

**MEETING OF THE OIE
TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION**

Paris, 8–12 February 2010

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**MEETING OF THE OIE
TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION**

Paris, 8–12 February 2010

Adopted agenda

A. MEETING WITH THE DIRECTOR GENERAL

1. Welcome – Director General

**B. UPDATE ON REPORTS OF OTHER COMMISSIONS AND
OTHER RELEVANT ACTIVITIES OF THE OIE**

1. Update on reports of other commissions; harmonisation with the *Aquatic Code*; 5th OIE Strategic Plan; and other relevant activities of the OIE – President of the Commission

C. TEXT FOR ADOPTION

- Item 1 General comments including deleted Chapters
- Item 2 Glossary
- Item 3 Criteria for listing diseases (Chapter 1.2.)
- Item 4 Animal health surveillance (Chapter 1.4.)
- Item 5 Surveillance for arthropod vectors of animal diseases (Chapter 1.5.)
- Item 6 Status for OIE listed diseases (Chapter 1.6.)
- Item 7 Import risk analysis
 - a) Revision to Chapter 2.1.
 - b) Final draft text of revised Volume 1, IRA Handbook
- Item 8 Evaluation of Veterinary Services
 - a) Revision to Chapter 3.1.
 - b) Revision to Chapter 3.2.
 - c) Report of the *ad hoc* Group in December 2009: new competencies in OIE PVS Tool
 - d) Veterinary Legislation initiative

Annex II (contd)

- Item 9 Design and implementation of identification systems to achieve animal traceability (Chapter 4.2.)
- Item 10 Zoning and compartmentalisation
- a) Zoning and compartmentalisation (Chapter 4.3.)
 - b) Application of compartmentalisation (Chapter 4.4.)
 - c) Update on ongoing projects
- Item 11 Semen and embryo chapters (Chapters 4.5.- 8., 10.)
- Item 12 Disposal of dead animals (Chapter 4.12.)
- Item 13 General obligations related to certification (Chapters 5.1. and 5.2)
- Item 14 Control of hazards of animal health and public health importance in animal feed (Chapter 6.3.)
- Item 15 Salmonellosis
- a) Biosecurity procedures in poultry production (revised Chapter 6.4.)
 - b) Prevention, detection and control of *Salmonella* in poultry (Chapter 6.5.) and *Salmonella* Enteritidis and *Salmonella* Typhimurium in poultry (Chapter 6.6.)
- Item 16 Introduction to the recommendations for controlling antimicrobial resistance (Chapter 6.7.)
- Item 17 Animal welfare
- a) Use of animals in research and education (new Chapter)
 - b) Updates on poultry (Chapter 7.3. – 6.)
 - c) Stray dog population control (Chapter 7.7.)
 - d) Draft new chapters on animal welfare and (1) broiler chicken production systems; (2) beef cattle production systems
- Item 18 Anthrax (Chapter 8.1.)
- Item 19 Aujeszky's disease (Chapter 8.2.)

Annex II (contd)

- Item 20 Bluetongue (Chapter 8.3.)
- Item 21 Foot and mouth disease (Chapter 8.5.)
- Item 22 Rift Valley fever (Chapter 8.11.)
- Item 23 West Nile fever (Chapter 8.16.)
- Item 24 Avian influenza (Chapter 10.4.)
- Item 25 Newcastle disease (Chapter 10.13.)
- Item 26 Bovine spongiform encephalopathy (Chapter 11.6.)
- Item 27 Tuberculosis
- a) Bovine tuberculosis (Chapter 11.7.)
 - b) Bovine tuberculosis of farmed cervidae (Chapter 11.8.)
- Item 28 Contagious bovine pleuropneumonia (Chapter 11.9.)
- Item 29 Enzootic bovine leukosis (Chapter 11.11.)
- Item 30 Infectious bovine rhinotracheitis/ infectious pustular vulvovaginitis (Chapter 11.13.)
- Item 31 Lumpy skin disease (Chapter 11.14.)
- Item 32 Equine diseases
- a) Discussion in the *ad hoc* Group on official recognition of disease status of African horse sickness
 - b) Equine influenza (Chapter 12.7.)
 - c) Equine viral arteritis (Chapter 12.10.)
- Item 33 Scrapie (Chapter 14.9.)
- Item 34 Classical swine fever (Chapter 15.3.)

D. TEXTS NOT FOR ADOPTION / FOR FURTHER DISCUSSION

- Item 35 Control of hazards of animal health and public health importance in heat treated pet food (new draft Chapter)
- Item 36 Paratuberculosis (Chapter 8.9.)

Annex II (contd)

- Item 37 Rabies (Chapter 8.10.)
 - Item 38 Vesicular stomatitis (Chapter 8.16.)
 - Item 39 Diseases of bees (Chapters 9.1.–6.)
 - Item 40 Bovine brucellosis (Chapter 11.3.)
 - Item 41 Swine vesicular disease (Chapter 15.5.)
 - Item 42 Porcine reproductive and respiratory syndrome (PRRS)
 - Item 43 Communication
 - Item 44 APFSWG Discussion paper on future priorities for Animal Production Food Safety Standard Setting
 - Item 45 Private standards for sanitary safety and animal welfare
 - Item 46 Trade in Animal Products (“commodities”) – report of the *ad hoc* Group
 - Item 47 Future work programme of the Code Commission
 - Item 48 Others
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~~CHAPTER 11.4.~~~~BOVINE CYSTICERCOSIS~~~~Article 11.4.1.~~~~**General provisions**~~~~Standards for diagnostic tests are described in the *Terrestrial Manual*.~~~~Article 11.4.2.~~~~**Recommendations for the importation of fresh meat of cattle**~~~~Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate attesting that the entire consignment of meat comes from animals which have been subjected to ante mortem and post mortem inspections as described in Chapter 6.2.~~

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~~CHAPTER 11.10.~~~~DERMATOPHILOSIS~~~~Article 11.10.1.~~~~**General provisions**~~~~Standards for diagnostic tests are described in the *Terrestrial Manual*.~~~~Article 11.10.2.~~~~**Recommendations for importation from countries considered infected with dermatophilosis**~~~~for ruminants and equines~~~~Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:~~

- ~~1. showed no clinical sign of dermatophilosis on the day of shipment;~~
- ~~2. were treated with acaricides prior to shipment and were completely free of ticks.~~

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~~CHAPTER 12.4.~~~~EPIZOOTIC LYMPHANGITIS~~~~Article 12.4.1.~~~~**General provisions**~~~~Standards for diagnostic tests are described in the *Terrestrial Manual*.~~~~Article 12.4.2.~~~~Recommendations for the importation of domestic horses~~~~*Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that the animals:~~

- ~~1. showed no clinical sign of epizootic lymphangitis on the day of shipment;~~
- ~~2. were kept in *establishments* in which no case of epizootic lymphangitis was officially reported during the 2 months prior to shipment.~~

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~~CHAPTER 12.12.~~~~HORSE MANGE~~~~Article 12.12.1.~~~~**General provisions**~~~~Standards for diagnostic tests are described in the *Terrestrial Manual*.~~~~Article 12.12.2.~~~~**Recommendations for the importation of equines**~~~~*Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that the animals:~~

- ~~1. showed no clinical sign of horse mange on the day of shipment;~~
- ~~2. were kept for the 3 months prior to shipment in an *establishment* where no *case* of horse mange was officially reported during that period.~~

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~~CHAPTER 12.13.~~~~HORSE POX~~~~Article 12.13.1.~~**Recommendations for the importation of equines**

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

- ~~1. showed no clinical sign of horse pox on the day of shipment;~~
- ~~2. were kept for the 3 months prior to shipment in an establishment where no case of horse pox was officially reported during that period.~~

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~~CHAPTER 15.2.~~~~ATROPHIC RHINITIS OF SWINE~~~~Article 15.2.1.~~~~**General provisions**~~~~Standards for diagnostic tests are described in the *Terrestrial Manual*.~~~~Article 15.2.2.~~~~**Recommendations for the importation of pigs for breeding or rearing**~~~~*Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that the animals:~~

- ~~1. showed no clinical sign of atrophic rhinitis on the day of shipment;~~
- ~~2. were kept in the *exporting country*, since birth or for the 6 months prior to shipment, in an *establishment* where no *case* of atrophic rhinitis was officially reported during the past year.~~

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CHAPTER 15.6.

~~TESCHOVIRUS ENCEPHALOMYELITIS~~
 (~~previously enterovirus encephalomyelitis, Teschen disease, Talfan disease~~)

Article 15.6.1.

General provisions

For the purposes of the ~~Terrestrial Code~~, the ~~incubation period~~ for ~~Teschovirus encephalomyelitis~~ shall be ~~40 days~~.

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

Article 15.6.2.

Teschovirus encephalomyelitis free country

A country may be considered free from ~~Teschovirus encephalomyelitis~~ when it has been shown that ~~Teschovirus encephalomyelitis~~ has not been present for at least the past ~~3 years~~.

~~This period shall be 6 months after the slaughter of the last affected animal for countries in which a stamping out policy is practised with or without vaccination against Teschovirus encephalomyelitis.~~

Article 15.6.3.

Teschovirus encephalomyelitis infected zone

A zone shall be considered as infected with ~~Teschovirus encephalomyelitis~~ until:

1. ~~at least 40 days have elapsed after the confirmation of the last case and the completion of a stamping out policy and disinfection procedures, or~~
2. ~~6 months have elapsed after the clinical recovery or death of the last affected animal if a stamping out policy was not practised.~~

Article 15.6.4.

Recommendations for importation from ~~Teschovirus encephalomyelitis~~ free countriesfor domestic pigs

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

1. ~~showed no clinical sign of ~~Teschovirus encephalomyelitis~~ on the day of shipment;~~
2. ~~were kept in a country free from ~~Teschovirus encephalomyelitis~~ since birth or for at least the past 40 days.~~

Annex III (contd)

Article 15.6.5.

~~Recommendations for importation from Teschovirus encephalomyelitis free countries~~~~for wild pigs~~

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

- ~~1. showed no clinical sign of Teschovirus encephalomyelitis on the day of shipment;~~
- ~~2. come from a country free from Teschovirus encephalomyelitis;~~

~~if the country of origin has a common border with a country considered infected with Teschovirus encephalomyelitis:~~

- ~~3. were kept in a quarantine station for the 40 days prior to shipment.~~

Article 15.6.6.

~~Recommendations for importation from countries considered infected with Teschovirus encephalomyelitis~~~~for domestic pigs~~

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

- ~~1. showed no clinical sign of Teschovirus encephalomyelitis on the day of shipment;~~
- ~~2. were kept since birth, or for the past 40 days, in an establishment where no case of Teschovirus encephalomyelitis was officially reported during that period, and that the establishment of origin was not situated in an Teschovirus encephalomyelitis infected zone; or~~
- ~~3. were kept in a quarantine station for the 40 days prior to shipment;~~
- ~~4. have not been vaccinated against Teschovirus encephalomyelitis; or~~
- ~~5. were vaccinated against Teschovirus encephalomyelitis, not less than 30 days and not more than one year prior to shipment (the nature of the vaccine used, whether inactivated or modified live virus, and the virus types and strains included shall also be stated in the certificate).~~

Article 15.6.7.

~~Recommendations for importation from countries considered infected with Teschovirus encephalomyelitis~~~~for wild pigs~~

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

- ~~1. showed no clinical sign of Teschovirus encephalomyelitis on the day of shipment;~~
- ~~2. were kept in a *quarantine station* for the 40 days prior to shipment;~~
- ~~3. have not been vaccinated against Teschovirus encephalomyelitis; or~~
- ~~4. were vaccinated against Teschovirus encephalomyelitis, not less than 30 days and not more than one year prior to shipment (the nature of the vaccine used, whether inactivated or modified live virus, and the virus types and strains included shall also be stated in the certificate).~~

~~Article 15.6.8.~~

~~Recommendations for importation from Teschovirus encephalomyelitis free countries~~

~~for semen of pigs~~

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

- ~~1. showed no clinical sign of Teschovirus encephalomyelitis on the day of collection of the semen;~~
- ~~2. were kept in a country free from Teschovirus encephalomyelitis for not less than 40 days prior to collection.~~

~~Article 15.6.9.~~

~~Recommendations for importation from countries considered infected with Teschovirus encephalomyelitis~~

~~for semen of pigs~~

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

- ~~1. showed no clinical sign of Teschovirus encephalomyelitis on the day of collection of the semen;~~
- ~~2. were kept in the *exporting country*, for the 40 days prior to collection, in an *establishment* or *artificial insemination centre* where no case of Teschovirus encephalomyelitis was officially reported during that period, and that the *establishment* or *artificial insemination centre* was not situated in an *Teschovirus encephalomyelitis infected zone*.~~

~~Article 15.6.10.~~

~~Recommendations for importation from Teschovirus encephalomyelitis free countries~~

~~for fresh meat of pigs~~

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

- ~~1. which have been kept in a country free from Teschovirus encephalomyelitis since birth or for at least the past 40 days;~~
- ~~2. which have been slaughtered in an approved *abattoir* and have been subjected to ante mortem and post mortem inspections for Teschovirus encephalomyelitis with favourable results.~~

Annex III (contd)

Article 15.6.11.

~~Recommendations for importation from countries considered infected with Teschovirus encephalomyelitis~~~~for fresh meat of pigs~~

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

- ~~1. which have not been kept in an Teschovirus encephalomyelitis infected zone;~~
- ~~2. which have been slaughtered in an approved abattoir not situated in an Teschovirus encephalomyelitis infected zone and have been subjected to ante mortem and post mortem inspections for Teschovirus encephalomyelitis with favourable results.~~

Article 15.6.12.

~~Recommendations for importation from countries considered infected with Teschovirus encephalomyelitis~~~~for meat products of pigs~~

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

- ~~1. the entire consignment of meat products comes from animals which have been slaughtered in an approved abattoir and have been subjected to ante mortem and post mortem inspections for Teschovirus encephalomyelitis with favourable results;~~
- ~~2. the meat products have been processed to ensure the destruction of the Teschovirus encephalomyelitis virus;~~
- ~~3. the necessary precautions were taken after processing to avoid contact of the meat with any source of Teschovirus encephalomyelitis virus.~~

Article 15.6.13.

~~Recommendations for importation from Teschovirus encephalomyelitis free countries~~~~for products of animal origin (from pigs) intended for use in animal feeding or for agricultural or industrial use~~

~~Veterinary Authorities should require the presentation of an international veterinary certificate attesting that these products come from animals which have been kept in a country free from Teschovirus encephalomyelitis since birth or for at least the past 40 days.~~

Article 15.6.14.

~~Recommendations for importation from countries considered infected with Teschovirus encephalomyelitis~~~~for meal and flour from blood, meat, defatted bones, hooves and claws (from pigs)~~

Annex III (contd)

~~Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products have been processed using heat treatment to ensure the destruction of *Teschovirus encephalomyelitis virus*.~~

~~Article 15.6.15.~~

~~Recommendations for importation from countries considered infected with *Teschovirus encephalomyelitis*~~

~~for bristles~~

~~Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of *Teschovirus encephalomyelitis virus*, in premises controlled and approved by the *Veterinary Authority* of the *exporting country*.~~

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GLOSSARY

For the purposes of the *Terrestrial Code*:

Antimicrobial agent

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

Central Bureau/Headquarters

means the Permanent Secretariat of the World Organisation for Animal Health ~~which headquarters are located at:~~

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Telephone: 33-(0)1 44 15 18 88

Fax: 33-(0)1 42 67 09 87

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WWW: <http://www.oie.int>

Competent Authority

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

Early detection system

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

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

Infected zone

means a *zone* in which ~~the absence of the *disease* under consideration has not been demonstrated by the requirements specified in the *Terrestrial Code* being met~~ a *disease* has been diagnosed.

Annex IV (contd)**Quarantine station**

means ~~a premises~~ 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 ~~prevent~~ ensure that there is no the transmission of specified pathogen(s) outside the establishment while the *animals* are undergoing observation for a specified length of time and, if appropriate, testing and treatment. The presence of disease or infection in imported animals in the quarantine station does not affect the animal health status of the country or zone.

Uncertainty

means the lack of precise knowledge of the input values which is due to measurement error or to lack of knowledge of the steps required, and the pathways from *hazard* to *risk*, when building the scenario being assessed.

Variability

~~means a real world complexity in which the value of an input is not the same for each case due to natural diversity in a given population.~~

Veterinary Services

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

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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* shall be provided with a *Veterinary Service* comprising personnel, equipment and premises as the case may be and, in particular, means for:

- a) making clinical examinations and obtaining specimens of material for diagnostic purposes from live *animals* or carcasses of *animals* affected or suspected of being affected by an epizootic *disease*, and obtaining specimens of animal products suspected of contamination;
- b) detecting and isolating *animals* affected by or suspected of being affected by an epizootic *disease*;
- c) carrying out *disinfection* and possibly *disinfestation* of *vehicles* used to transport *animals* and animal products.

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

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 **must** **should**, however, comply with the conditions required by *Veterinary Authorities*, especially to prevent 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 *Central Bureau* and any interested country on request:

Annex IV (contd)

- a) a list of *border posts, quarantine stations*, approved *abattoirs* and storage depots in its territory which are approved for *international trade*,
- b) the period of time required for notice to be given for the application of the arrangements contained in point 2 of Articles 5.7.1. to 5.7.4.;
- c) a list of airports in its territory which are provided with an area of direct transit, approved by the relevant *Veterinary Authority* and placed under its immediate control, where *animals* stay for a short time pending further transport to their final destination.

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CHAPTER 1.2.
LISTED DISEASES

Article 1.2.1.

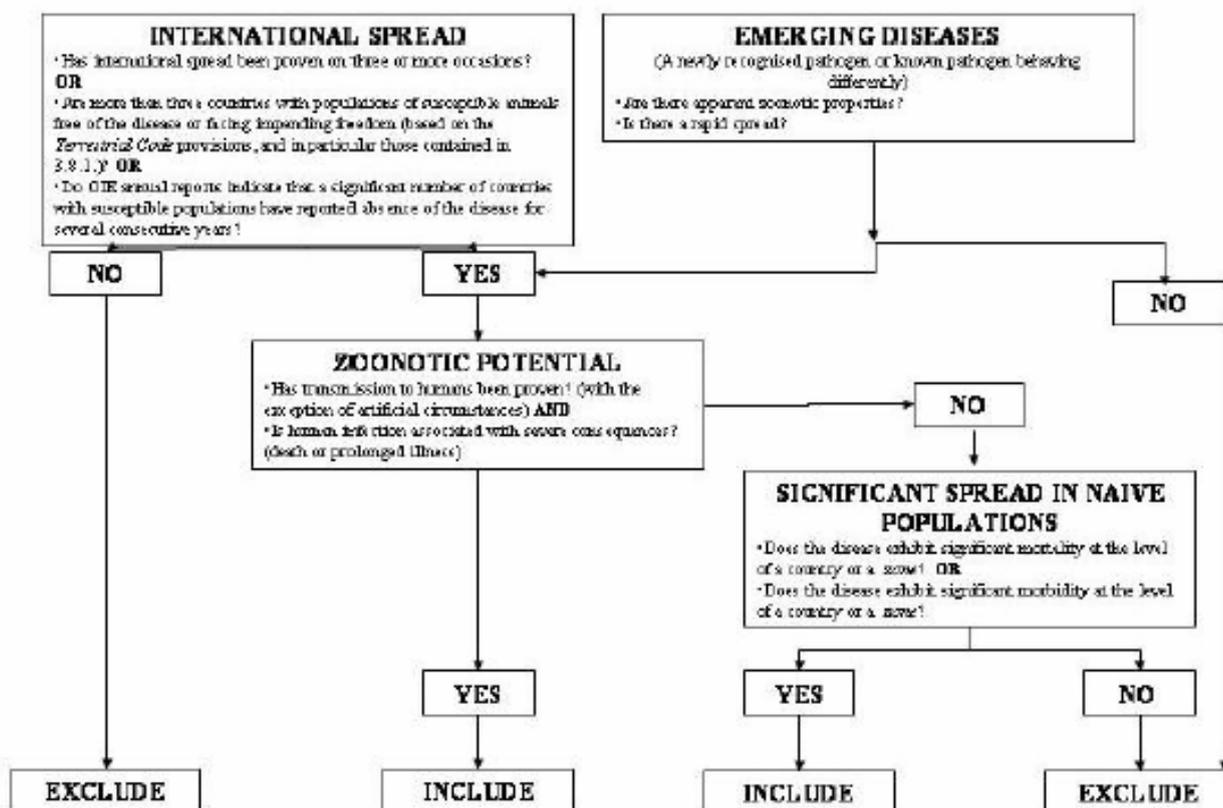
The criteria for the inclusion of a *disease* in the OIE List are as follows:

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

Annex V (contd)

Article 1.2.2.

