensure good hygiene and minimise risk of diseases.

If bedding or rubber matting is provided it should be maintained to provide pigs with a clean, dry and comfortable place on which to lie.

Animal-based criteria (or measurables): physical appearance (e.g. injuries, presence of faeces on the skin, bursitis), lameness and morbidity rates (e.g. respiratory disorders, reproductive tract infections).

Article 7.13.15.

Air quality

Good air quality and ventilation are important for the welfare and health of pigs and reduce the risk of respiratory discomfort, diseases and abnormal behaviour. Dust, toxins, microorganisms and noxious gases, including ammonia, hydrogen sulphide, and methane caused by decomposing animal waste, can be problematic in indoor systems.

Air quality is influenced strongly by management and building design in housed systems. Air composition is influenced by stocking density, the size of the pigs, flooring, bedding, waste management, building design and ventilation system.

Proper ventilation, without draughts, particularly for young pigs, is important for effective heat dissipation in pigs and to prevent the build-up of effluent gases (e.g. ammonia and hydrogen sulphide), including those from manure and dust in the housing unit. The ammonia concentration in enclosed housing should not exceed 25 ppm. A useful indicator is that if air quality at the level of the pigs is unpleasant for humans it is most likely a problem for pigs.

Animal-based criteria (or measurables): morbidity, mortality and culling rates, physical appearance, behaviour (especially respiratory rate, coughing and tail biting), change in body weight and body condition.

Article 7.13.16.

Thermal environment

Although pigs can adapt to a range of thermal environments, particularly if appropriate breeds and housing are used for the anticipated conditions, sudden fluctuations in temperature can cause heat or cold stress.

1. Heat stress

Heat stress is a serious problem in pig production. It can cause significant discomfort, as well as reductions in weight gain and fertility, or sudden death.

The risk of heat stress for pigs is influenced by environmental factors including air temperature, solar radiation, relative humidity, wind speed, ventilation rates, stocking density, shade and wallow availability in outdoor systems and animal factors including breed, age and body condition.

At a given temperature, the heavier pigs are, the more susceptible they are to heat stress.

Animal handlers should be aware of the risk that heat stress poses to pigs and of the thresholds in relation to heat and humidity that may require action. If the risk of heat stress reaches too high levels the *animal handlers* should institute an emergency action plan that gives priority to access to additional water and could include provision of shade and wallows in outdoor systems, fans, reduction of stocking density, water-based cooling systems (dripping or misting), and provision of cooling systems as appropriate for the local conditions.

Animal-based criteria (or measurables): behaviour (*feed* and water intake, respiratory rate, panting, lying postures and patterns, agonistic behaviour), physical appearance (presence of faeces on the skin, sunburn), morbidity, mortality and culling rates, and reproductive efficiency.

2. Cold stress

Protection from cold should be provided when conditions are likely to compromise the welfare of pigs, particularly in neonates and young pigs and others that are physiologically compromised (e.g. ill animals). Protection can be provided by insulation, extra bedding, heat mats or lamps and natural or man-made shelters in outdoor systems.

Animal-based criteria (or measurables): morbidity, mortality and culling rates, physical appearance (piloerection), behaviour (especially abnormal postures, shivering and huddling) and changes in body weight and body condition.

Article 7.13.17.

Noise

Exposure of pigs to sudden or prolonged loud noises should be avoided to prevent increased aggression, stress and fear. Ventilation fans, feeding machinery or other indoor or outdoor equipment should be constructed, placed, operated and maintained in such a way that they cause the least possible amount of noise.

Animal-based criteria (or measurables): behaviour (e.g. fleeing and abnormal or excessive vocalisation), physical appearance (e.g. injuries), reproductive efficiency, changes in body weight and body condition.

Article 7.13.18.

Lighting

Indoor systems should have light levels sufficient to allow all pigs to see one another, to investigate their surroundings visually and to show other normal behaviour patterns and to be seen clearly by staff to allow adequate inspection of the pigs. The lighting regime should be such as to prevent health and behavioural problems. It should follow a 24-hour rhythm and include sufficient uninterrupted dark and light periods, preferably no less than 6 hours for both.

Artificial light sources should be located so as not to cause discomfort to the pigs.

Animal-based criteria (or measurables): behaviour (locomotive behaviour), morbidity rate, reproductive efficiency, physical appearance (injuries) and changes in body weight and body condition.

Article 7.13.19.

Farrowing and lactation

Sows and gilts need time to adjust to their farrowing accommodation before farrowing. Nesting material should be available to sows and gilts where possible for at least one day prior to. Sows and gilts should be observed frequently around their expected farrowing times. As some sows and gilts need assistance during farrowing, there should be sufficient space and competent staff.