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



Article 1.2.3.

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

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

1. The following *diseases* are included within the category of multiple species *diseases*:

- Anthrax
- Aujeszky's disease
- Bluetongue
- Brucellosis (*Brucella abortus*)
- Brucellosis (*Brucella melitensis*)
- Brucellosis (*Brucella suis*)
- Crimean Congo haemorrhagic fever
- Echinococcosis/hydatidosis

- Epizootic haemorrhagic disease
 - Equine encephalomyelitis (Eastern)
 - Foot and mouth disease
 - Heartwater
 - Japanese encephalitis
 - Leptospirosis
 - New world screwworm (*Cochliomyia hominivorax*)
 - Old world screwworm (*Chrysomya bezziana*)
 - Paratuberculosis
 - Q fever
 - Rabies
 - Rift Valley fever
 - Rinderpest
 - Surra (*Trypanosoma evansi*)
 - Trichinellosis
 - Tularemia
 - Vesicular stomatitis
 - West Nile fever.
2. The following *diseases* are included within the category of cattle *diseases*:
- Bovine anaplasmosis
 - Bovine babesiosis
 - Bovine genital campylobacteriosis
 - Bovine spongiform encephalopathy
 - Bovine tuberculosis
 - Bovine viral diarrhoea
 - Contagious bovine pleuropneumonia
 - Enzootic bovine leukosis
 - Haemorrhagic septicaemia
 - Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
 - Lumpy skin disease

Annex V (contd)

- Theileriosis
 - Trichomonosis
 - Trypanosomosis (tsetse-transmitted).
3. The following *diseases* are included within the category of sheep and goat *diseases*:
- Caprine arthritis/encephalitis
 - Contagious agalactia
 - Contagious caprine pleuropneumonia
 - Enzootic abortion of ewes (ovine chlamydiosis)
 - Maedi-visna
 - Nairobi sheep disease
 - Ovine epididymitis (*Brucella ovis*)
 - Peste des petits ruminants
 - Salmonellosis (*S. abortusovis*)
 - Scrapie
 - Sheep pox and goat pox.
4. The following *diseases* are included within the category of equine *diseases*:
- African horse sickness
 - Contagious equine metritis
 - Dourine
 - Equine encephalomyelitis (Western)
 - Equine infectious anaemia
 - Equine influenza
 - Equine piroplasmosis
 - Equine rhinopneumonitis
 - Equine viral arteritis
 - Glanders
 - Venezuelan equine encephalomyelitis.

5. The following *diseases* are included within the category of swine *diseases*:
 - African swine fever
 - Classical swine fever
 - Nipah virus encephalitis
 - Porcine cysticercosis
 - Porcine reproductive and respiratory syndrome
 - Swine vesicular disease
 - Transmissible gastroenteritis.
6. The following *diseases* are included within the category of avian *diseases*:
 - Avian chlamydiosis
 - Avian infectious bronchitis
 - Avian infectious laryngotracheitis
 - Avian mycoplasmosis (*Mycoplasma gallisepticum*)
 - Avian mycoplasmosis (*Mycoplasma synoviae*)
 - Duck virus hepatitis
 - Fowl cholera
 - Fowl typhoid
 - Highly pathogenic avian influenza in birds and low pathogenicity notifiable avian influenza in poultry as defined in Chapter 9.5.
 - Infectious bursal disease (Gumboro disease)
 - Marek's disease
 - Newcastle disease
 - Pullorum disease
 - Turkey rhinotracheitis.
7. The following *diseases* are included within the category of lagomorph *diseases*:
 - Myxomatosis
 - Rabbit haemorrhagic disease.

Annex V (contd)

8. The following *diseases* are included within the category of bee *diseases*:

- Acarapisosis of honey bees
- American foulbrood of honey bees
- European foulbrood of honey bees
- Small hive beetle infestation (*Aethina tumida*)
- *Tropilaelaps* infestation of honey bees
- Varroosis of honey bees.

9. The following *diseases* are included within the category of other *diseases*:

- Camel pox
 - Leishmaniosis.
-

CHAPTER 1.4.

ANIMAL HEALTH SURVEILLANCE

Article 1.4.1.

Introduction and objectives

1. In general, *surveillance* is aimed at demonstrating the absence of *disease* or *infection*, determining the occurrence or distribution of *disease* or *infection*, while also detecting as early as possible exotic or *emerging diseases*. The type of *surveillance* applied depends on the desired outputs needed to support decision-making. The following recommendations may be applied to all *diseases*, their agents and all susceptible species (including wildlife) as listed in the *Terrestrial Code*, and are designed to assist with the development of *surveillance* methodologies. Except where a specific *surveillance* method for a certain *disease* or *infection* is already described in the *Terrestrial Code*, the recommendations in this chapter may be used to further refine the general approaches described for a specific *disease* or *infection*. Where detailed *disease/infection*-specific information is not available, suitable approaches should be based on the recommendations in this chapter.
2. Animal health *surveillance* is an essential tool to detect *disease* or *infection*, to monitor disease trends, to facilitate the control of *disease* or *infection*, to support claims for freedom from *disease* or *infection*, to provide data for use in *risk analysis*, for animal and/or public health purposes, and to substantiate the rationale for sanitary measures. Both domestic and wild *animals* are susceptible to certain *disease/infection*. However, ~~in the presence of appropriate biosecurity measures,~~ *disease/infection* in wild *animals* does not ~~imply~~ imply mean that the same *disease/infection* is necessarily present in domestic *animals* in the same country or zone or vice versa. *Surveillance* data underpin the quality of disease status reports and should satisfy information requirements of *risk analysis* for *international trade* and for national decision-making. Wildlife may be included because they can serve as reservoirs and as indicators of human and domestic animal and wildlife *disease*. Wildlife *disease/infection surveillance* presents specific challenges that may differ significantly from *surveillance* in livestock domestic animals.
3. Prerequisites to enable an OIE Member to provide information for the evaluation of its animal health status are:
 - a) that the Member complies with the provisions of Chapter 3.1. of the *Terrestrial Code*;
 - b) that, where possible, *surveillance* data be complemented by other sources of information (e.g. scientific publications, research data, documented field observations and other non-survey data);
 - c) that transparency in the planning and execution of *surveillance* activities and the analysis and availability of data and information, be maintained at all times, in accordance with Chapter 1.1. of the *Terrestrial Code*.
4. The objectives of this chapter are to:
 - a) provide guidance to the type of outputs that a *surveillance* system should generate;
 - b) provide recommendations to assess the quality of *disease/infection surveillance* systems.

Article 1.4.2.

Definitions

The following definitions apply for the purposes of this chapter:

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

Case definition: ~~means a set of criteria used to classify an animal as a case.~~

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

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

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

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

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

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

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

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

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

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

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

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

Article 1.4.3.

Principles of surveillance1. Types of surveillance

- a) *Surveillance* may be based on many different data sources and can be classified in a number of ways, including:
- i) the means by which data are collected (active versus passive *surveillance*);
 - ii) the disease focus (pathogen-specific versus general *surveillance*); and
 - iii) the way in which units for observation are selected (structured surveys versus non-random data sources).
- b) In this chapter, *surveillance* activities are classified as being based on:

EITHER

- i) structured population-based surveys, such as:
- systematic sampling at *slaughter*;
 - random surveys;
 - surveys for *infection* in clinically normal *animals*, including wildlife;

OR

- ii) structured non-random *surveillance* activities, such as:
- *disease* reporting or notifications;
 - control programmes/health schemes;
 - targeted testing/screening;
 - ante-mortem and post-mortem inspections;
 - laboratory investigation records;
 - biological specimen banks;
 - sentinel units;
 - field observations;
 - farm production records;
 - wildlife disease data.

Annex VI (contd)

- c) In addition, *surveillance* data should be supported by related information, such as:
- i) data on the epidemiology of the *disease/infection*, including environmental, host population distribution, and climatic information;
 - ii) data on animal movements, including transhumance, as well as natural wildlife migrations;
 - iii) trading patterns for *animals* and animal products;
 - iv) national animal health regulations, including information on compliance with them and their effectiveness;
 - v) history of imports of potentially infected material; and
 - vi) biosecurity measures in place;
 - vii) the ~~risk~~ likelihood and consequence of *disease/infection* introduction.
- d) The sources of evidence should be fully described. In the case of a structured survey, this should include a description of the sampling strategy used for the selection of units for testing. For structured non-random data sources, a full description of the system is required including the source(s) of the data, when the data were collected, and a consideration of any biases that may be inherent in the system.

2. Critical elements

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

a) Populations

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

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

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

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

c) Epidemiological unit

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

d) Clustering

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

e) Case definition

A ~~clear case definition~~ should be defined ~~developed~~ for each *disease /infection* under *surveillance*, using clear criteria and, where they exist, the standards in the *Terrestrial Code*. For wildlife *disease/infection surveillance*, it is essential to correctly identify and report host animal taxonomy (including genus and species).

f) Analytical methodologies

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

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

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

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

g) Testing

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

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

Annex VI (contd)

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

h) Quality assurance

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

i) Validation

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

j) Data collection and management

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

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

Article 1.4.4.

Structured population-based surveys

In addition to the principles for *surveillance* discussed above, the following recommendations should be used when planning, implementing and analysing surveys.

1. Types of surveys

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

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

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

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

2. Survey design

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

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

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

3. Sampling

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

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

Annex VI (contd)4. Sampling methods

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

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

5. Sample size

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

Article 1.4.5.

Structured non-random surveillance

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

1. Common non-random surveillance sources

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

a) Disease reporting or notification systems

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

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

b) Control programmes / health schemes

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

c) Targeted testing / screening

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

d) Ante-mortem and post-mortem inspections

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

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

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

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

e) Laboratory investigation records

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

f) Biological specimen banks

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

Annex VI (contd)

g) Sentinel units

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

h) Field observations

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

i) Farm production records

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

j) Wildlife data

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

2. Critical elements for structured non-random surveillance

There are a number of critical factors which should be taken into account when using structured non-random *surveillance* data such as coverage of the population, duplication of data, and sensitivity and specificity of tests that may give rise to difficulties in the interpretation of data. *Surveillance* data from non-random sources can, however, be a cost-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 ~~just one year~~ a shorter period of time.

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

Article 1.4.6.

Surveillance to demonstrate freedom from disease/infection

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

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

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

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

a) Historically free

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

- i) there has never been occurrence of *disease*, or
- ii) eradication has been achieved or the *disease/infection* has ceased to occur for at least 25 years, provided that for at least the past 10 years:
- iii) it has been a *notifiable disease*;

Annex VI (contd)

- iv) an early detection system has been in place for all relevant species;
- v) measures to prevent *disease/infection* introduction have been in place; no vaccination against the *disease* has been carried out unless otherwise provided in the *Terrestrial Code*;
- vi) *infection* is not known to be established in wildlife within the country or *zone* intended to be declared free. A country or *zone* cannot apply for historical freedom if there is any evidence of *infection* in wildlife.

b) Last occurrence within the previous 25 years

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

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

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

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

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

3. Self declaration of disease/infection

Members may make a self declaration that a country, *zone* or *compartment* is free from a *listed disease*, based on the implementation of the provisions of the *Terrestrial Code* and the *Terrestrial Manual* - see relevant provisions in Chapter 1.5. The *Veterinary Authority* may wish to transmit this information to the OIE ~~Central Bureau~~ Headquarters which may publish the information.

4. International recognition of disease/infection free status

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

5. Demonstration of freedom from infection

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

Freedom from *infection* implies the absence of the pathogenic agent in the country, *zone* or *compartment*. Scientific methods cannot provide absolute certainty of the absence of *infection*. Demonstrating freedom from *infection* involves providing sufficient evidence to demonstrate (to a level of confidence acceptable to Members) that *infection* with a specified pathogen is not present in a population. In practice, it is not possible to prove (i.e., be 100% confident) that a population is free from *infection* (unless every member of the population is examined simultaneously with a perfect test with both sensitivity and specificity equal to 100%). Instead, the aim is to provide adequate evidence (to an acceptable level of confidence), that *infection*, if present, is present in less than a specified proportion of the population.

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

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

Article 1.4.7.

Surveillance for distribution and occurrence of infection

Surveillance to determine distribution and occurrence of *infection* or of other relevant health related events is widely used to assess progress in the control or eradication of selected *diseases* and pathogens and as an aid to decision making. It has, however, relevance for the international movement of *animals* and products when movement occurs among infected countries.

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

Annex VI (contd)

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

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CHAPTER 1.5.

SURVEILLANCE OF 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 additional advice on the *surveillance of for vectors* themselves. This chapter only addresses *surveillance* for arthropod *vectors*.

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

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

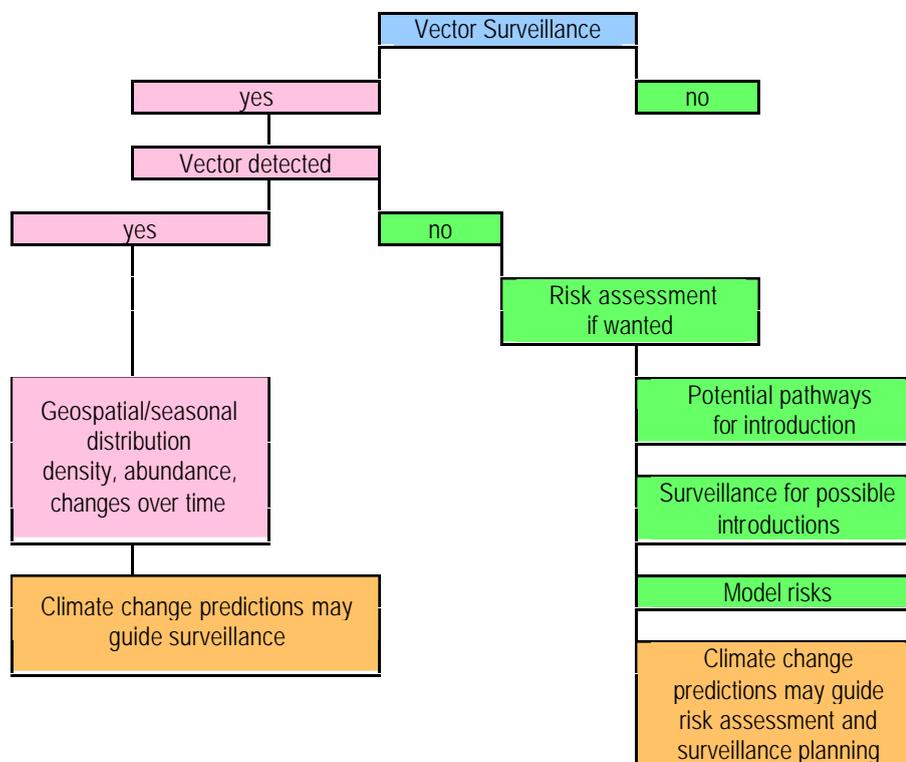
Article 1.5.2.

Objectives

The objective of these recommendations is to provide methods for:

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

Figure 1 Decision Tree for Vector Surveillance



Article 1.5.3.

Sampling methodology

1. Sampling plan

- a) The objective of the *surveillance* programme should be determined and stated before planning begins.
- b) ~~All~~ available historical data on the *vector* or the *disease* for the country or *zone* should be collated and assessed.
- c) The sampling plan should consider the following:
 - i) the biology and ecology of the *vector(s)*,
 - ii) the presence, distribution and abundance of the *vectors'* host animal population(s),
 - iii) the environmental, climatic, ecological and topographic conditions of relevance to *vector* ecology,
 - iv) the need for a *risk assessment* to indicate the areas at highest *risk* of introduction of a *vector* that is unlikely to be present.

- d) Sampling should be aimed at:
- i) establishing *vector* presence or confirming *vector* absence in the country or *zone*,
 - ii) describing the distribution of the *vector(s)* within the country or *zone*,
 - iii) providing additional information on *vector* density and spatial/temporal variability (both over the short- and the long-term),
 - iv) early detection of *vectors* or *vector*-borne pathogenic agents in areas with *risks* of entry and establishment.
- e) The sampling plan should be designed to provide appropriate estimates of the indicators listed above. Consideration should be given to the following:

The recommended general approach to sampling is via a three-stage hierarchy:

- i) Stratification based on ecological criteria (where possible), and *risk assessment* for *vector* introduction,
- ii) subdivision of strata into spatial sampling units, and
- iii) establishment of actual sampling sites within selected spatial sampling units.

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 ~~homogenous~~ homogeneous as possible with respect to the following known or suspected *risk*-factors, as appropriate for the country or *zone*:

- iv) domestic or wild populations of host animals preferred by the *vector*,
- v) *vector* habitat suitability,
- vi) climatic patterns (including seasonal),
- vii) areas endemically and/or epidemically affected by the disease(s) of concern,
- viii) areas of known *vector* occurrences,
- ix) fringe *zone(s)* around areas of known *vector* occurrences or other high *risks* areas for *vector* introduction, such as ports,
- x) areas in which the *disease(s)* or *vector(s)* of concern have not been reported currently or historically,
- xi) each stratum (or the whole country or *zone*, if not stratified) should be divided into spatial sampling units according to standard methodologies such as a grid system,
- xii) the number and size of the spatial sampling units should be defined to provide appropriate estimates of the indicators listed above,
- xiii) 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,

Annex VII (contd)

xiv) different levels of sampling intensity (spatial sampling unit size, number of units sampled, number of sites sampled within units, and sampling frequency) may be applied to different strata into which the country or *zone* has been divided. For example, more intensive sampling might be carried out in strata where *vector* presence seems most likely, based on biological or statistical criteria.

2. Sampling methods

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

- a) The collection methods used should be adapted as required to ensure reasonable confidence of collecting the *vector(s)* of concern.
- b) Collection methods should obtain the various developmental stages (such as eggs, larvae, nymphs, adults) and adult age categories, as appropriate to the species in question and the objectives of the surveillance. For example, if a vector is not believed to be present, collection methods should target the developmental stages most likely to be introduced, or that are most readily detected. If the vector is present, life stages required to estimate population survival rates and population dynamics in relation to *disease* transmission should be collected.
- c) Different collection methods may be required to obtain samples from a single *vector* species, depending on the life stage or place of capture (such as from the environment or from the host animals). The collection method must should be appropriate to the species and life stage of interest.

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

3. Data management, analysis and interpretation

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

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CHAPTER 1.6.

STATUS FOR OIE LISTED DISEASES: PROCEDURES FOR SELF DECLARATION AND FOR OFFICIAL RECOGNITION BY THE OIE

Article 1.6.1.

General principles

Members may wish to make a self declaration as to the freedom of a country, *zone* or *compartment* from an OIE *listed disease*. The Member may inform the OIE of its claimed status and the OIE may publish the claim. Publication does not imply endorsement of the claim. The OIE does not ~~recognise~~ publish self declaration for bovine spongiform encephalopathy (BSE), foot and mouth disease (FMD), rinderpest and contagious bovine pleuropneumonia (CBPP).

Members may request official recognition by the OIE as to:

1. the risk status of a country or *zone* with regard to BSE;
2. the freedom of a country or *zone* from FMD, with or without vaccination;
3. the freedom of a country from rinderpest;
4. the freedom of a country or *zone* from CBPP.

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

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

When requesting official recognition of disease status, the Member should submit to the OIE Scientific and Technical Department a dossier providing the information requested (as appropriate) in Articles 1.6.2. (for BSE), 1.6.3. (for FMD), 1.6.4. (for rinderpest) or 1.6.5. (for CBPP).

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

Article 1.6.2.

Questionnaire on bovine spongiform encephalopathy

GENERAL INTRODUCTION

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

Annex VIII (contd)

Article 11.6.2. of the *Terrestrial Code* Chapter on BSE prescribes the criteria to determine the BSE risk status of the cattle population of a country, *zone* or *compartment*. This document is the means whereby a claim for negligible risk (Article 11.6.3.) or controlled risk (Article 11.6.4.) can be made to the OIE.

The document comprises the following:

- Section 1 – Risk assessment (see point 1 of Article 11.6.2.)
- Section 2 – Other requirements of points 2 to 4 of Article 11.6.2.
 - Ongoing awareness programme
 - Compulsory notification and investigation
 - Diagnostic capability
- Section 3 – Surveillance (Article 11.6.2. and Articles 11.6.20. to 11.6.22.)
- Section 4 – BSE history of the country, *zone* or *compartment* (Articles 11.6.3. and 11.6.4.).

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

SECTION 1: RISK ASSESSMENT (see point 1 of Article 11.6.2.)

Introduction

The first step in determining the BSE risk status of the cattle population of a country, *zone* or *compartment* is to conduct a *risk assessment* (reviewed annually), based on Sections 2. and 3. and Chapter 4.3. of the *Terrestrial Code*, identifying all potential factors for BSE occurrence and their historic perspective.

Documentation guidelines

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

Release assessment:

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

Exposure assessment:

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

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

Release assessment

1. The potential for the release of the BSE agent through importation of meat-and-bone meal or greaves

Question to be answered: Has *meat-and-bone meal*, *greaves*, or feedstuffs containing either, been imported within the past 8 years? If so, where from and in what quantities?

Rationale: Knowledge of the origin of *meat-and-bone meal*, *greaves* or feedstuffs containing either *meat-and-bone meal* or *greaves*, is necessary to assess the risk of release of BSE agent. *Meat-and-bone meal* and *greaves* originating in countries of high BSE risk pose a higher release risk than that from low risk countries. *Meat-and-bone meal* and *greaves* originating in countries of unknown BSE risk pose an unknown release risk.

This point is irrelevant if the exposure assessment outlined below in Article 11.6.27. indicates that *meat-and-bone meal* or *greaves* has not been fed, either deliberately or accidentally, in the past 8 years. Nevertheless, documentation should be provided on the control systems (including relevant legislation) in place to ensure that *meat-and-bone meal* or *greaves* has not been fed to cattle.

Evidence required:

- a) Documentation to support claims that *meat-and-bone meal*, *greaves* or feedstuffs containing either *meat-and-bone meal* or *greaves* have not been imported, OR
 - b) Documentation on annual volume, by country of origin, of *meat-and-bone meal*, *greaves* or feedstuffs containing them imported during the past 8 years.
 - c) Documentation describing the species composition of the imported *meat-and-bone meal*, *greaves* or feedstuffs containing them.
 - d) Documentation, from the *Veterinary Service* of the country of production, supporting why the rendering processes used to produce *meat-and-bone meal*, *greaves* or feedstuffs containing them would have inactivated, or significantly reduced the titre of BSE agent, should it be present.
- ### **2. The potential for the release of the BSE agent through the importation of potentially infected live cattle**

Question to be answered: Have live cattle been imported within the past 7 years?

Rationale: The release risks are dependent on:

Annex VIII (contd)

- country, *zone* or *compartment* of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical *disease*, or following active *surveillance*, or assessment of geographical BSE risk;
- feeding and management of the imported cattle in the country, *zone* or *compartment* of origin;
- use to which the *commodity* has been put as apart from representing risk of developing clinical *disease*, the *slaughter*, rendering and recycling in *meat-and-bone meal* of imported cattle represents a potential route of exposure of indigenous livestock even if *meat-and-bone meal* and *greaves*, or feedstuffs containing them, have not been imported;
- dairy versus meat breeds, where there are differences in exposure in the country, *zone* or *compartment* of origin because feeding practices result in greater exposure of one category;
- age at *slaughter*.

Evidence required:

- a) Documentation including tables on the country, *zone* or *compartment* of origin of imports. This should identify the country, *zone* or *compartment* of origin of the cattle, the length of time they lived in that country, *zone* or *compartment* and of any other country in which they have resided during their lifetime.
- b) Documentation including tables describing origin and volume of imports.
- c) Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country, *zone* or *compartment* of origin.

3. The potential for the release of the BSE agent through the importation of potentially infected products of bovine origin

Question to be answered: What products of bovine origin have been imported within the past 7 years?

Rationale: The release risks are dependent on:

- the origin of the cattle products and whether these products contain tissues known to contain BSE infectivity (Article 11.6.13.);
- country, *zone* or *compartment* of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical *disease*, or following active *surveillance*, or assessment of geographical BSE risk;
- feeding and *management* of the cattle in the country, *zone* or *compartment* of origin;
- use to which the *commodity* has been put as apart from representing risk of developing clinical *disease*, the *slaughter*, rendering and recycling in *meat-and-bone meal* of imported cattle represents a potential route of exposure of indigenous livestock even if *meat-and-bone meal* and *greaves*, or feedstuffs containing them, have not been imported;
- dairy versus meat breeds, where there are differences in exposure in the country, *zone* or *compartment* of origin because feeding practices result in greater exposure of one category;
- age at *slaughter*.

Evidence required:

- a) Documentation on the country, *zone* or *compartment* of origin of imports. This should identify the country, *zone* or *compartment* of origin of cattle from which the products were derived, the length of time they lived in that country, *zone* or *compartment* and of any other country in which they have resided during their lifetime.
- b) Documentation describing origin and volume of imports.
- c) Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country, *zone* or *compartment* of origin.

Exposure assessment

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

Question to be answered: How have bovine carcasses, by-products and *slaughterhouse* waste been processed over the past 8 years?

Rationale: The overall risk of BSE in the cattle population of a country, *zone* or *compartment* is proportional to the level of known or potential exposure to BSE infectivity and the potential for recycling and amplification of the infectivity through livestock feeding practices. For the *risk assessment* to conclude that the cattle population of a country, *zone* or *compartment* is of negligible or controlled BSE risk, it must have demonstrated that appropriate measures have been taken to manage any risks identified. If potentially infected cattle or contaminated materials are rendered, there is a risk that the resulting *meat-and-bone meal* could retain BSE infectivity. Where *meat-and-bone meal* is utilized in the production of any cattle feed, the risk of cross-contamination exists.

Evidence required:

- a) Documentation describing the collection and disposal of fallen stock and materials condemned as unfit for human consumption.
- b) Documentation including tables describing the fate of imported cattle, including their age at *slaughter* or *death*.
- c) Documentation describing the definition and disposal of specified risk material, if any.
- d) Documentation describing the rendering process and parameters used to produce *meat-and-bone meal* and *greaves*.
- e) Documentation describing methods of animal feed production, including details of ingredients used, the extent of use of *meat-and-bone meal* in any livestock feed, and measures that prevent cross-contamination of cattle feed with ingredients used in monogastric feed.
- f) Documentation describing the end use of imported cattle products and the disposal of waste.
- g) Documentation describing monitoring and enforcement of the above.

Annex VIII (contd)

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

Question to be answered: Has *meat-and-bone meal* or *greaves* of bovine origin been fed to cattle within the past 8 years (Articles 11.6.3. and 11.6.4. in the *Terrestrial Code*)?

Rationale: If cattle have not been fed products of bovine origin (other than milk or blood) potentially containing *meat-and-bone meal* or *greaves* of bovine origin within the past 8 years, *meat-and-bone meal* and *greaves* can be dismissed as a risk.

In the case of countries applying for negligible risk status, it will be required to demonstrate that the ruminant feed ban has been effective for at least 8 years following the birth of the youngest *case*.

Evidence required:

- a) Documentation describing the use of imported *meat-and-bone meal* and *greaves*, including the feeding of any animal species.
- b) Documentation describing the use made of *meat-and-bone meal* and *greaves* produced from domestic cattle, including the feeding of any animal species.
- c) Documentation on the measures taken to control cross-contamination of cattle feedstuffs with the *meat-and-bone meal* and *greaves* including the risk of cross-contamination during production, transport, storage and feeding.
- d) Documentation, in the form of the following table, on the audit findings in rendering plants and feed mills processing ruminant material or mixed species containing ruminant material, related to the prohibition of the feeding to ruminants of *meat-and-bone meal* and *greaves*.

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

Annex VIII (contd)

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

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

- f) Documentation, in the form of the following table, on each plant above processing ruminant material or mixed species containing ruminant material with infractions, specifying the type of infraction and the method of resolution.

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

Annex VIII (contd)

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

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

- h) Documentation explaining why, in light of the findings displayed in the preceding four tables, it is considered that there has been no significant exposure of cattle to the BSE agent through consumption of *meat-and-bone meal* or *greaves* of bovine origin.
- i) Documentation of husbandry practices (multiple species farms) which could lend themselves to cross-contamination of cattle feed with meat-and-bone meal and greaves destined to other species.

SECTION 2: OTHER REQUIREMENTS (see points 2 to 4 of Article 11.6.2.)

1. Awareness programme (see point 2 of Article 11.6.2.)

Questions to be answered:

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

Rationale:

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

Evidence required:

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

2. Compulsory notification and investigation (see point 3 of Article 11.6.2.)

Questions to be answered:

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

Rationale:

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

Evidence required:

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

3. Examination in an approved laboratory of brain or other tissues collected within the framework of the aforementioned surveillance system (see point 4 of Article 11.6.2.)

Questions to be answered:

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

Rationale:

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

Annex VIII (contd)*Evidence required:*

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

SECTION 3: BSE SURVEILLANCE AND MONITORING SYSTEM (see point 4 of Article 11.6.2.)*Questions to be answered:*

- Does the BSE *surveillance* programme comply with the guidelines in Articles 11.6.20. to 11.6.22. of the *Terrestrial Code*?
- What were the results of the investigations?

Rationale:

Point 4 of Article 11.6.2. and Articles 11.6.20. to 11.6.22. prescribe the number of cattle, by subpopulation, that need to be tested in order to ensure the detection of BSE at or above a minimal threshold prevalence.

Evidence required:

1. Documentation that the samples collected are representative of the distribution of cattle population in the country, *zone* or *compartment*.
2. Documentation of the methods applied to assess the ages of *animals* sampled and the proportions for each method (individual identification, dentition, other methods to be specified).
3. Documentation of the means and procedures whereby samples were assigned to the cattle subpopulations described in Article 11.6.21., including the specific provisions applied to ensure that *animals* described as clinical met the conditions of point 1 of Article 11.6.21.
4. Documentation of the number of *animals* meeting the conditions in point 1 of Article 11.6.21. as compared to the numbers of clinical samples submitted in previous years in accordance to the former provisions in the *Terrestrial Code*, and explanation of possible differences.
5. Documentation, based on the following table, of all clinically suspect *cases* notified complying with the definition in point 1 of Article 11.6.21.

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

6. Documentation according to the following table, that the number of target points applicable to the country, *zone* or *compartment* and its BSE *surveillance* requirements (Type A or type B *surveillance* as a result of the *risk assessment* of section 1) are met as described in Articles 11.6.21. and 11.6.22.

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

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

SECTION 4: BSE HISTORY OF THE COUNTRY, ZONE OR COMPARTMENT (see Articles 11.6.3. and 11.6.4.)

Questions to be answered:

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

Rationale:

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

Annex VIII (contd)*Evidence required:*

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

In the case of positive BSE findings:

2. Documentation on the origin of each BSE *case* in respect to the country, *zone* or *compartment*. Indicate the birth date and place of birth.
3. Indicate the most recent year of birth in relation to all BSE *cases*.
4. Documentation that:
 - the *case(s)* and all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the *disease*, and
 - all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or
 - if the results of the investigation are inconclusive, all cattle born in the same *herd* as, and within 12 months of the birth of, the BSE *cases*,
 - if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.

Article 1.6.3.

Questionnaire on foot and mouth disease

FMD FREE COUNTRY WHERE VACCINATION IS NOT PRACTISED

Report of a Member which applies for recognition of status, under Chapter 8.5.
of the *Terrestrial Animal Health Code* (2009), as a FMD free country not practising vaccination

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

1. Introduction

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

2. Veterinary system

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

3. FMD eradication

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

4. FMD diagnosis

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

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

Annex VIII (contd)5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with the provisions of Articles 8.5.40. to 8.5.46. of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspect *cases*, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis).
- b) Serological surveillance. Are serological surveys conducted? If so, provide detailed information on the survey design (confidence level, sample size, stratification). How frequently are they conducted? Are wildlife susceptible species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* and numbers of *animals* examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.
- c) Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many *herds*, *flocks*, etc., of each susceptible species are in the country? How are they distributed (e.g. *herd density*, etc.)? Provide tables and maps as appropriate.
- d) Wildlife demographics. What susceptible species are present in the country? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and wildlife susceptible species?
- e) Slaughterhouses and markets. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the *animals* transported and handled during these transactions?

6. FMD prevention

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

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

- i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of.
- iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:
 - *animals*,
 - genetic material (semen and embryos),
 - animal products,
 - veterinary medicinal products (i.e. biologics).
- iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

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

8. Compliance with the *Terrestrial Code*

- a) In addition to the documentary evidence that the provisions of Article 8.5.2. are properly implemented and supervised, the Delegate of the country must submit a declaration indicating:
 - i) there has been no *outbreak* of FMD during the past 12 months;

Annex VIII (contd)

- ii) no evidence of FMDV *infection* has been found during the past 12 months;
 - iii) no vaccination against FMD has been carried out during the past 12 months,
- b) and should confirm that since the cessation of vaccination no *animals* vaccinated against FMD have been imported.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 8.5.8. of the *Terrestrial Code* and provide detailed information as specified in sections 3.a), 3.b), 3.c) and 5.b) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

FMD FREE COUNTRY WHERE VACCINATION IS PRACTISED

Report of a Member which applies for recognition of status, under Chapter 8.5.
of the *Terrestrial Animal Health Code* (2009), as a FMD free country practising vaccination

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

1. Introduction

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

2. Veterinary system

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

3. FMD eradication

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

4. FMD diagnosis

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

- a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to and the follow-up procedures and the timeframe for obtaining results.
- b) Provide an overview of the FMD approved laboratories, in particular to address the following points:
 - i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.
 - ii) Give details of participation in inter-laboratory validation tests (ring tests).
 - iii) Is live virus handled?
 - iv) Biosecurity measures applied.
 - v) Details of the type of tests undertaken.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with the provisions of Articles 8.5.40. to 8.5.46. of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

Annex VIII (contd)

- a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspect *cases*, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis).
- b) Surveillance. Are serological and virological surveys conducted, in particular applying the provisions of Article 8.5.44.? If so, provide detailed information on the survey design (confidence level, sample size, stratification). How frequently are they conducted? Are wildlife susceptible species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMD and FMDV, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* and numbers of *animals* examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.
- c) Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many *herds, flocks, etc.*, of each susceptible species are in the country? How are they distributed (e.g. *herd density, etc.*)? Provide tables and maps as appropriate.
- d) Wildlife demographics. What susceptible species are present in the country? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and wildlife susceptible species?
- e) Slaughterhouses and markets. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the *animals* transported and handled during these transactions?

6. FMD prevention

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

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

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

- ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of.
- iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:
 - *animals*,
 - genetic material (semen and embryos),
 - animal products,
 - veterinary medicinal products (i.e. biologics).
- iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

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

8. Compliance with the *Terrestrial Code*

In addition to the documentary evidence that the provisions of Article 8.5.3. are properly implemented and supervised, the Delegate of the country must submit a declaration indicating that there has been no *outbreak* of FMD for the past 2 years and no evidence of FMDV circulation for the past 12 months, with documented evidence that:

- a) *surveillance* for FMD and FMDV circulation in accordance with Articles 8.5.40. to 8.5.46. is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;

Annex VIII (contd)

- b) routine vaccination is carried out for the purpose of the prevention of FMD;
- c) the vaccine used complies with the standards described in the *Terrestrial Manual*.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 8.5.8. of the *Terrestrial Code* and provide detailed information as specified in sections 3.a), 3.b), 3.c) and 5.b) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

FMD FREE ZONE WHERE VACCINATION IS NOT PRACTISED

Report of a Member which applies for recognition of status, under Chapter 8.5. of the *Terrestrial Animal Health Code* (2009), as a FMD free zone not practising vaccination

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

1. Introduction

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

2. Veterinary system

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

3. FMD eradication

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

- b) Strategy. Describe how FMD was controlled and eradicated in the *zone* (e.g. stamping-out, modified stamping-out), provide timeframe for eradication.
- c) Vaccines and vaccination. If vaccination is used in the rest of the country, what type of vaccine is used? What species are vaccinated? Provide evidence that the vaccine used complies with Chapter 2.1.5. of the *Terrestrial Manual*. Describe the vaccination programme, including records kept, and provide evidence to show its effectiveness (e.g. vaccination coverage, serosurveillance, etc.).
- d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.
- e) Animal identification and movement control. Are susceptible *animals* identified (individually or at a group level)? Provide a description of the methods of animal identification, *herd* registration and traceability. How are animal movements controlled in and between *zones* of the same or different status, in particular if the provisions of the *Terrestrial Code* in Article 8.5.9. are applied? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and the related paths of movement.

4. FMD diagnosis

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

- a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to. Indicate the laboratory(ies) where samples originating from the *zone* are diagnosed, the follow-up procedures and the time frame for obtaining results.
- b) Provide an overview of the FMD approved laboratories, in particular to address the following points:
 - a) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.
 - b) Give details of participation in inter-laboratory validation tests (ring tests).
 - c) Is live virus handled?
 - d) Biosecurity measures applied.
 - e) Details of the type of tests undertaken.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the *zone* complies with the provisions of Articles 8.5.40. to 8.5.46. of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

Annex VIII (contd)

- a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis).
- b) Serological surveillance. Are serological surveys conducted? If so, provide detailed information on the survey design (confidence level, sample size, stratification). How frequently are they conducted? Are wildlife susceptible species included in serological surveys? Provide a summary table indicating, for the past 2 years, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* and numbers of *animals* examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.
- c) Livestock demographics and economics. What is the susceptible animal population by species and production systems in the country and the *zone*? How many *herds*, *flocks*, etc., of each susceptible species are in the country? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.
- d) Wildlife demographics. What susceptible species are present in the country and the *zone*? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and wildlife susceptible species?
- e) Slaughterhouses and markets. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the *animals* transported and handled during these transactions?