Farrowing accommodation should also provide comfort, warmth and protection to the piglets.

Animal-based criteria (or measurables): mortality and culling rates (piglets; gilts and sows), morbidity rates (metritis and mastitis), behaviour (restlessness and savaging), reproductive efficiency, physical appearance (injuries).

Article 7.13.20.

Weaning

Weaning is a stressful time for sows and piglets and good management is required. Problems associated with weaning are generally related to the piglets' size and physiological maturity. Weaned piglets should be moved into clean and disinfected housing separate from where sows are kept, in order to minimise the transmission of diseases to the piglets.

Piglets should be weaned at three weeks or older, unless otherwise recommended by a *veterinarian* for disease control purposes. Early weaning systems require good management and nutrition of the piglets.

Delaying weaning to the age of four weeks or more may produce benefits such as improved gut immunity, less diarrhoea and less use of *antimicrobial agents*.

Regardless of age, low weight piglets require additional care and can benefit from being kept in small groups in specialised pens until they are able to be moved to the common nursery area.

Newly weaned pigs are susceptible to disease challenges, so adherence to high-level hygiene protocols and appropriate diet is important. The area that piglets are weaned into should be clean, dry and warm.

All newly weaned pigs should be monitored carefully during the first two weeks after weaning for any signs of ill-health or abnormal stress.

Animal-based criteria (or measurables): mortality and culling rates (piglets), morbidity rates (respiratory disease, diarrhoea), behaviour (belly nosing and ear sucking), physical appearance (injuries) and changes in body weight and body condition.

Article 7.13.21.

Mixing

Mixing of unfamiliar pigs can result in fighting to establish a dominance hierarchy, and therefore mixing should be minimised as much as possible. When mixing, strategies to reduce aggression should be implemented. Animals should be observed after mixing and interventions applied if the aggression is intense or prolonged, to minimise stress and injury.

Measures to prevent excessive fighting and injuries can include:

- providing additional space and a non-slippery floor,
- feeding before mixing,
- feeding on the floor in the mixing area,
- providing straw or other suitable enrichment materials in the mixing area,
- providing opportunities to escape and to hide from other pigs, such as visual barriers,
- mixing previously familiarised animals whenever possible,
- mixing young animals as soon after weaning as possible,
- avoiding the addition of one or small number of animals to a large established group.

Animal-based criteria (or measurables): mortality, morbidity and culling rates, behaviour (agonistic), physical appearance (injuries), changes in body weight and body condition and reproductive efficiency.

Article 7.13.22.

Genetic selection

Welfare and health considerations should balance any decisions on productivity and growth rate when choosing a breed or crossbreed for a particular location or production system.

Selective breeding can improve the welfare of pigs for example by selection to improve maternal behaviour, piglet viability, temperament and resistance to stress and disease and to reduce tail biting and aggressive behaviour. Including genetic characteristics related to social behaviour into breeding programmes may also reduce negative social interactions and increase positive ones and may have major positive effects on group-housed animals.

Animalbased criteria (or measurables): physical appearance, behaviour (e.g. maternal and agonistic behaviour), changes in body weight and body condition, handling response, reproductive efficiency, lameness, and morbidity, mortality and culling rates.

Article 7.13.23.

Protection from predators and pests

In outdoor and combination systems pigs should be protected from predators.

Where practicable, pigs should also be protected from pests such as excessive numbers of flies and mosquitoes.

Animal-based criteria (or measurables): morbidity, mortality and culling rates, behaviour, and physical appearance (injuries).

Article 7.13.24.

Biosecurity and animal health (biosecurity and disease prevention)

Biosecurity plans should be designed, implemented and maintained, commensurate with the best possible *herd* health status, available resources and infrastructure, and current disease risk and, for *listed diseases* in accordance with relevant recommendations in the *Terrestrial Code*.

These *biosecurity plans* should address the control of the major sources and pathways for spread of pathogenic agents including:

- introductions to the *herd*, especially from different sources,
- semen,
- other domestic animals, *wildlife* and pests,
- people, including sanitation practices,
- equipment, including *vehicles*, tools and facilities,
- air, water, *feed* and bedding,
- waste, including manure garbage and disposal of dead animals.

Animal-based criteria (or measurables): morbidity, mortality and culling rates, reproductive efficiency, changes in weight and body condition, physical appearance (signs of disease).

1. Animal health management

Animal health management should optimise the welfare and health of pigs in the *herd*. It includes the prevention, treatment and control of diseases and conditions affecting the *herd* (in particular respiratory, reproductive and enteric diseases).