6. FMD prevention

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

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

- b) Import control procedures

From what countries or *zones* does the country authorize the import of susceptible *animals* or their products into a free *zone*? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such *animals* and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported *animals* of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible *animals* and their products for the past 2 years, specifying country or *zone* of origin, species and volume.

- i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 2 years, of the quantity disposed of.
- iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:
 - *animals*,
 - genetic material (semen and embryos),
 - animal products,
 - veterinary medicinal products (i.e. biologics).
- iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

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

Annex VIII (contd)8. Compliance with the *Terrestrial Code*

In addition to the documentary evidence that the provisions of Article 8.5.4. are properly implemented and supervised, the Delegate of the country must submit a declaration indicating:

- a) there has been no *outbreak* of FMD during the past 12 months;
- b) no evidence of FMDV *infection* has been found during the past 12 months;
- c) no vaccination against FMD has been carried out during the past 12 months;
- d) no vaccinated animal has been introduced into the *zone* since the cessation of vaccination, except in accordance with Article 8.5.9.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 8.5.8. of the *Terrestrial Code* and provide detailed information as specified in sections 3.a), 3.b), 3.c) and 5.b) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

FMD FREE ZONE WHERE VACCINATION IS PRACTISED

Report of a Member which applies for recognition of status, under Chapter 8.5.
of the *Terrestrial Animal Health Code* (2009), as a FMD free zone practising vaccination

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

1. Introduction

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

2. Veterinary system

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

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

3. FMD eradication

- a) History. Provide a description of the FMD history in the country and *zone*, provide date of first detection, origin of *infection*, date of eradication in the *zone* (date of last *case*), types and subtypes present.
- b) Strategy. Describe how FMD was controlled and eradicated in the *zone* (e.g. stamping-out, modified stamping-out), provide timeframe for eradication.
- c) Vaccines and vaccination. What type of vaccine is used? What species are vaccinated? Provide evidence that the vaccine used complies with Chapter 2.1.5. of the *Terrestrial Manual*. Describe the vaccination programme in the country and in the *zone*, including records kept, and provide evidence to show its effectiveness (e.g. vaccination coverage, serosurveillance, etc.).
- d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.
- e) Animal identification and movement control. Are susceptible *animals* identified (individually or at a group level)? Provide a description of the methods of animal identification, *herd* registration and traceability, including vaccination data. How are animal movements controlled in and between *zones* of the same or different status, in particular if the provisions of the *Terrestrial Code* in Article 8.5.9. are applied? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and the related paths of movement.

4. FMD diagnosis

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

- a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results. Indicate the laboratory(ies) where samples originating from the *zone* are diagnosed.
- b) Provide an overview of the FMD approved laboratories, in particular to address the following points.
 - i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.
 - ii) Give details of participation in inter-laboratory validation tests (ring tests).
 - iii) Is live virus handled?
 - iv) Biosecurity measures applied.
 - v) Details of the type of tests undertaken.

Annex VIII (contd)5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the *zone* complies with the provisions of Articles 8.5.40. to 8.5.46. of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis).
- b) Surveillance. Are serological and virological surveys conducted, in particular applying the provisions of Article 8.5.44.? If so, provide detailed information on the survey design (confidence level, sample size, stratification). How frequently are they conducted? Are wildlife susceptible species included in serological surveys? Provide a summary table indicating, for the past 2 years, the number of samples tested for FMD and FMDV, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* and numbers of *animals* examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.
- c) Livestock demographics and economics. What is the susceptible animal population by species and production systems in the country and the *zone*? How many *herds*, *flocks*, etc., of each susceptible species are in the country? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.
- d) Wildlife demographics. What susceptible species are present in the country and in the *zone*? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and wildlife susceptible species?
- e) Slaughterhouses and markets. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the *animals* transported and handled during these transactions?

6. FMD prevention

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

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

b) Import control procedures

From what countries or *zones* does the country authorize the import of susceptible *animals* or their products into a free *zone*? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such *animals* and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported *animals* of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible *animals* and their products for the past 2 years, specifying the country or *zone* of origin, the species and the volume.

- i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 2 years, of the quantity disposed of.
- iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:
 - *animals*,
 - genetic material (semen and embryos),
 - animal products,
 - veterinary medicinal products (i.e. biologics).
- iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

- a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of FMD.
- b) Is quarantine imposed on premises with suspicious *cases*, pending final diagnosis? What other procedures are followed regarding suspicious *cases*?
- c) In the event of an FMD *outbreak*:
 - i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;
 - ii) describe the actions taken to control the disease situation in and around any holdings found to be infected with FMD;

Annex VIII (contd)

- iii) indicate the control and/or eradication procedures (e.g. vaccination, stamping-out, partial *slaughter*/vaccination, etc.) that would be taken. Include details on antigen and vaccine banks;
- iv) describe the procedures used to confirm that an *outbreak* has been successfully controlled/eradicated, including any restrictions on restocking;
- v) give details of any compensation payments made available to farmers, etc. when *animals* are slaughtered for *disease* control/eradication purposes and their prescribed timetable.

8. Compliance with the Terrestrial Code

In addition to the documentary evidence that the provisions of Article 8.5.5. are properly implemented and supervised, the Delegate of the country must submit a declaration indicating:

- a) that there has been no *outbreak* of FMD for the past 2 years,
- b) no evidence of FMDV circulation for the past 12 months,
- c) *surveillance* for FMD and FMDV circulation in accordance with Articles 8.5.40. to 8.5.46. is in operation.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 8.5.8. of the *Terrestrial Code* and provide detailed information as specified in sections 3.a), 3.b), 3.c) and 5.b) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Article 1.6.4.

Questionnaire on rinderpest

RINDERPEST FREE COUNTRY

Report of a Member which applies for recognition of status, under Chapter 8.12. of the *Terrestrial Animal Health Code* (2009), as a rinderpest infection free country

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

1. Introduction

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

2. Veterinary system

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

3. Rinderpest eradication

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

4. Rinderpest diagnosis

Provide evidence that a system is in place for the rapid confirmation of a suspected *outbreak* i.e. that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.15. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

- a) Is rinderpest laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow up procedures and the time frame for obtaining results.
- b) Provide an overview of the rinderpest approved laboratories, in particular to address the following points:
 - i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.

Annex VIII (contd)

- ii) Give details of participation in inter-laboratory validation tests (ring tests).
- iii) Is live virus handled?
- iv) Biosecurity measures applied.
- v) Details of the type of tests undertaken.

5. Rinderpest surveillance

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

- a) Clinical suspicion. What are the criteria for raising a suspicion of rinderpest? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for rinderpest virus, species, type of sample, testing method(s) and results (including differential diagnosis). In particular, provide evidence of compliance with the provisions of Articles 8.12.20. to 8.12.27. of the *Terrestrial Code*.
- b) Serological surveillance. Are serological surveys conducted? If so, provide detailed information on the survey design in accordance with Articles 8.12.20. to 8.12.27. of the *Terrestrial Code*^a. Are wildlife susceptible species included in serological surveys? If not, explain the rationale. Provide a summary table indicating, for the past 2 years, the number of samples tested for rinderpest virus, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* and numbers of *animals* examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.
- c) Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many *herds*, *flocks*, etc., of each susceptible species are in the country? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.
- d) Wildlife demographics. What susceptible species are present in the country? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and wildlife susceptible species?
- e) Slaughterhouses and markets. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the *animals* transported and handled during these transactions.

6. Rinderpest prevention

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

b) Import control procedures

From what countries or *zones* does the country authorize the import of susceptible *animals* or their products? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such *animals* and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported *animals* of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible *animals* and their products for the past 2 years, specifying country or *zone* of origin, species and volume.

- i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- ii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:
 - *animals*,
 - genetic material (semen and embryos),
 - animal products,
 - veterinary medicinal products (i.e. biologics).
- iii) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

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

Annex VIII (contd)8. Compliance with the *Terrestrial Code*

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

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 8.12.3. of the *Terrestrial Code* and provide detailed information as specified in sections 3.a), 3.b), 3.c) and 5.b) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Article 1.6.5.

Questionnaire on contagious bovine pleuropneumonia

CBPP FREE COUNTRY

Report of a Member which applies for recognition of status, under Chapter 11.9. of the *Terrestrial Animal Health Code* (2009), as a CBPP free country

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

1. Introduction

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

2. Veterinary system

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

3. CBPP eradication

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

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

4. CBPP diagnosis

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

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

5. CBPP surveillance

Provide documentary evidence that *surveillance* for CBPP in the country complies with the provisions of Articles 11.9.12. to 11.9.17. of the *Terrestrial Code* and Chapter 2.4.9. of the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) Clinical surveillance. What are the criteria for raising a suspicion of CBPP? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for CBPP agent, species, type of sample, testing method(s) and results (including differential diagnosis).

Annex VIII (contd)

- b) Slaughterhouses, *slaughter* slabs, *abattoirs*. What are the criteria for raising a suspicion of CBPP lesion? What is the procedure to notify (by whom and to whom)? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for CBPP agent, species, type of sample, testing method(s) and results (including differential diagnosis).
- c) Provide details on training programmes for personnel involved in clinical and *slaughter* facilities *surveillance*, and the approaches used to increase community involvement in CBPP *surveillance* programmes.
- d) For countries where a significant proportion of *animals* are not slaughtered in controlled *abattoirs*, what are the alternative *surveillance* measures applied to detect CBPP (e.g. active clinical *surveillance* programmes, laboratory follow-up).
- e) Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many *herds* of each susceptible species are in the country? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.
- f) Slaughterhouses and markets. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the *animals* transported and handled during these transactions?
- g) Provide a description of the means employed during the 2 years preceding this application to rule out the presence of any *MmmSC* strain in the susceptible population. Provide criteria for selection of populations for targeted *surveillance* and numbers of *animals* examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.

6. CBPP prevention

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

From what countries or *zones* does the country authorize the import of susceptible *animals*? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such *animals*, and subsequent internal movement? What import conditions and test procedures are required? Are imported *animals* of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible *animals* for the past 2 years, specifying country or *zone* of origin, species and volume.

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

- ii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:
 - *animals*,
 - veterinary medicinal products (i.e. biologics).
- iii) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

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

8. Compliance with the *Terrestrial Code*

In addition to the documentary evidence that the provisions of Article 11.9.3. are properly implemented and supervised, the Delegate of the country must submit a declaration indicating:

- a) no clinical CBPP has been detected for at least 2 years;
- b) no CBPP vaccines have been used for at least 2 years in any susceptible species;
- c) the country operates both clinical *surveillance* and *disease* reporting systems for CBPP adequate to detect clinical *disease* if it were present;
- d) all clinical and pathological evidence suggestive of CBPP is investigated by field and laboratory methods (including serological assessment) to refute a possible diagnosis of CBPP;
- e) there are effective measures in force to prevent the re-introduction of the *disease*.

Annex VIII (contd)9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 11.9.4. of the *Terrestrial Code* and provide detailed information as specified in sections 3.a), 3.b), 3.c), 5.b), 5.c) and 5.d) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

CBPP FREE ZONE

Report of a Member which applies for recognition of status, under Chapter 11.9. of the *Terrestrial Animal Health Code* (2009), as a CBPP free zone

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

1. Introduction

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

2. Veterinary system

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

3. CBPP eradication

- a) History. Provide a description of the CBPP history in the *zone*, date of first detection, origin of *infection*, date of eradication (date of last *case*).
- b) Strategy. Describe how CBPP was controlled and eradicated in the *zone* (e.g. stamping-out, modified stamping-out, zoning) and provide timeframe for eradication.
- c) Vaccines and vaccination. Was CBPP vaccine ever used? In the entire country? If vaccination was used, when was the last vaccination carried out? Where in the country?

- d) Legislation, organisation and implementation of the CBPP eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.
- e) Animal identification and movement control. Are susceptible *animals* identified (individually or at a group level)? Provide a description of the methods of animal identification, *herd* registration and traceability. How are animal movements controlled in the *zone*? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and the related paths of movement.

4. CBPP diagnosis

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

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

5. CBPP surveillance

Provide documentary evidence that *surveillance* for CBPP in the country complies with the provisions of Articles 11.9.12. to 11.9.17. of the *Terrestrial Code* and Chapter 2.4.9. of the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) Clinical surveillance. What are the criteria for raising a suspicion of CBPP? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for CBPP agent, species, type of sample, testing method(s) and results (including differential diagnosis).
- b) Slaughterhouses, *slaughter* slabs, abattoirs. What are the criteria for raising a suspicion of CBPP lesion? What is the procedure to notify (by whom and to whom)? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for CBPP agent, species, type of sample, testing method(s) and results (including differential diagnosis).
- c) Provide details on training programmes for personnel involved in clinical and *slaughter* facilities *surveillance*, and the approaches used to increase community involvement in CBPP *surveillance* programmes.

Annex VIII (contd)

- d) For countries where a significant proportion of *animals* in the *zone* are not slaughtered in controlled *abattoirs*, what are the alternative *surveillance* measures applied to detect CBPP (e.g. active clinical *surveillance* programme, laboratory follow-up).
- e) Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many *herds* of each susceptible species are in the *zone*? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.
- f) Slaughterhouses and *markets*. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country and the *zone*? How are the *animals* transported and handled during these transactions?
- g) Provide a description of the means employed during the 2 years preceding this application to rule out the presence of any *MmmSC* strain in the susceptible population of the *zone*. Provide criteria for selection of populations for targeted *surveillance* and numbers of *animals* examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.

6. CBPP prevention

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

From what countries or *zones* does the country authorize the import of susceptible *animals*? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such *animals*, and subsequent internal movement? What import conditions and test procedures are required? Are imported *animals* of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible *animals* for the past 2 years, specifying country or *zone* of origin, species and volume.

- i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- ii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the *zone* and/or their final destination, concerning the import and follow-up of the following:
 - *animals*,
 - veterinary medicinal products (i.e. biologics).
- iii) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

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

8. Compliance with the *Terrestrial Code*

In addition to the documentary evidence that the provisions of Article 11.9.3. are properly implemented and supervised, the Delegate of the country must submit a declaration indicating that in the *zone*:

- a) no clinical CBPP has been detected for at least 2 years;
- b) no CBPP vaccines have been used for at least 2 years in any susceptible species;
- c) the country operates both clinical *surveillance* and *disease* reporting systems for CBPP adequate to detect clinical *disease* if it were present in the *zone*;
- d) all clinical and pathological suggestive of CBPP is investigated by field and laboratory methods (including serological assessment) to refute a possible diagnosis of CBPP;
- e) there are effective measures in force to prevent the re-introduction of the *disease*.

Annex VIII (contd)9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 11.9.4. of the *Terrestrial Code* and provide detailed information as specified in sections 3.a), 3.b), 3.c), 5.b), 5.c) and 5.d) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

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

CHAPTER 2.1.

IMPORT RISK ANALYSIS

Article 2.1.1.

Introduction

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

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

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

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

Chapter 2.2. provides recommendations and principles for conducting transparent, objective and defensible *risk analyses* for *international trade*. The components of *risk analysis* described in that Chapter are *hazard identification*, *risk assessment*, *risk management* and *risk communication* (Figure 1).

Fig. 1. The four components of risk analysis



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

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

Annex IX (contd)

Article 2.1.2.

Hazard identification

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

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

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

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

An *importing country* may decide to permit the importation solely based on 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* **must 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. ~~Although quantitative assessment is recognised as being able to provide deeper insights into a particular problem, qualitative methods may be more relevant when available data are limited.~~
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 steps1. Release assessment

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

a) Biological factors

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

b) Country factors

- incidence/prevalence
- evaluation of *Veterinary Services, surveillance* and control programmes and zoning and compartmentalisation systems of the *exporting country*.

c) Commodity factors

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

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

2. Exposure assessment

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

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

Annex IX (contd)

- a) Biological factors
 - properties of the agent.
- b) Country factors
 - presence of potential vectors
 - human and animal demographics
 - customs and cultural practices
 - geographical and environmental characteristics.
- c) Commodity factors
 - quantity of *commodity* to be imported
 - intended use of the imported *animals* or products
 - disposal practices.

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

3. Consequence assessment

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

- a) Direct consequences
 - animal *infection, disease* and production losses
 - public health consequences.
- b) Indirect consequences
 - *surveillance* and control costs
 - compensation costs
 - potential trade losses
 - adverse consequences to the environment.

4. Risk estimation

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

For a quantitative assessment, the final outputs may include:

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

Article 2.1.5.

Principles of risk management

1. *Risk management* is the process of deciding upon and implementing measures to achieve the Member's appropriate level of protection, whilst at the same time ensuring that negative effects on trade are minimized. The objective is to manage *risk* appropriately to ensure that a balance is achieved between a country's desire to minimize the likelihood or frequency of *disease* incursions and their consequences and its desire to import *commodities* and fulfil its obligations under *international trade* agreements.
2. The international standards of the OIE are the preferred choice of *sanitary measures* for *risk management*. The application of these *sanitary measures* should be in accordance with the intentions in the standards.

Article 2.1.6.

Risk management components

1. Risk evaluation - the process of comparing the *risk* estimated in the *risk assessment* with the Member's appropriate level of protection.
2. Option evaluation - the process of identifying, evaluating the efficacy and feasibility of, and selecting measures to reduce the *risk* associated with an importation in order to bring it into line with the Members appropriate level of protection. The efficacy is the degree to which an option reduces the likelihood and/or magnitude of adverse health and economic consequences. Evaluating the efficacy of the options selected is an iterative process that involves their incorporation into the *risk assessment* and then comparing the resulting level of *risk* with that considered acceptable. The evaluation for feasibility normally focuses on technical, operational and economic factors affecting the implementation of the *risk management* options.
3. Implementation - the process of following through with the *risk management* decision and ensuring that the *risk management* measures are in place.
4. Monitoring and review - the ongoing process by which the *risk management* measures are continuously audited to ensure that they are achieving the results intended.

Annex IX (contd)

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.

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CHAPTER 3.1.

VETERINARY SERVICES

Article 3.1.1.

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

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

The same fundamental principles should apply in countries where the responsibility for establishing or applying certain animal health 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 1 of the *Terrestrial Code* (notification, principles of certification, etc.).

The quality of *Veterinary Services*, including veterinary legislation and regulations, 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.

Annex X (contd)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 a fundamental element of quality as it supports good governance and provides 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.

6.7. General organisation

The *Veterinary Services* **must** **should** be able to demonstrate by means of appropriate legislation, sufficient financial resources and effective organisation that they are in a position to have control of the establishment and application of animal health **and animal welfare** measures, and of international veterinary certification activities. ~~Legislation should be suitably flexible to allow for judgements of equivalence and efficient responses to changing situations. In particular, they 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.~~

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

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

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

78. Quality policy

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

89. Procedures and standards

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

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

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

910. Information, complaints and appeals

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

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

1011. Documentation

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

Annex X (contd)412. 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.

4213. Communication

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

4314. Human and financial resources

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

Article 3.1.3.

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

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

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

Article 3.1.4.

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

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

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

The outcome of the evaluation conducted by a Member should be provided in writing as soon as possible, and in any case within 4 months of receipt of the relevant information, to the Member which has undergone the evaluation. The evaluation report should detail any findings which affect trade prospects. The Member which conducts the evaluation should clarify in detail any points of the evaluation on request.

In the event of a dispute between two Members over the conduct or the conclusions of the evaluation of the *Veterinary Services*, the matter should be dealt with having regard to the procedures set out in Article 5.3.8.

Article 3.1.5.

Evaluation facilitated by OIE experts under the auspices of the OIE

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

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

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

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

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

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

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CHAPTER 3.2.

EVALUATION OF VETERINARY SERVICES

Article 3.2.1.

General considerations

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

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

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

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

3. The purpose of evaluation may be either to assist a national authority in the decision-making process regarding priorities to be given to its own *Veterinary Services* (self-evaluation) or to assist the process of *risk analysis in international trade in animals* and animal-derived products to which official sanitary and/or zoosanitary controls apply.
4. In both situations, the evaluation should demonstrate that the *Veterinary Services* have the capability for effective control of the sanitary and zoosanitary status of *animals* and animal products. Key elements to be covered in this process include ~~resource~~ adequacy of resources, management capability, legislative and administrative infrastructures, independence in the exercise of official functions and history of performance ~~history~~, including *disease* reporting.
5. Good governance is the key to competence, and integrity and are qualities on which others base their confidence in individuals or organisations. Mutual confidence between relevant official *Veterinary Services* of trading partner countries contributes fundamentally to stability in *international trade in animals* and animal-related products. In this situation, scrutiny is directed more at the *exporting country* than at the *importing country*.

Annex X (contd)

6. Although quantitative data can be provided on *Veterinary Services*, the ultimate evaluation will be essentially qualitative. While it is appropriate to evaluate resources and infrastructure (organisational, administrative and legislative), it is also appropriate to place emphasis on the evaluation of the quality of outputs and performance of *Veterinary Services*. Evaluation should take into consideration any quality systems used by *Veterinary Services*.
7. An *importing country* has a right of assurance that information on sanitary/zoosanitary situations provided by the *Veterinary Services* of an *exporting country* is objective, meaningful and correct. Furthermore, the *Veterinary Services* of the *importing country* are entitled to expect validity in the veterinary certification of export.
8. An *exporting country* is entitled to expect that its *animals* and animal products will receive reasonable and valid treatment when they are subjected to import inspection in the country of destination. The country should also be able to expect that any evaluation of its standards and performance will be conducted on a non-discriminatory basis. The *importing country* should be prepared and able to defend any position which it takes as a consequence of the evaluation.
9. As the *veterinary statutory body* is not a part of the *Veterinary Services*, an evaluation of that body should be carried out to ensure that the registration/licensing of *veterinarians* and authorisation of *veterinary para-professionals* is included.

Article 3.2.2.

Scope

1. In the evaluation of *Veterinary Services*, the following items may be considered, depending on the purpose of the evaluation:
 - organisation, structure and authority of the *Veterinary Services*;
 - human resources;
 - material (including financial) resources;
 - veterinary legislation and regulations functional capabilities and legislative support;
 - animal health, animal welfare and veterinary public health controls;
 - formal quality systems including quality policy;
 - performance assessment and audit programmes;
 - participation in OIE activities and compliance with OIE Members' obligations.
2. To complement the evaluation of *Veterinary Services*, the legislative and regulatory framework, organisational structure and functioning of the *veterinary statutory body* should also be considered.

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

Article 3.2.3.

Evaluation criteria for the organisational structure of the Veterinary Services

1. A key element in the evaluation is the study of the organisation and structure of the official *Veterinary Services*. The *Veterinary Services* should define and set out their policy, objectives and commitment to quality systems and standards. These organisational and policy statements should be described in detail. Organisational charts and details of functional responsibilities of staff should be available for evaluation. The role and responsibility of the Chief Veterinary Officer/Veterinary Director should be clearly defined. Lines of command should also be described.
2. The organisational structure should also clearly set out the interface relationships of government Ministers and departmental Authorities with the Chief Veterinary Officer/Veterinary Director and the *Veterinary Services*. Formal relationships with statutory authorities and with industry organisations and associations should also be described. It is recognised that Services may be subject to changes in structure from time to time. Major changes should be notified to trading partners so that the effects of re-structuring may be assessed.
3. Organisational components of *Veterinary Services* which have responsibility for key functional capabilities should be identified. These capabilities include epidemiological *surveillance*, *disease* control, import controls, animal disease reporting systems, animal identification systems, traceability systems, animal movement control systems, communication of epidemiological information, training, inspection and certification. Laboratory and field systems and their organisational relationships should be described.
4. To reinforce the reliability and credibility of their services, the *Veterinary Services* may have set up quality systems that correspond with their fields of activity and to the nature and scale of activities that they carry out. Evaluation of such systems should be as objective as possible.
5. The *Veterinary Authority* alone speaks for the country as far as official international dialogue is concerned. This is also particularly important to cases where zoning and compartmentalisation are being applied. The responsibilities of the *Veterinary Authority* should be made clear in the process of evaluation of *Veterinary Services*.
6. The *Veterinary Authority* is defined in the Glossary of the *Terrestrial Code*. As some countries have some relevant roles of the *Veterinary Authority* vested in autonomous sub-national (state/provincial, municipal) government bodies, there is an important need to assess the role and function of these Services. Details of their roles, relationship (legal and administrative) to each other and to the *Veterinary Authority* should be available for evaluation. Annual reports, review findings and access to other information pertinent to the animal health activities of such bodies should also be available.

Annex X (contd)

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 **must should** include *veterinarians*. It should also include administrative officials and *veterinary para-professionals*. The human resources may also include part-time and private sector *veterinarians* and *veterinary para-professionals*. It is essential that all the above categories of personnel be subject to legal disciplinary provisions. Data relating to the resource base of the *Veterinary Services* undergoing evaluation should be available.
2. In addition to raw quantitative data on this resource base, the functions of the various categories of personnel in the *Veterinary Services* should be described in detail. This is necessary for analysis and estimation of the appropriateness of the application of qualified skills to the tasks undertaken by the *Veterinary Services* and may be relevant, for example, to the roles of *veterinarians* and *veterinary para-professionals* in field services. In this case, the evaluation should provide assurances that *disease monitoring* is being conducted by a sufficient number of qualified, experienced field *veterinarians* who are directly involved in farm visits; there should not be an over-reliance on *veterinary para-professionals* for this task.
3. Analysis of these data can be used to estimate the potential of the *Veterinary Services* to have reliable knowledge of the state of animal health in the country and to support an optimal level of animal disease control programmes. A large population of private *veterinarians* would not provide the *Veterinary Services* with an effective epizootiological information base without legislative (e.g. compulsory reporting of *notifiable diseases*) and administrative (e.g. official animal health *surveillance* and reporting systems) mechanisms in place.
4. These data should be assessed in close conjunction with the other information described in this chapter. For example, a large field staff (*veterinarians* and *veterinary para-professionals*) need fixed, mobile and budgetary resources for animal health activities in the livestock farming territory of the country. If deficiencies are evident, there would be reason to challenge the validity of epizootiological information.

Article 3.2.6.

Evaluation criteria for material resources1. Financial

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

2. Administrative

a) Accommodation

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

b) Communications

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

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

c) Transport systems

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

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

Annex X (contd)3. Technical

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

a) Cold chain for laboratory samples and veterinary medicines

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

b) Diagnostic laboratories

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

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

c. Research

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

Article 3.2.7.

Legislation and functional capabilities and legislative support1. Animal health, animal welfare and veterinary public health

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

2. Export/import inspection

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

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

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

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

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

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

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

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* **must** **should** be fundamental reference points. The evaluation should consider the recent history of the compliance of the country with its obligations regarding international notification of animal *diseases*. In the case of an OIE Member, failure to provide the necessary animal health reports consistent with OIE requirements will detract from the overall outcome of the evaluation of the country.

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

2. Animal health control

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

3. National animal disease reporting systems

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

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

Article 3.2.9.

Veterinary public health controls1. 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.

Annex X (contd)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/commission the function of which is to critically scrutinise their operations. The aim of this unit should be to ensure consistent and high integrity in the work of the individual officials in the *Veterinary Services* and of the corporate body itself. The existence of such a body can be important to the establishment of international confidence in the *Veterinary Services*.

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

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

4. Veterinary Services administration

a) Annual reports

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

b) Reports of government review bodies

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

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

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

d) In-service training and development programme for staff

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

e) Publications

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

f) Formal linkages with sources of independent scientific expertise

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

g) Trade performance history

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

Annex X (contd)

Article 3.2.11.

Participation in OIE activities

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

Article 3.2.12.

Evaluation of veterinary statutory 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, autonomy and functional capacity;
- c) the composition and representation of the body's membership;
- d) accountability and transparency of decision-making;
- e) sources and management of funding;
- f) administration of training programmes and continuing professional development for *veterinarians* and *veterinary para-professionals*.

2. Evaluation of objectives and functions

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

- a) to regulate *veterinarians* and *veterinary para-professionals* through licensing and/or registration of such persons;
- b) to determine the minimum standards of education (initial and continuing) required for degrees, diplomas and certificates entitling the holders thereof to be registered as *veterinarians* and *veterinary para-professionals*;
- c) to determine the standards of professional conduct of *veterinarians* and *veterinary para-professionals* and to ensure these standards are met.

3. Evaluation of legislative basis, autonomy and functional capacity

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

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

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

4. Evaluation of membership representation

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

- a) *veterinarians* designated by the *Veterinary Authority*, such as the Chief Veterinary Officer;
- b) *veterinarians* elected by members registered by the *veterinary statutory body*;
- c) *veterinarians* designated or nominated by the veterinary association(s);
- d) representative(s) of veterinary para-professions;
- e) representative(s) of veterinary academia;
- f) representative(s) of other stakeholders from the private sector;
- g) election procedures and duration of appointment;
- h) qualification requirements for members.

5. Evaluation of accountability and transparency of decision-making

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

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

6. Evaluation of financial sources and financial management

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

Annex X (contd)7. Evaluation of training programmes and programmes for continuing professional development, for veterinarians and veterinary para-professionals

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

Article 3.2.13.

1. The *Veterinary Services* of a country may undertake self-evaluation against the above criteria for such purposes as national interest, improvement of internal efficiency or export trade facilitation. The way in which the results of self-evaluation are used or distributed is a matter for the country concerned.
2. A prospective *importing country* may undertake an evaluation of the *Veterinary Services* of an *exporting country* as part of a *risk analysis* process, which is necessary to determine the sanitary or zoosanitary measures which the country will use to protect human or animal life or health from *disease* or pest threats posed by imports. Periodic evaluation reviews are also valid following the commencement of trade.
3. In the case of evaluation for the purposes of *international trade*, the authorities of an *importing country* should use the principles elaborated above as the basis for the evaluation and should attempt to acquire information according to the model questionnaire outlined in Article 3.2.14. The *Veterinary Services* of the *importing country* are responsible for the analysis of details and for determining the outcome of the evaluation after taking into account all the relevant information. The relative ranking of importance ascribed, in the evaluation, to the criteria described in this chapter will necessarily vary according to case-by-case circumstances. This ranking should be established in an objective and justifiable way. Analysis of the information obtained in the course of an evaluation study **must 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 **must should** be willing to defend any position taken on the basis of this type of information, if challenged by the other party.

Article 3.2.14.

This article outlines appropriate information requirements for the self-evaluation or evaluation of the *Veterinary Services* of a country.

1. Organisation and structure of Veterinary Services

a) National Veterinary Authority

Organisational chart including numbers, positions and numbers of vacancies.

b) Sub-national components of the Veterinary Authority

Organisational charts including numbers, positions and number of vacancies.

c) Other providers of veterinary services

Description of any linkage with other providers of veterinary services.

2. National information on human resources

a) Veterinarians

i) Total numbers of *veterinarians* registered/licensed by the *Veterinary statutory body* of the country.

ii) Numbers of:

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

iii) Animal health:

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

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

iv) Veterinary public health:

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

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

v) Numbers of veterinarians relative to certain national indices:

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

Annex X (contd)

vi) Veterinary education:

- number of veterinary schools;
- length of veterinary course (years);
- international recognition of veterinary degree.

vii) Veterinary professional associations.

b) Graduate personnel (non-veterinary)

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

c) Veterinary para-professionals employed by the Veterinary Services

i) Animal health:

- Categories and numbers involved with farm livestock on a majority time basis:
 - by geographical area;
 - proportional to numbers of field Veterinary Officers in the *Veterinary Services*, by geographical area.
- Education/training details.

ii) Veterinary public health:

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

d) Support personnel

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

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

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

g) Additional information and/or comments.

3. Financial management information

- a) Total budgetary allocations to the *Veterinary Authority* for the current and past two fiscal years:
 - i) for the national *Veterinary Authority*,
 - ii) for each of any sub-national components of the *Veterinary Authority*,
 - iii) for other relevant government-funded institutions.
- b) Sources of the budgetary allocations and amount:
 - i) government budget;
 - ii) sub-national authorities;
 - iii) taxes and fines;
 - iv) grants;
 - v) private services.
- c) Proportional allocations of the amounts in a) above for operational activities and for the programme components of *Veterinary Services*.
- d) Total allocation proportionate of national public sector budget. *[This data may be necessary for comparative assessment with other countries which should take into account the contexts of the importance of the livestock sector to the national economy and of the animal health status of the country.]*
- e) Actual and proportional contribution of animal production to gross domestic product.

4. Administration details

a) Accommodation

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

b) Communications

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

c) Transport

- i) Itemised numbers of types of functional transport available on a full-time basis for the *Veterinary Services*. In addition provide details of transport means available part-time.
- ii) Details of annual funds available for maintenance and replacement of motor vehicles.

Annex X (contd)5. Laboratory services

- a) Diagnostic laboratories (laboratories engaged primarily in diagnosis)
 - i) Descriptive summary of the organisational structure and role of the government veterinary laboratory service in particular its relevance to the field *Veterinary Services*.
 - ii) Numbers of veterinary diagnostic laboratories operating in the country:
 - government operated laboratories;
 - private laboratories accredited by government for the purposes of supporting official or officially-endorsed animal health control or public health testing and monitoring programmes and import/export testing.
 - iii) Descriptive summary of accreditation procedures and standards for private *laboratories*.
 - iv) Human and financial resources allocated to the government veterinary *laboratories*, including staff numbers, graduate and post-graduate qualifications and opportunities for further training.
 - v) List of diagnostic methodologies available against major *diseases* of farm livestock (including *poultry*).
 - vi) Details of collaboration with external *laboratories* including international reference laboratories and details on numbers of samples submitted.
 - vii) Details of quality control and assessment (or validation) programmes operating within the veterinary laboratory service.
 - viii) Recent published reports of the official veterinary laboratory service which should include details of specimens received and foreign animal disease investigations made.
 - ix) Details of procedures for storage and retrieval of information on specimen submission and results.
 - x) Reports of independent reviews of the laboratory service conducted by government or private organisations (if available).
 - xi) Strategic and operational plans for the official veterinary laboratory service (if available).
- b) Research laboratories (laboratories engaged primarily in research)
 - i) Numbers of veterinary research *laboratories* operating in the country:
 - government operated *laboratories*;
 - private *laboratories* involved in full time research directly related to animal health and veterinary public health matters involving production animal species.
 - ii) Summary of human and financial resources allocated by government to veterinary research.
 - iii) Published programmes of future government sponsored veterinary research.
 - iv) Annual reports of the government research *laboratories*.

6. Veterinary legislation, regulations and functional capabilities and legislative support

a) Animal health and veterinary public health

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

- animal and veterinary public health controls at national frontiers;
- control of endemic animal diseases, including *zoonoses*;
- emergency powers for control of exotic disease outbreaks, including *zoonoses*;
- inspection and registration of facilities;

▪ animal feeding:

- veterinary public health controls of the production, processing, storage and marketing of *meat* for domestic consumption;
- veterinary public health controls of the production, processing, storage and marketing of fish, dairy products and other foods of animal origin for domestic consumption;
- registration and use of veterinary pharmaceutical products including vaccines.

▪ animal welfare

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

b) Export/import inspection

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

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

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

Annex X (contd)7. Animal health and veterinary public health controls

a) Animal health

- i) Description of and sample reference data from any national animal disease reporting system controlled and operated or coordinated by the *Veterinary Services*.
- ii) Description of and sample reference data from other national animal disease reporting systems controlled and operated by other organisations which make data and results available to *Veterinary Services*.
- iii) Description and relevant data of current official control programmes including:
 - epidemiological *surveillance* or monitoring programmes;
 - officially approved industry administered control or eradication programmes for specific *diseases*.
- iv) Description and relevant details of animal disease emergency preparedness and response plans.
- v) Recent history of animal disease status:
 - animal *diseases* eradicated nationally or from defined sub-national zones in the last ten years;
 - animal *diseases* of which the prevalence has been controlled to a low level in the last ten years;
 - animal *diseases* introduced to the country or to previously free sub national regions in the last ten years;
 - *emerging diseases* in the last ten years;
 - animal *diseases* of which the prevalence has increased in the last ten years.

b) Veterinary public health

i) Food hygiene

- Annual national *slaughter* statistics for the past three years according to official data by species of *animals* (bovine, ovine, porcine, caprine, *poultry*, farmed game, wild game, equine, other).
- Estimate of total annual slaughterings which occur but are not recorded under official statistics.
- Proportion of total national *slaughter* which occurs in registered export establishments, by category of *animal*.
- Proportion of total national *slaughter* which occurs under veterinary control, by category of *animal*.

Annex X (contd)

- Numbers of commercial *fresh meat* establishments in the country which are registered for export by the *Veterinary Authority*:
 - *slaughterhouses* (indicate species of *animals*);
 - cutting/packing plants (indicate *meat* type);
 - *meat* processing establishments (indicate *meat* type);
 - cold stores.
 - Numbers of commercial *fresh meat* establishments in the country approved by other *importing countries* which operate international assessment inspection programmes associated with approval procedures.
 - Numbers of commercial *fresh meat* establishments under direct public health control of the *Veterinary Services* (including details of category and numbers of inspection staff associated with these premises).
 - Description of the veterinary public health programme related to production and processing of animal products for human consumption (including *fresh meat, poultry meat, meat products, game meat, dairy products, fish, fishery products, molluscs and crustaceans* and other foods of animal origin) especially including details applying to exports of these *commodities*.
 - Descriptive summary of the roles and relationships of other official organisations in public health programmes for the products listed above if the *Veterinary Authority* does not have responsibility for those programmes which apply to national production destined to domestic consumption and/or exports of the *commodities* concerned.
- ii) Zoonoses
- Descriptive summary of the numbers and functions of staff of the *Veterinary Authority* involved primarily with monitoring and control of zoonotic diseases.
 - Descriptive summary of the role and relationships of other official organisations involved in monitoring and control of *zoonoses* to be provided if the *Veterinary Authority* does not have these responsibilities.
- iii) Chemical residue testing programmes
- Descriptive summary of national *surveillance* and monitoring programmes for environmental and chemical residues and contaminants applied to animal-derived foodstuffs, *animals* and animal feedstuffs.
 - Role and function in these programmes of the *Veterinary Authority* and other *Veterinary Services* to be described in summary form.
 - Descriptive summary of the analytical methodologies used and their consistency with internationally recognised standards.