There should be an effective programme for the prevention and treatment of diseases and conditions, formulated in consultation with a *veterinarian*. This programme should include *biosecurity* and quarantine protocols, the acclimatisation of replacements, *vaccinations*, and good colostrum management, the recording of production data

(e.g. number of sows, piglets per sow per year, *feed* conversion, and body weight at weaning), morbidity, mortality and culling rate and medical treatments. It should be kept up to date by the *animal handler*. Regular monitoring of records aids management and quickly reveals problem areas for intervention.

For parasitic burdens (e.g. endoparasites, ectoparasites and protozoa) and insect and rodents control, a programme should be implemented to monitor, control and treat, as appropriate.

Lameness can be a problem in pigs. *Animal handlers* should monitor the state of feet and legs and take measures to prevent lameness and maintain foot and leg health.

Those responsible for the care of pigs should be aware of early specific signs of disease, pain, distress or suffering, such as coughing, abortion, diarrhoea, changes in locomotory behaviour or apathetic behaviour, and non-specific signs such as reduced *feed* and water intake, changes in weight and body condition, changes in behaviour or abnormal physical appearance.

Pigs at higher risk will require more frequent inspection by *animal handlers*. If *animal handlers* suspect the presence of a disease or are not able to correct the causes of disease, pain, distress or suffering, they should seek advice from those having training and experience, such as *veterinarians* or other qualified advisers, as appropriate. Nonambulatory pigs should not be transported or moved unless absolutely necessary for treatment, recovery, or diagnosis. Such movements should be done carefully using methods that avoid dragging the animal or lifting it in a way that might cause further pain, suffering or exacerbate injuries.

Animal handlers should also be competent in assessing fitness to transport, as described in Chapter 7.3.

In case of disease or injury, when treatment has failed, is not feasible or recovery is unlikely (e.g. pigs that are unable to stand up unaided or refuse to eat or drink), or severe pain that cannot be alleviated the animal should be humanely killed as soon as possible in accordance with Chapter 7.6.

Animalbased criteria (or measurables): morbidity, mortality and culling rates, reproductive efficiency, behaviour (apathetic behaviour), lameness, physical appearance (injuries) and changes in body weight and body condition.

2. Emergency plans for disease outbreaks

Emergency plans should cover the management of the farm in the event of a disease *outbreak*, consistent with national programmes and recommendations of *Veterinary Services* as appropriate.

Article 7.13.25.

Contingency plans

Where the failure of power, water or *feed* supply systems could compromise *animal welfare*, pig producers should have contingency plans in place. These plans may include the provision of fail-safe alarms to detect malfunctions, back-up generators, contact information for key service providers, ability to store water on farm, access to water cartage services, adequate on-farm storage of *feed* and an alternative *feed* supply.

Preventive measures for emergencies should be input-based rather than outcome-based. Alarms and back-up systems should be checked regularly. Contingency plans should be documented and communicated to all responsible parties.

Article 7.13.26.

Disaster management

Plans should be in place to minimise and mitigate the effect of disasters (e.g. earthquake, fire, flooding, blizzard and hurricane). Such plans may include evacuation procedures, identifying high ground, maintaining emergency *feed* and water stores, destocking and humane *killing* when necessary.

Procedures for humane *killing* of sick or injured pigs should be part of the disaster management plan and should follow the recommendations of Chapter 7.6.

Reference to contingency plans can also be found in Article 7.13.25.

Article 7.13.27.

Humane killing

Allowing a sick or injured animal to linger unnecessarily is unacceptable. Therefore, for sick and injured pigs a prompt diagnosis should be made to determine whether the animal should be treated or humanely killed.

The decision to kill an animal humanely and the procedure itself should be undertaken by a competent person.

For a description of acceptable methods for humane *killing* of pigs see Chapter 7.6.

The *establishment* should have documented procedures and the necessary equipment for on-farm humane *killing*. Staff should be trained in humane *killing* procedures appropriate for each class of pig.

Reasons for humane *killing* may include:

- severe emaciation, weak pigs that are nonambulatory or at risk of becoming nonambulatory,
- severely injured or nonambulatory pigs that will not stand up, refuse to eat or drink, or have not responded to treatment,
- rapid deterioration of a medical condition for which treatment has been unsuccessful,
- severe pain that cannot be alleviated,
- multiple joint *infections* with chronic weight loss,
- piglets that are premature and unlikely to survive, or have a debilitating congenital defect, and
- as part of disaster management response.

NB: FIRST ADOPTED IN 2018.

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