Annex X (contd)

iv) Veterinary medicines

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

8. Quality systems

a) Accreditation

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

b) Quality manuals

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

c) Audit

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

9. Performance assessment and audit programmes

a) Strategic plans and review

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

b) Compliance

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

c) Annual reports of the Veterinary Authority

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

d) Other reports

- i) Copies of reports of official reviews into the function or role of the *Veterinary Services* which have been conducted within the past three years.
- ii) Descriptive summary (and copy of reports if available) of subsequent action taken on recommendations made in these reviews.

e) Training

- i) Descriptive summary of in-service and development programmes provided by the *Veterinary Services* (or their parent Ministries) for relevant staff.
- ii) Summary descriptions of training courses and duration.
- iii) Details of staff numbers (and their function) who participated in these training courses in the last three years.

f) Publications

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

g) Sources of independent scientific expertise

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

10. Membership of the OIE

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

11. Other assessment criteria

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CHAPTER 4.2.

DESIGN AND IMPLEMENTATION OF IDENTIFICATION SYSTEMS TO ACHIEVE ANIMAL TRACEABILITY

Article 4.2.1.

Introduction and objectives

These recommendations are based on the general principles presented in Article 4.1.1. The recommendations outline for Members the basic elements that need to be taken into account in the design and implementation of an *animal identification system* to achieve *animal traceability*. Whatever *animal identification system* the country adopts, it should comply with relevant OIE standards, including Chapters 5.10. to 5.12. for *animals* and animal products intended for export. Each country should design a programme in accordance with the scope and relevant performance criteria to ensure that the desired *animal traceability* outcomes can be achieved.

Article 4.2.2.

Glossary Definitions

For the purpose of this chapter:

Desired outcomes describe the overall goals of a programme and are usually expressed in qualitative terms, e.g. 'to help ensure that *animals* and/or animal products are safe and suitable for use'. Safety and suitability for use could be defined in terms such as animal health, food safety, trade and aspects of animal husbandry.

Performance criteria are specifications for performance of a programme and are usually expressed in quantitative terms, such as 'all *animals* can be traced to the *establishment* of birth within 48 hours of an enquiry'.

Reporting means advising the *Veterinary Authority* and other partner organisations as appropriate in accordance with the procedures listed in the programme.

Scope specifies the targeted species, population and/or production/trade sector within a defined area (country, *zone*) or *compartment* that is the subject of the *identification* and *traceability* programme.

Transhumance: periodic/seasonal movements of *animals* between different pastures within or between countries.

Article 4.2.3.

Key elements of the animal identification system1. Desired outcomes

Desired outcomes should be defined through consultation between the *Veterinary Authority* and other parties, which should include (depending on scope) animal producers and food processors, private sector veterinarians, scientific research organisations and other government agencies. Desired outcomes may be defined in terms of any or all of the following:

Annex XI (contd)

- a) animal health (e.g. *disease surveillance* and notification; detection and control of *disease*, vaccination programmes);
- b) public health (e.g. *surveillance* and control of zoonotic diseases and food safety);
- c) management of emergencies e.g. natural catastrophies or man-made events;
- d) trade (support for inspection and certification activities of *Veterinary Services*, as described in Chapters 5.10. to 5.12. which reproduce model international veterinary certificates);
- e) aspects of animal husbandry such as animal performance, and genetic data.

2. Scope

Scope should also be defined through consultation between the *Veterinary Authority* and other parties, as discussed above. The scope of *animal identification systems* is often based on the definition of a species and sector, to take account of particular characteristics of the farming systems e.g. pigs in pork export production; *poultry* in a defined *compartment*; cattle within a defined FMD free *zone*. Different systems will be appropriate according to the production systems used in countries and the nature of their industries and trade.

3. Performance criteria

Performance criteria are also designed in consultation with other parties, as discussed above. The performance criteria depend on the desired outcomes and scope of the programme. They are usually described in quantitative terms according to the epidemiology of the *disease*. For example, some countries consider it necessary to trace susceptible *animals* within 24-48 hours when dealing with highly contagious *diseases* such as FMD and avian influenza. For food safety, animal tracing to support investigation of incidents may also be urgent. For chronic animal *diseases* that are not *zoonoses*, it may be considered appropriate that *animals* can be traced over a longer period.

4. Preliminary studies

In designing *animal identification systems* it is useful to conduct preliminary studies, which should take into account:

- a) animal populations, species, distribution, *herd* management,
- b) farming and industry structures, production and location,
- c) animal health,
- d) public health,
- e) trade issues,
- f) aspects of animal husbandry,
- g) zoning and compartmentalisation,
- h) animal movement patterns (including transhumance),
- i) information management and communication,

- j) availability of resources (human and financial),
- k) social and cultural aspects,
- l) stakeholder knowledge of the issues and expectations,
- m) gaps between current enabling legislation and what is needed long term,
- n) international experience,
- o) national experience,
- p) available technology options,
- q) existing identification system(s),
- r) expected benefits from the *animal identification systems* and *animal traceability* and to whom they accrue,
- s) issues pertaining to data ownership and access rights,
- t) reporting requirements.

Pilot projects may form part of the preliminary study to test the *animal identification system* and *animal traceability* and to gather information for the design and the implementation of the programme.

Economic analysis may consider costs, benefits, funding mechanisms and sustainability.

5. Design of the programme

a) General provisions

The programme should be designed in consultation with the stakeholders to facilitate the implementation of the *animal identification system* and *animal traceability*. It should take into account the scope, performance criteria and desired outcomes as well as the results of any preliminary study.

All the specified documentation should be standardised as to format, content and context.

To protect and enhance the integrity of the system, procedures should be incorporated into the design of the programme to prevent, detect and correct errors e.g. use of algorithms to prevent duplication of identification numbers and to ensure plausibility of data.

b) Means of animal identification

The choice of a physical animal or group identifier should consider elements such as the durability, human resources, species and age of the *animals* to be identified, required period of identification, cultural aspects, *animal welfare*, technology, compatibility and relevant standards, farming practices, production systems, animal population, climatic conditions, resistance to tampering, trade considerations, cost, and retention and readability of the identification method.

Annex XI (contd)

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 ~~on an establishment~~ should be identified;
- ii) when *animals* are introduced into an *establishment*;
- iii) when an *animal* loses its identification or the identifier becomes unusable;
- iv) arrangements and rules for the destruction and/or reuse of identifiers;
- v) penalties for the tampering and/or removal of official animal identification devices.

Where group identification without a physical identifier is adequate, documentation should be created specifying at least the number of *animals* in the group, the species, the date of identification, the person legally responsible for the *animals* and/or *establishment*. This documentation constitutes a unique group identifier and it should be updated to be traceable if there are any changes.

Where all *animals* in the group are physically identified with a group identifier, documentation should also specify the unique group identifier.

c) Registration

Procedures need to be incorporated into the design of the programme in order to ensure that relevant events and information are registered in a timely and accurate manner.

Depending on the scope, performance criteria and desired outcomes, records as described below should specify, at least, the species, the unique animal or group identifier, the date of the event, the identifier of the *establishment* where the event took place, and the code for the event itself.

i) Establishments/owners or responsible keepers

Establishments where *animals* are kept should be identified and registered, including at least their physical location (such as geographical coordinates or street address), the type of establishment and the species kept. The register should include the name of the person legally responsible for the *animals* at the establishment.

The types of establishments that may need to be registered include holdings (farms), assembly centres (e.g. agriculture shows and fairs, sporting events, transit centres, breeding centres), *markets*, *abattoirs*, rendering plants, dead stock collection points, transhumance areas, centres for necropsy and diagnosis, research centres, zoos, *border posts*, *quarantine stations*.

In cases where the registration of establishments is not applicable (e.g. some transhumance systems), the animal owner, the owner's place of residence and the species kept should be recorded.

ii) Animals

Animal identification and species should be registered for each establishment/owner. Other relevant information about the *animals* at each establishment/owner may also be recorded (e.g. date of birth, production category, sex, breed, number of animals of each species, *animal identification* of the parents).

iii) Events including movements

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. Movement recording may also include means of *transport* and the *vehicle* / identifier.

~~When establishments are not registered as part of the *animal identification system*, ownership and location changes constitute a movement record. Movement recording may also include means of *transport* and the *vehicle* / identifier.~~

Procedures should be in place to maintain *animal traceability* during *transport* and when *animals* arrive at and leave an establishment.

iv) Events other than movements

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.).

Annex XI (contd)

d) Documentation

Documentation requirements should be clearly defined and standardised, according to the scope, performance criteria and desired outcomes and supported by the legal framework.

e) Reporting

Depending on the scope, performance criteria and desired outcomes, relevant information (such as *animal identification*, movement, events, changes in numbers of livestock, *establishments*) should be reported to the *Veterinary Authority* by the person responsible for the *animals*.

f) Information system

An information system should be designed according to the scope, performance criteria and desired outcomes. This may be paper based or electronic. The system should provide for the collection, compilation, storage and retrieval of information on matters relevant to *registration*. The following considerations are important:

- have the potential for linkage to traceability in the other parts of the food chain;
- minimize duplication;
- relevant components, including databases, should be compatible;
- confidentiality of data;
- appropriate safeguards to prevent the loss of data, including a system for backing up the data.

The *Veterinary Authority* should have access to this information system as appropriate to meet the scope, performance criteria and desired outcomes.

g) Laboratories

The results of diagnostic tests should record the animal identifier or the group identifier, the date the sample was taken from the animal and the establishment where the sample was collected.

h) Abattoirs, rendering plants, dead stock collection points, markets and assembly centres

Abattoirs, rendering plants, dead stock collection points, *markets* and assembly centres should document arrangements for the maintenance of *animal identification* and *animal traceability* in compliance with the legal framework.

These establishments are critical points for control of animal health and food safety.

Animal identification should be recorded on documents accompanying samples collected for analysis.

The components of the *animal identification system* operating within *abattoirs* should complement and be compatible with arrangements for tracking animal products throughout the food chain. At an *abattoir*, *animal identification* should be maintained during the processing of the *animal's* carcass until the carcass is deemed fit for human consumption.

The *animal identification* and the establishment from which the *animal* was dispatched should be registered by the *abattoir*, rendering plant and dead stock collection points.

Abattoirs, rendering plants and dead stock collection points should ensure that identifiers are collected and disposed of according to the procedures established and regulated within the legal framework. These procedures should minimize the risk of unauthorized reuse and, if appropriate, should establish arrangements and rules for the reuse of identifiers.

Reporting of movement by *abattoirs*, rendering plants and dead stock collection points should occur according to the scope, performance criteria and desired outcomes and the legal framework.

i) Penalties

Different levels and types of penalties should be defined in the programme and supported by the legal framework.

6. Legal framework

The *Veterinary Authority*, with other relevant governmental agencies and in consultation with stakeholders, should establish a legal framework for the implementation and enforcement of *animal identification system* and *animal traceability* in the country. The structure of this framework will vary from country to country.

Animal identification, *animal traceability* and animal movement should be under the responsibility of the *Veterinary Authority*.

This legal framework should address:

- i) desired outcomes and scope;
- ii) obligations of the *Veterinary Authority* and other parties;
- iii) organisational arrangements, including the choice of technologies and methods used for the *animal identification system* and *animal traceability*;
- iv) management of animal movement;
- v) confidentiality of data;
- vi) data access / accessibility;
- vii) checking, verification, inspection and penalties;
- viii) where relevant, funding mechanisms;
- ix) where relevant, arrangements to support a pilot project.

7. Implementation

a) Action plan

For implementing the *animal identification system*, an action plan should be prepared specifying the timetable and including the milestones and performance indicators, the human and financial resources, and checking, enforcement and verification arrangements.

Annex XI (contd)

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.

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CHAPTER 4.3.

ZONING AND COMPARTMENTALISATION

Article 4.3.1.

Introduction

For the purposes of the *Terrestrial Code*, 'zoning' and 'regionalisation' have the same meaning.

Establishing and maintaining a disease free-status throughout the country should be the final goal for OIE Members. However, given the difficulty of establishing and maintaining a *disease* free status for an entire territory, especially for *diseases* the entry of which is difficult to control through measures at national boundaries, there may be benefits to a Member in establishing and maintaining a *subpopulation* with a distinct health status within its territory. *Subpopulations* may be separated by natural or artificial geographical barriers or, in certain situations, by the application of appropriate management practices.

Zoning and compartmentalisation are procedures implemented by a Member under the provisions of this Chapter with a view to defining *subpopulations* of distinct health status within its territory for the purpose of *disease* control and/or *international trade*. While zoning applies to an animal *subpopulation* defined primarily on a geographical basis (using natural, artificial or legal boundaries), compartmentalisation applies to an animal *subpopulation* defined primarily by management and husbandry practices related to biosecurity. In practice, spatial considerations and good management including *biosecurity plans* play important roles in the application of both concepts.

A particular application of the concept of zoning is the establishment of a *containment zone*. In the event of limited *outbreaks* of a specified *disease* within an otherwise free country or *zone*, a single *containment zone*, which includes all *cases*, can be established for the purpose of minimizing the impact on the entire country or *zone*.

This Chapter is to assist OIE Members wishing to establish and maintain different *subpopulations* within their territory using the principles of compartmentalisation and zoning. These principles should be applied in accordance with the measures recommended in the relevant *disease* Chapter(s). This Chapter also outlines a process through which trading partners may recognise such *subpopulations*. This process is best implemented by trading partners through establishing parameters and gaining agreement on the necessary measures prior to *disease outbreaks*.

Before trade in *animals* or their products may occur, an *importing country* needs to be satisfied that its *animal health status* will be appropriately protected. In most cases, the import regulations developed will rely in part on judgements made about the effectiveness of sanitary procedures undertaken by the *exporting country*, both at its borders and within its territory.

As well as contributing to the safety of *international trade*, zoning and compartmentalisation may assist *disease* control or eradication within a Member's territory. Zoning may encourage the more efficient use of resources within certain parts of a country and compartmentalisation may allow the functional separation of a *subpopulation* from other domestic or wild animals through biosecurity measures, which a *zone* (through geographical separation) would not achieve. Following a *disease outbreak*, the use of compartmentalisation may allow a Member to take advantage of epidemiological links among *subpopulations* or common practices relating to biosecurity, despite diverse geographical locations, to facilitate *disease* control and/or the continuation of trade.

Annex XII (contd)

Zoning and compartmentalisation cannot be applied to all *diseases* but separate requirements will be developed for each *disease* for which the application of zoning or compartmentalisation is considered appropriate.

To regain free status following a *disease outbreak* in a *zone* or *compartment*, Members should follow the recommendations in the relevant *disease* Chapter in the *Terrestrial Code*.

Article 4.3.2.

General considerations

The *Veterinary Services* of an *exporting country* which is establishing a *zone* or *compartment* within its territory for *international trade* purposes should clearly define the *subpopulation* in accordance with the recommendations in the relevant Chapters in the *Terrestrial Code*, including those on *surveillance*, and the *identification* and *traceability* of live *animals*. The *Veterinary Services* of an *exporting country* should be able to explain to the *Veterinary Services* of an *importing country* the basis for claiming a distinct *animal health status* for the given *zone* or *compartment* under consideration.

The procedures used to establish and maintain the distinct *animal health status* of a *zone* or *compartment* should be appropriate to the particular circumstances, and will depend on the epidemiology of the *disease*, in particular, the presence and importance of susceptible wildlife species, environmental factors and applicable appropriate biosecurity measures.

The authority, organisation and infrastructure of the *Veterinary Services*, including *laboratories*, **must should** be clearly documented in accordance with the Chapter on the evaluation of *Veterinary Services* of the *Terrestrial Code*, to provide confidence in the integrity of the *zone* or *compartment*. The final authority of the *zone* or *compartment*, for the purposes of domestic and *international trade*, lies with the *Veterinary Authority*.

In the context of maintaining the *health status* of a *population*, references to 'import', 'importation' and 'imported animals/products' found in the *Terrestrial Code* apply both to importation into a country and to the movement of *animals* and their products into *zones* and *compartments*. Such movements should be the subject of appropriate measures to preserve the *animal health status* of the *zone/compartment*.

The *exporting country* should be able to demonstrate, through detailed documentation provided to the *importing country*, that it has implemented the recommendations in the *Terrestrial Code* for establishing and maintaining such a *zone* or *compartment*.

An *importing country* should recognise the existence of this *zone* or *compartment* when the appropriate measures recommended in the *Terrestrial Code* are applied and the *Veterinary Authority* of the *exporting country* certifies that this is the case.

The *exporting country* should conduct an assessment of the resources needed and available to establish and maintain a *zone* or *compartment* for *international trade* purposes. These include the human and financial resources, and the technical capability of the *Veterinary Services* (and of the relevant industry, in the case of a *compartment*) including *disease surveillance* and diagnosis.

Biosecurity and *surveillance* are essential components of zoning and compartmentalisation, and the arrangements should be developed through cooperation of industry and *Veterinary Services*.

Industry's responsibilities include the application of biosecurity measures, documenting and recording movements of *animals* and personnel, quality assurance schemes, monitoring the efficacy of the measures, documenting corrective actions, conducting *surveillance*, rapid reporting and maintenance of records in a readily accessible form.

The *Veterinary Services* should provide movement certification, and carry out documented periodic inspections of facilities, biosecurity measures, records and *surveillance* procedures. *Veterinary Services* should conduct or audit *surveillance*, reporting and *laboratory* diagnostic examinations.

Article 4.3.3.

Principles for defining a zone or compartment, including protection and containment zones

In conjunction with the above considerations, the following principles should apply when Members define a *zone* or a *compartment*.

1. The extent of a *zone* and its geographical limits should be established by the *Veterinary Authority* on the basis of natural, artificial and/or legal boundaries, and made public through official channels.

2. A protection zone may be established to preserve the health status of animals in a free country or zone, from adjacent countries or zones of different animal health status. Measures should be implemented based on the epidemiology of the disease under consideration to prevent introduction of the pathogenic agent.

These measures should include intensified movement control and surveillance and may also include:

- animal identification and traceability.
- vaccination of all or at risk susceptible animals
- testing and/or vaccination of animals moved.
- specific procedures for sample handling, sending and testing.
- enhanced cleansing – disinfection procedures for transport means, and possible compulsory routes.
- specific surveillance of susceptible wildlife species.
- awareness campaigns to the public or targeted at breeders, traders, hunters, veterinarians.

vaccination, special identification, raised awareness or other measures.

The application of these measures can be in the entire free zone or in a defined area within and/or outside the free zone.

23. In the event of limited *outbreaks* in a country or *zone* previously free of a *disease*, a *containment zone* may be established for the purposes of trade. Establishment of a *containment zone* should be based on a rapid response including:
- a) appropriate standstill of movement of *animals* and *commodities* upon notification of suspicion of the specified *disease* and the demonstration that the *outbreaks* are contained within this zone through epidemiological investigation (trace-back, trace-forward) after confirmation of *infection*. The primary *outbreak* and likely source of the *outbreak* should be identified and all *cases* shown to be epidemiologically linked.

Annex XII (contd)

- b) A *stamping-out policy* or another effective control strategy aimed at eradicating the *disease* should be applied and the susceptible animal population within the *containment zones* should be clearly identifiable as belonging to the *containment zone*. Increased passive and targeted *surveillance* in accordance with Chapter 1.4. in the rest of the country or *zone* should be carried out and has not detected any evidence of *infection*.
 - c) Measures consistent with the disease specific chapter should be in place to prevent spread of the *infection* from the *containment zone* to the rest of the country or *zone*, including ongoing *surveillance* in the *containment zone*.
 - d) For the effective establishment of a *containment zone*, it is necessary to demonstrate that there have been no new *cases* in the *containment zone* within a minimum of two *incubation periods* from the last detected *case*.
 - e) The free status of the areas outside the *containment zone* would be suspended pending the establishment of the *containment zone*. The free status of these areas could be reinstated, once the *containment zone* is clearly established, irrespective of the provisions of the disease specific chapter.
 - f) The *containment zone* should be managed in such a way that it can be demonstrated that *commodities* for *international trade* can be shown to have originated outside the *containment zone*.
 - g) The recovery of the free status of the *containment zone* should follow the provisions of the disease specific chapter.
34. The factors defining a *compartment* should be established by the *Veterinary Authority* on the basis of relevant criteria such as management and husbandry practices related to biosecurity, and made public through official channels.
45. *Animals* and *herds* belonging to such *subpopulations* need to be recognisable as such through a clear epidemiological separation from other animals and all things presenting a *disease risk*. For a *zone* or *compartment*, the *Veterinary Authority* should document in detail the measures taken to ensure the identification of the *subpopulation* and the establishment and maintenance of its health status through a *biosecurity plan*. The measures used to establish and maintain the distinct *animal health status* of a *zone* or *compartment* should be appropriate to the particular circumstances, and will depend on the epidemiology of the *disease*, environmental factors, the health status of *animals* in adjacent areas, applicable biosecurity measures (including movement controls, use of natural and artificial boundaries, the spatial separation of *animals*, and commercial management and husbandry practices), and *surveillance*.
56. Relevant *animals* within the *zone* or *compartment* should be identified in such a way that their history can be audited. Depending on the system of production, identification may be done at the *herd, flock* lot or individual animal level. Relevant animal movements into and out of the *zone* or *compartment* should be well documented, controlled and supervised. The existence of a valid *animal identification system* is a prerequisite to assess the integrity of the *zone* or *compartment*.

67. For a *compartment*, the *biosecurity plan* should describe the partnership between the relevant industry and the *Veterinary Authority*, and their respective responsibilities. It should also describe the routine operating procedures to provide clear evidence that the *surveillance* conducted, the live *animal identification* and *traceability* system, and the management practices are adequate to meet the definition of the *compartment*. In addition to information on animal movement controls, the plan should include *herd* or *flock* production records, feed sources, *surveillance* results, birth and *death* records, visitor logbook, morbidity and mortality history, medications, vaccinations, documentation of training of relevant personnel and any other criteria necessary for evaluation of *risk* mitigation. The information required may vary according to the species and *disease(s)* under consideration. The *biosecurity plan* should also describe how the measures will be audited to ensure that the *risks* are regularly re-assessed and the measures adjusted accordingly.

— text deleted

CHAPTER 4.4.

APPLICATION OF COMPARTMENTALISATION

Article 4.4.1.

Introduction and objectives

The recommendations in this Chapter provide a structured framework for the application and recognition of *compartments* within countries or *zones*, based on the provisions of Chapter 4.3. with the objective to facilitate trade in *animals* and products of animal origin and as a tool for *disease* management.

Establishing and maintaining a disease free-status throughout the country should be the final goal for OIE Members. However, establishing and maintaining a *disease*-free status for an entire country may be difficult, especially in the case of *diseases* that can easily cross international boundaries. For many *diseases*, OIE Members have traditionally applied the concept of zoning to establish and maintain an animal *subpopulation* with a different animal health status within national boundaries.

The essential difference between zoning and compartmentalisation is that the recognition of *zones* is based on geographical boundaries whereas the recognition of *compartments* is based of management practices and biosecurity. However, spatial considerations and good management practices play a role in the application of both concepts.

Compartmentalisation is not a new concept for *Veterinary Services*; in fact, it has been applied for a long time in many *disease* control programmes that are based on the concept of *disease*-free *herds/flocks*.

The fundamental requirement for compartmentalisation is the implementation and documentation of management and biosecurity measures to create a functional separation of *subpopulations*.

For example, an animal production operation in an infected country or *zone* might have biosecurity measures and management practices that result in negligible *risk* from *diseases* or agents. The concept of a *compartment* extends the application of a 'risk boundary' beyond that of a geographical interface and considers all epidemiological factors that can help to create an effective *disease*-specific separation between *subpopulations*.

In *disease*-free countries or *zones*, *compartments* preferably should be defined prior to the occurrence of a *disease outbreak*. In the event of an *outbreak* or in infected countries or *zones*, compartmentalisation may be used to facilitate trade.

For the purpose of *international trade*, *compartments* **must should** be under the responsibility of the *Veterinary Authority* in the country. For the purposes of this Chapter, compliance by the Members with Chapters 1.1. and 3.1. is an essential prerequisite.

Article 4.4.2.

Principles for defining a compartment

A *compartment* may be established with respect of a specific *disease* or *diseases*. A *compartment* **must should** be clearly defined, indicating the location of all its components including *establishments*, as well as related functional units (such as feed mills, *slaughterhouses*, rendering plants, etc.), their interrelationships and their contribution to an epidemiological separation between the *animals* in a *compartment* and *subpopulations* with a different health status. The definition of *compartment* may revolve around *disease* specific epidemiological factors, animal production systems, biosecurity practices infrastructural factors and *surveillance*.

Annex XII (contd)

Article 4.4.3.

Separation of a compartment from potential sources of infection

The management of a *compartment* ~~must~~ should provide to the *Veterinary Authority* documented evidence on the following:

1. Physical or spatial factors that affect the status of biosecurity in a compartment

While a *compartment* is primarily based on management and biosecurity measures, a review of geographical factors is needed to ensure that the functional boundary provides adequate separation of a *compartment* from adjacent animal populations with a different health status. The following factors should be taken into consideration in conjunction with biosecurity measures and, in some instances, may alter the degree of confidence achieved by general biosecurity and *surveillance* measures:

- a) disease status in adjacent areas and in areas epidemiologically linked to the *compartment*;
- b) location, disease status and biosecurity of the nearest *epidemiological units* or other epidemiologically relevant premises. Consideration should be given to the distance and physical separation from:
 - i) *flocks* or *herds* with a different health status in close proximity to the *compartment*, including wildlife and their migratory routes;
 - ii) *slaughterhouses*, rendering plants or feed mills;
 - iii) *markets*, fairs, agricultural shows, sporting events, zoos, circuses and other points of animal concentration.

2. Infrastructural factors

Structural aspects of the *establishments* within a *compartment* contribute to the effectiveness of its biosecurity. Consideration should be given to:

- a) fencing or other effective means of physical separation;
- b) facilities for people entry including access control, changing area and showers;
- c) *vehicle* access including washing and *disinfection* procedures;
- d) *unloading* and *loading* facilities;
- e) isolation facilities for introduced *animals*;
- f) facilities for the introduction of material and equipment;
- g) infrastructure to store feed and veterinary products;
- h) disposal of carcasses, manure and waste;
- i) water supply;
- j) measures to prevent exposure to living mechanical or biological vectors such as insects, rodents and wild birds;
- k) air supply;
- l) feed supply/source.

More detailed recommendations for certain *establishments* can be found in Sections 4 and 6 of the *Terrestrial Code*.

3. Biosecurity plan

The integrity of the *compartment* relies on effective biosecurity. The management of the *compartment* should develop, implement and monitor a comprehensive *biosecurity plan*.

The *biosecurity plan* should describe in detail:

- a) potential pathways for introduction and spread into the *compartment* of the agents for which the *compartment* was defined, including animal movements, rodents, fauna, aerosols, arthropods, *vehicles*, people, biological products, equipment, fomites, feed, waterways, drainage or other means. Consideration should also be given to the survivability of the agent in the environment;
- b) the critical control points for each pathway;
- c) measures to mitigate exposure for each critical control point;
- d) standard operating procedures including:
 - i) implementation, maintenance, monitoring of the measures,
 - ii) application of corrective actions,
 - iii) verification of the process,
 - iv) record keeping;
- e) contingency plan in the event of a change in the level of exposure;
- f) reporting procedures to the *Veterinary Authority*;
- g) the programme for educating and training workers to ensure that all persons involved are knowledgeable and informed on biosecurity principles and practices;
- h) the *surveillance* programme in place.

In any case, sufficient evidence should be submitted to assess the efficacy of the *biosecurity plan* in accordance with the level of *risk* for each identified pathway. This evidence should be structured in line with the principles of Hazard Analysis and Critical Control Point (HACCP). The biosecurity risk of all operations of the *compartment* should be regularly re-assessed and documented at least on a yearly basis. Based on the outcome of the assessment, concrete and documented mitigation steps should be taken to reduce the likelihood of introduction of the disease agent into the *compartment*.

4. Traceability system

A prerequisite for assessing the integrity of a *compartment* is the existence of a valid *traceability* system. All *animals* within a *compartment* should be individually identified and registered in such a way that their history and movements can be documented and audited. In cases where individual identification may not be feasible, such as broilers and day-old chicks, the *Veterinary Authority* should provide sufficient assurance of *traceability*.

All animal movements into and out of the *compartment* should be recorded at the *compartment* level, and when needed, based on a *risk assessment*, certified by the *Veterinary Authority*. Movements within the *compartment* need not be certified but should be recorded at the *compartment* level.

Annex XII (contd)

Article 4.4.4.

Documentation

Documentation **must should** provide clear evidence that the biosecurity, *surveillance*, *traceability* and management practices defined for a *compartment* are effectively and consistently applied. In addition to animal movement information, the necessary documentation should include *herd* or *flock* production records, feed sources, *laboratory* tests, birth and *death* records, the visitor logbook, morbidity history, medication and vaccination records, *biosecurity plans*, training documentation and any other criteria necessary for the evaluation of *disease* exclusion.

The historical status of a *compartment* for the *disease(s)* for which it was defined should be documented and demonstrate compliance with the requirements for freedom in the relevant *Terrestrial Code* Chapter.

In addition, a *compartment* seeking recognition should submit to the *Veterinary Authority* a baseline animal health report indicating the presence or absence of OIE *listed diseases*. This report should be regularly updated to reflect the current animal health situation of the *compartment*.

Vaccination records including the type of vaccine and frequency of administration **must should** be available to enable interpretation of *surveillance* data.

The time period for which all records should be kept may vary according to the species and *disease(s)* for which the *compartment* was defined.

All relevant information **must should** be recorded in a transparent manner and be easily accessible so as to be auditable by the *Veterinary Authority*.

Article 4.4.5.

Surveillance for the agent or disease

The *surveillance* system should comply with Chapter 1.4. on Surveillance and the specific recommendations for *surveillance* for the *disease(s)* for which the *compartment* was defined, if available.

If there is an increased *risk* of exposure to the agent for which the *compartment* has been defined, the **detection level sensitivity** of the internal and external *surveillance system* should be reviewed and, where necessary, **raised increased**. At the same time, biosecurity measures in place should be reassessed and increased if necessary.

1. Internal surveillance

Surveillance should involve the collection and analysis of *disease/infection* data so that the *Veterinary Authority* can certify that the animal *subpopulation* contained in all the *establishments* comply with the defined status of that *compartment*. A *surveillance* system that is able to ensure early detection in the event that the agent enters a *subpopulation* is essential. Depending on the *disease(s)* for which the *compartment* was defined, different *surveillance* strategies may be applied to achieve the desired confidence in *disease* freedom.

2. External surveillance

The biosecurity measures applied in a *compartment* **must should** be appropriate to the level of exposure of the *compartment*. External *surveillance* will help identify a significant change in the level of exposure for the identified pathways for *disease* introduction into the *compartment*.

An appropriate combination of active and passive *surveillance* is necessary to achieve the goals described above. Based on the recommendations of Chapter 1.4., targeted *surveillance* based on an assessment of *risk* factors may be the most efficient *surveillance* approach. Targeted *surveillance* should in particular include *epidemiological units* in close proximity to the *compartment* or those that have a potential epidemiological link with it.

Article 4.4.6.

Diagnostic capabilities and procedures

Officially-designated *laboratory* facilities complying with the OIE standards for quality assurance, as defined in Chapter 1.1.3. of the *Terrestrial Manual*, should be available for sample testing. All *laboratory* tests and procedures should comply with the recommendations of the *laboratory* for the specific *disease*. Each *laboratory* that conducts testing should have systematic procedures in place for rapid reporting of *disease* results to the *Veterinary Authority*. Where appropriate, results should be confirmed by an OIE Reference Laboratory.

Article 4.4.7.

Emergency response and notification

Early detection, diagnosis and notification of *disease* are critical to minimize the consequences of *outbreaks*.

In the event of suspicion of occurrence of the *disease* for which the *compartment* was defined, ~~export certification~~ 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 Chapter 1.1.

In case of an occurrence of any infectious *disease* not present according to the baseline animal health report of the *compartment* referred to in Article 4.4.4., the management of the *compartment* should notify the *Veterinary Authority*, and initiate a review to determine whether there has been a breach in the biosecurity measures. If a significant breach in biosecurity, even in the absence of *outbreak*, is detected, export certification as a free *compartment* should be suspended. Disease free status of the *compartment* may only be reinstated after the *compartment* has adopted the necessary measures to re-establish the original biosecurity level and the *Veterinary Authority* re-approves the status of the *compartment*.

In the event of a *compartment* being at risk from a change, in the surrounding area, in the disease situation for which the *compartment* was defined, the *Veterinary Authority* should re-evaluate without delay the status of the *compartment* and ~~consider~~ 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*, ~~must~~ should be clearly documented in accordance with the Chapter on the Evaluation of *Veterinary Services* of the *Terrestrial Code*, to provide confidence in the integrity of the *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*.

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CHAPTER 4.56.

COLLECTION AND PROCESSING OF
BOVINE, SMALL RUMINANT AND PORCINE SEMEN

Article 4.56.1.

General considerations

The purposes of official sanitary control of semen production are to:

1. maintain the health of *animals* on an *artificial insemination centre* at a level which permits the international distribution of semen with a negligible *risk* of infecting other *animals* or humans with pathogens transmissible by semen;
2. ensure that semen is hygienically collected, processed and stored.

Artificial insemination centres should comply with recommendations in Chapter 4.65.

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

Article 4.56.2.

Conditions applicable to testing of bulls and teaser animals

Bulls and teaser animals should enter an *artificial insemination centre* only **if when** they fulfil the following requirements.

1. Pre quarantine Prior to entering pre-entry isolation facility

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

- a) Bovine brucellosis ~~—The animals should comply with~~ point 3 or 4 of Article 11.3.5.
- b) Bovine tuberculosis ~~—The animals should comply with~~ point 3 or 4 of Article 11.7.5.
- c) Bovine viral diarrhoea-mucosal disease (BVD-MD)

The *animals* should be subjected to ~~the following tests~~:

- i) a virus isolation test or a test for virus antigen, with negative results; **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 11.13.3.; or
 - ii) be subjected, with negative results, to a serological test for IBR/IPV on a blood sample.

Annex XIII (contd)

e) Bluetongue

The *animals* should comply with Articles 8.3.6., 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 ~~quarantine station~~ 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 ~~quarantine station~~ pre-entry isolation facility for at least 28 days. The *animals* should be ~~subjected to diagnostic tests~~ tested as described below a minimum of 21 days after entering the ~~quarantine station~~ pre-entry isolation facility, except for *Campylobacter fetus* subsp. *venerealis* and *Tritrichomonas foetus*, for which testing may commence after 7 days in ~~quarantine~~ pre-entry isolation. All the results should be negative except in the case of BVD-MD antibody serological testing (see point 2b)i) below).

a) Bovine brucellosis

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

b) BVD-MD

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

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

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

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

iv) If sero-conversion occurs, all the *animals* that remain seronegative should be kept in quarantine pre-entry isolation ~~over a prolonged time~~ until there is no more seroconversion in the group for a period of 3 weeks. Serologically positive *animals* may be allowed entry into the semen collection facilities.

c) *Campylobacter fetus* subsp. *venerealis*

i) *Animals* less than 6 months old or kept since that age only in a single sex group prior to quarantine pre-entry isolation should be tested once on a preputial specimen, with a negative result.

ii) *Animals* aged 6 months or older that could have had contact with females prior to quarantine 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 6 months old or kept since that age only in a single sex group prior to ~~quarantine~~ pre-entry isolation, should be tested once on a preputial specimen, with a negative result.
- ii) *Animals* aged 6 months or older that could have had contact with females prior to ~~quarantine~~ 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 ~~quarantine station~~ pre-entry isolation facility and the other *animals* of the same group should remain in ~~quarantine~~ 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 8.3.696., 8.3.7197. or 8.3.8118., depending on the bluetongue status of the country or zone where the pre-entry isolation facility semen collection centre is located of origin of the *animals*.

3. ~~Testing for BVD MD prior to the initial dispatch of semen from each serologically positive bull~~

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

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

~~Each aliquot of frozen semen should be tested as per Article 11.13.7.~~

5.3. 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 centre is facilities are located of origin is not free:

- a) Bovine brucellosis
- b) Bovine tuberculosis
- c) BVD-MD

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

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

Annex XIII (contd)d) *Campylobacter fetus* subsp. *venerealis*

- i) A preputial specimen should be cultured 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 6 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 Articles ~~8.3.6., 8.3.7. or 8.3.8~~11., ~~depending on the bluetongue status of the country of origin of the animals.~~

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 6 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 11.13.3.

4. Testing for BVD-MD prior to the initial dispatch of semen from each serologically positive bull

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

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

Each aliquot of frozen semen should be tested as per Article 11.13.7.

Article 4.56.3.

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. Pre quarantine Prior to entering pre-entry isolation facility

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

- a) Caprine and ovine brucellosis = ~~The animals should comply with~~ Article 14.1.6.
- b) Ovine epididymitis = ~~The animals should comply with~~ Article 14.7.3.

- c) Contagious agalactia = ~~The animals should comply with~~ points 1 and 2 of Article 14.3.1.
- d) Peste des petits ruminants = ~~The animals should comply with~~ points 1, 2, and 4 or 5 of Article 14.8.7.
- e) Contagious caprine pleuropneumonia = ~~The animals should comply with~~ Article 14.4.5. or Article 14.4.7., depending on the CCPP status of the country or zone of origin of the *animals*.
- f) Paratuberculosis = ~~The animals should be~~ free from clinical signs for the past 2 years.
- g) ~~Scrapie~~

~~If the animals do not originate from a scrapie free country or zone as defined in Article 14.9.3., the animals should comply with Article 14.9.6.~~

~~Hg) Maedi-visna = The animals should comply with Article 14.6.2.~~

~~Hh) Caprine arthritis/encephalitis = In the case of goats, the animals should comply with Article 14.2.2.~~

~~Ji) Bluetongue~~

~~The animals should comply with Articles 8.3.6., 8.3.7. or 8.3.8., depending on the bluetongue status of the country or zone of origin of the animals.~~

~~Kj) Tuberculosis = In the case of goats, the animals should be subject to a single or comparative tuberculin test, with negative results.~~

~~l) Border disease~~

~~The animals should be subject to a viral agent isolation test with negative results.~~

2. Testing in the ~~quarantine station~~ pre-entry isolation facility ~~station~~ 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 quarantine station pre-entry isolation facility for at least 28 days. The *animals* should be ~~subjected to diagnostic tests~~ tested as described below a minimum of 21 days after entering the quarantine station pre-entry isolation facility, with negative results.

- a) Caprine and ovine brucellosis = ~~The animals should be subject to testing as described in~~ point 1c) of Article 14.1.8.
- b) Ovine epididymitis = ~~The animals and semen should be subject to testing as described in~~ points 1d) and 2 of Article 14.7.4.
- c) Maedi-visna and caprine arthritis/encephalitis = ~~The animals and semen should be subjected to a serological test~~ for antibodies on animals and semen.
- d) Bluetongue

The *animals* should comply with the provisions referred to in Articles 8.3.696., 8.3.7107. or 8.3.8118., depending on the bluetongue status of the country or zone where the pre-entry isolation semen collection centre facility is located of origin of the *animals*.

Annex XIII (contd)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 ~~centre facilities is are~~ located of origin is not free:

- a) caprine and ovine brucellosis;
- b) ovine epididymitis;
- c) Maedi-visna and caprine arthritis/encephalitis;
- d) tuberculosis (for goats only);
- e) bluetongue

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

Article 4.56.4.

Conditions applicable to testing of boars

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

1. Pre quarantine 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 ~~quarantine station~~ pre-entry isolation facility where the country or zone of origin is not free from the diseases in question.

- a) Porcine brucellosis = ~~The animals should comply with~~ Article 15.4.3.
- b) Foot and mouth disease = ~~The animals should comply with~~ Articles 8.5.10., 8.5.11. or 8.5.12.
- c) Aujeszky's disease = ~~The animals should comply with~~ Article 8.2.8. or Article 8.2.9.
- d) ~~Teschovirus encephalomyelitis~~

~~The animals should comply with Article 15.6.4. or Article 15.6.6.~~

- e) Transmissible gastroenteritis = ~~The animals should comply with~~ Article 15.7.2.
- f) Swine vesicular disease = ~~The animals should comply with~~ Article 15.5.5. or Article 15.5.7.
- g) African swine fever = ~~The animals should comply with~~ Article 15.1.5. or Article 15.1.6.
- h) Classical swine fever = ~~The animals should comply with~~ Articles 15.3.5. or 15.3.6.
- i) Porcine reproductive and respiratory syndrome = ~~The animals should be subject to the test complying with the standards in the~~ *Terrestrial Manual*.

2. Testing in the ~~quarantine station~~ 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 ~~quarantine station~~ 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 ~~quarantine station~~ pre-entry isolation facility, with negative results.

- a) Porcine brucellosis = ~~The animals should comply with~~ Article 15.4.5.
- b) Foot and mouth disease = ~~The animals should comply with~~ Articles 8.5.13., 8.5.14., 8.5.15. or 8.5.16.
- c) Aujeszky's disease = ~~The animals should comply with~~ Articles 8.2.12., 8.2.13. or 8.2.14.
- d) ~~Teschevirus encephalomyelitis~~
~~The animals should comply with Article 15.6.8. or Article 15.6.9.~~
- e) ~~Transmissible gastroenteritis = The animals should comply with~~ Article 15.7.4.
- f) ~~Swine vesicular disease = The animals should comply with~~ Article 15.5.9. or Article 15.5.10.
- g) ~~African swine fever = The animals should comply with~~ Article 15.1.8. or Article 15.1.9.
- h) ~~Classical swine fever = The animals should comply with~~ Articles 15.3.8. or 15.3.9.
- i) ~~Porcine reproductive and respiratory syndrome = The animals should be subject to the test complying with~~ 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 ~~compartment/zone or~~ country ~~or zone where the semen collection facilities are located~~ is not free:

- a) Porcine brucellosis = ~~The animals should comply with~~ Article 15.4.5.
- b) Foot and mouth disease = ~~The animals should comply with~~ Articles 8.5.13., 8.5.14., 8.5.15. or 8.5.16.
- c) Aujeszky's disease = ~~The animals should comply with~~ Articles 8.2.12., 8.2.13. or 8.2.14. regarding testing every four months.
- d) ~~Teschevirus encephalomyelitis~~
~~The animals should comply with Article 15.6.8. or Article 15.6.9.~~
- e) ~~Transmissible gastroenteritis = The animals should comply with~~ Article 15.7.4.
- f) ~~Swine vesicular disease = The animals should comply with~~ Article 15.5.9. or Article 15.5.10.

Annex XIII (contd)

- Gf) African swine fever = ~~The animals should comply with~~ Article 15.1.8. or Article 15.1.9. Routine test to be applied at least every six months.
- Hg) Classical swine fever = ~~The animals should comply with~~ Articles 15.3.8. or 15.3.9.
- hh) Porcine reproductive and respiratory syndrome = ~~The animals should be subject to~~ the test complying with the standards in the *Terrestrial Manual*.

Article 4.56.5.

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 4.56.6.

Conditions applicable to the collection of semen

1. The floor of the mounting area should be **easy to clean and to disinfect** **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 animal should be sanitized after the collection of each ejaculate. Disposable plastic covers may be used.
3. The hand of the person collecting the semen 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 4.5.6.7.

Conditions applicable to the handling of semen and preparation of semen samples in the laboratory1. Diluents

- a) All receptacles used should have been sterilised.
- b) Buffer solutions employed in diluents prepared on the premises should be sterilized by filtration (0.22 µm) or by autoclaving (121°C for 30 minutes) or be prepared using sterile water before adding egg yolk (if applicable) or equivalent additive and antibiotics.
- c) If the constituents of a diluent are supplied in commercially available powder form, the water used **must should** have been distilled or demineralised, sterilized (121°C for 30 minutes or equivalent), stored correctly and allowed to cool before use.
- d) Whenever milk, egg yolk or any other animal protein is used in preparing the semen diluent, the product **must should** be free of pathogens or sterilised; milk heat-treated at 92°C for 35 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 **must should** also be sterilized before use.
- e) Diluent should not be stored for more than 72 hours at +5°C before use. A longer storage period is permissible for storage at -20°C. Storage vessels should be stoppered.
- f) A mixture of antibiotics should be included with a bactericidal activity at least equivalent to that of the following mixtures in each ml of frozen semen: gentamicin (250 µg), tylosin (50 µg), lincomycin-spectinomycin (150/300 µg); penicillin (500 IU), streptomycin (500 µg), lincomycin-spectinomycin (150/300 µg); or amikacin (75µg), divekacin (25µg).

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

2. Procedure for dilution and packing

- a) The tube containing freshly collected semen should be sealed as soon as possible after collection, and kept sealed until processed.
- b) After dilution and during refrigeration, the semen should also be kept in a stoppered container.
- c) During the course of filling receptacles for dispatch (such as insemination straws), the receptacles and other disposable items should be used immediately after being unpacked. Materials for repeated use should be disinfected with alcohol, ethylene oxide, steam or other approved *disinfection* techniques.
- d) If sealing powder is used, care should be taken to avoid its being contaminated.

3. Conditions applicable to the storage of semen

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

Annex XIII (contd)

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

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

4. Sperm sorting

Equipment used for sex-sorting sperm should be clean and disinfected between *animals* according to the ~~manufacturer's~~ recommendations of the licensor of the system.

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

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1. The ICAR international standards on straws are contained in *Recording Guidelines* - Appendices to the international agreement of recording practices.

The text of this document is available at the following web site: www.icar.org

CHAPTER 4.65.

GENERAL HYGIENE IN SEMEN COLLECTION AND PROCESSING CENTRES

Article 4.65.1.

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 bacteria which are potentially pathogenic.

Article 4.65.2.

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 quarantine station a pre-entry isolation facility which is not compulsory in case of horses may also be attached to either situated on the same premises as a), b) and c) above but isolated from the aforementioned, or be established at a different site to the centre, provided that it is on a different location from that of those two first parts.
- ~~2.~~ The centre should be officially approved by the Veterinary Authority.
- ~~3.~~ 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 6 months, of protocols, procedures and prescribed records on the health and welfare of the animals in the centre and on the hygienic production, storage and dispatch of semen.
- ~~42.~~ The centre should be under the direct supervision and control of an Official centre ~~by~~ Veterinarian.
- ~~53.~~ Only swine 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 ~~the swine~~ these animals.
- ~~64.~~ Swine 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.
75. The entry of visitors should be strictly controlled. Personnel at a centre should be technically competent and observe high standards of personal hygiene to preclude the introduction of pathogenic organisms. Protective clothing and footwear for use only on the centre should be provided.
86. Individual semen containers and storage rooms should be capable of being disinfected.

Annex XIII (contd)

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 6 months, of protocols, procedures and prescribed records on the health and welfare of the animals in the centre and on the hygienic production, storage and dispatch of semen.

Article 4.65.3.

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 ~~must~~ should meet the minimum health requirements for donors.
3. The donors and teasers should be adequately isolated to prevent the transmission of *diseases* from farm livestock and other *animals*. Measures should be in place to prevent the entry of wild *animals* susceptible to ruminant and swine *diseases* transmissible via semen.
4. Personnel at the centre should be technically competent and observe high standards of personal hygiene to preclude the introduction of pathogenic organisms. Special protective clothing and footwear for use only at the semen collection facilities should be provided and worn at all times inside.
5. Visitors to the semen collection facilities should be kept to a minimum, and visits should be subject to formal authorisation and control. Equipment for use with the livestock should be dedicated to the semen collection facilities or disinfected prior to entry. All equipment and tools brought on to the premises ~~must~~ 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 ~~and semen collection areas~~ should be kept ~~cleaned~~ and disinfected at least once a year.
8. Fodder introduction and manure removal should be done in a manner which poses no significant animal health risk.

Article 4.65.4.

Conditions applicable to semen laboratories

1. The semen laboratory should be physically separated from the semen collection facilities, and include separate areas for artificial vagina cleaning and preparation, semen evaluation and processing, semen pre-storage and storage. Entry to the laboratory should be prohibited to unauthorised personnel.

2. The laboratory personnel should be technically competent and observe high standards of personal hygiene to preclude the introduction of pathogenic organisms during semen evaluation, processing and storage.
3. Visitors to the laboratory should be kept to a minimum, and visits should be subject to formal authorisation and control.
4. The laboratory should be constructed with materials that permit effective cleaning and *disinfection*.
5. The laboratory should be regularly cleaned. Work surfaces for semen evaluation and processing should be cleaned and disinfected at the end of each workday.
6. The laboratory should be treated against rodents and insects on a regular basis as needed to control these pests.
7. The storage rooms and individual semen containers should be easy to clean and disinfect.
8. Only semen collected from donors having a health status equivalent to or better than the donors at the semen collection facilities should be processed in the laboratory.

Article 4.65.5.

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 ~~must~~ should be kept clean and renewed as often as necessary.
2. The coat of the *animal* should be kept clean.
3. For bulls, ~~the length of~~ the tuft of hairs at the preputial orifice, which is ~~invariably~~ 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 ~~must~~ 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, ~~for such materials are always heavily contaminated.~~

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CHAPTER 4.7.

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

Article 4.7.1.

Aims of control

The purpose of official sanitary control of *in vivo* derived embryos intended for movement internationally is to ensure that specific pathogenic organisms, which could be associated with embryos, are controlled and transmission of *infection* to recipient animals and progeny is avoided.

Article 4.7.2.

Conditions applicable to the embryo collection team

The embryo collection team is a group of competent technicians, including at least one *veterinarian*, to perform the collection, processing and storage of embryos. The following conditions should apply:

1. The team should be approved by the *Competent Authority*.
- ~~2~~. The team should be supervised by a team *veterinarian*.
- ~~3~~. The team *veterinarian* is responsible for all team operations which include verification of donor health status, sanitary handling and surgery of donors and *disinfection* and hygienic procedures.
- ~~4~~. ~~The team *veterinarian* should be specifically approved for this purpose.~~
- ~~5~~. 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*.
- ~~6~~. 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.

- ~~7~~. 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 2 years after the embryos have been exported.
- ~~8~~. 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.

Annex XIII (contd)

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 animals1. Donor animals

- a) The *Veterinary Authority* should have knowledge of, and authority over, the *herd/ flock* from which the donor animals have been sourced.
- b) The donor animals should not be situated in a *herd/ flock* subject to veterinary restrictions for OIE *listed disease* or pathogens for relevant species (see Chapter 1.2. of the *Terrestrial Code*), other than those that are in IETS Category 1 for the species of embryos being collected (see Article 4.7.14., and footnote¹).
- c) At the time of collection, the donor animals should be clinically inspected by the team *veterinarian*, or by a *veterinarian* responsible to the team *veterinarian* and certified to be free of clinical signs of *diseases*.

2. Semen donors

- a) Semen used to inseminate donor animals artificially should have been produced and processed in accordance with the provisions of Chapter 4.56.

- 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 ~~subject~~ an aliquot of semen from the same collection date ~~to testing~~.
- c) Where natural service or fresh semen is used, donor sires should meet the health conditions set out in Chapter 4.56, 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 categorisation¹ (Article 4.7.14.), comprises the risk potential for embryo contamination and depends on:
 - a) the disease situation in the *exporting country* and/or *zone*;
 - b) the health status of the *herds/flocks* and the donors from which the embryos are collected;
 - c) the pathogenic characteristics of the specified disease agents that are of concern to the *Veterinary Authority* of the *importing country*.
2. The second phase covers risk mitigation by use of internationally accepted procedures for processing of embryos which are set out in the IETS Manual². These include the following:
 - a) The embryos must should be washed at least ten times with at least 100-fold dilutions between each wash, and a fresh pipette must should be used for transferring the embryos through each wash.
 - b) Only embryos from the same donor should be washed together, and no more than ten embryos should be washed at any one time.
 - c) Sometimes, for example when inactivation or removal of certain viruses (e.g. bovine herpesvirus-1, and Aujeszky's disease virus) is required, the standard washing procedure should be modified to include additional washes with the enzyme trypsin, as described in the IETS Manual².
 - d) The zona pellucida of each embryo, after washing, must should be examined over its entire surface area at not less than 50X magnification to ensure that it is intact and free of adherent material.

[NOTE: All shipments of embryos must 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:

Annex XIII (contd)

- a) post-collection *surveillance* of the donors and donor *herd/ flock* based on the recognized *incubation periods* of the *diseases* of concern to determine retrospectively the health status of donors whilst the embryos are stored (in species where effective storage by cryopreservation is possible) in the *exporting country*;
- b) testing of embryo-collection (flushing) fluids and non-viable embryos, or other samples such as blood, in a laboratory for presence of specified disease agents.

Article 4.7.6.

Conditions applicable to the collection and storage of embryos

1. Media

Any biological product of animal origin used in the media and solutions for collection, processing, washing or storage of embryos should be free of pathogenic micro-organisms. Media and solutions used in the collection and storage of embryos should be sterilized by approved methods according to the IETS Manual² 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 Manual².

2. Equipment

- a) All equipment used to collect, handle, wash, freeze and store embryos should ideally be new or at least sterilized prior to use as recommended in the IETS Manual².
- b) Used equipment should not be transferred between countries for re-use by the embryo collection team.

Article 4.7.7.

Optional tests and treatments

1. The testing of samples can be requested by an *importing country* to confirm the absence of pathogenic organisms that may be transmitted via *in vivo* derived embryos, or to help assess whether the degree of quality control of the collection team (with regard to adherence to procedures as described in the IETS Manual²) is at an acceptable level. Samples may include:

- a) Non-viable embryos/oocytes

Where the viable, zona pellucida intact embryos from a donor are intended for export, all non-fertilized oocytes and degenerated or zona pellucida compromised embryos collected from that donor should be washed according to the IETS Manual² and pooled for testing if requested by the *importing country*. Non-viable embryos/oocytes from the donor should be processed and stored together.

- b) Embryo collection (flushing) fluids

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

c) Washing fluids

The last four washes of the embryos/oocytes should be pooled (IETS Manual²).

d) Samples

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

2. When treatment of the viable embryos is modified to include additional washings with the enzyme trypsin (see paragraph 2c) in Article 4.7.5.), the procedure should be carried out according to the IETS Manual². Enzyme treatment is necessary only when pathogens for which the IETS recommends this additional treatment (such as with trypsin) may be present. It should be noted that such treatment is not necessarily always beneficial and it should not be regarded as a general disinfectant. It may also have adverse effects on embryo viability, for instance in the case of equine embryos where the embryonic capsule could be damaged by the enzyme.

Article 4.7.8.

Conditions applicable to the storage and transport of embryos

1. The embryos for export should be stored in sealed sterile ampoules, vials or straws under strict hygienic conditions at a storage place approved by the *Veterinary Authority* of the *exporting country* where there is no risk of contamination of the embryos.
2. Only embryos from the same individual donor should be stored together in the same ampoule, vial or straw.
3. The embryos should if possible, depending on the species, be frozen, stored with fresh liquid nitrogen in cleaned and sterilized tanks or containers under strict hygienic conditions at the approved storage place.
4. Ampoules, vials or straws should be sealed at the time of freezing (or prior to export where cryopreservation is not possible), and they should be clearly identified by labels according to the standardised system recommended in the IETS Manual².
5. Liquid nitrogen containers should be sealed under the supervision of the *Official Veterinarian* prior to shipment from the *exporting country*.
6. Embryos **must should** not be exported until the appropriate veterinary certificates are completed.

Article 4.7.9.

Procedure for micromanipulation

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

Article 4.7.10.

Specific conditions applicable to porcine embryos

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

Annex XIII (contd)

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

Article 4.7.11.

Specific conditions/comments applicable to equine embryos

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

Article 4.7.12.

Specific conditions/comments applicable to camelid embryos

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

Article 4.7.13.

Specific conditions/comments applicable to cervid embryos

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

Article 4.7.14.

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

The IETS has categorised¹ the following *diseases* and pathogenic agents into four categories, which applies only to *in vivo* derived embryos.

1. Category 1

- a) Category 1 *diseases* or pathogenic agents are those for which sufficient evidence has accrued to show that the risk of transmission is negligible provided that the embryos are properly handled between collection and transfer according to the IETS Manual².
- b) The following *diseases* or pathogenic agents are in category 1:
 - Aujeszky's disease (pseudorabies) (swine): trypsin treatment required
 - Bluetongue (cattle)
 - Bovine spongiform encephalopathy (cattle)

- *Brucella abortus* (cattle)
- Enzootic bovine leukosis
- Foot and mouth disease (cattle)
- Infectious bovine rhinotracheitis: trypsin treatment required.

▪ Scrapie (sheep).

2. Category 2

a) Category 2 *diseases* are those for which substantial evidence has accrued to show that the risk of transmission is negligible provided that the embryos are properly handled between collection and transfer according to the IETS Manual², but for which additional transfers are required to verify existing data. pathogenic agents are in category 2:

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

▪ Scrapie (sheep).

3. Category 3

a) Category 3 *diseases* or pathogenic agents are those for which preliminary evidence indicates that the risk of transmission is negligible provided that the embryos are properly handled between collection and transfer according to the IETS Manual², but for which additional *in vitro* and *in vivo* experimental data are required to substantiate the preliminary findings.

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

- Bovine immunodeficiency virus
- Bovine spongiform encephalopathy (goats)
- Bovine viral diarrhea virus (cattle)
- *Campylobacter fetus* (sheep)
- Foot and mouth disease (swine, sheep and goats)
- *Haemophilus somnus* (cattle)
- Maedi-visna (sheep)
- *Mycobacterium paratuberculosis* (cattle)
- *Neospora caninum* (cattle)
- Ovine pulmonary adenomatosis
- Porcine reproductive and respiratory disease syndrome (PRRS)
- Rinderpest (cattle)
- Swine vesicular disease.

Annex XIII (contd)4. Category 4

- a) Category 4 *diseases* or pathogenic agents are those for which studies have been done, or are in progress, that indicate:
- i) that no conclusions are yet possible with regard to the level of transmission risk; or
 - ii) the risk of transmission via embryo transfer might not be negligible even if the embryos are properly handled according to the IETS Manual² between collection and transfer.
- b) The following *diseases* or pathogenic agents are in category 4:
- African swine fever
 - Akabane (cattle)
 - Bovine anaplasmosis
 - Bluetongue (goats)
 - Border disease (sheep)
 - Bovine herpesvirus-4
 - *Chlamydia psittaci* (cattle, sheep)
 - Contagious equine metritis
 - Enterovirus (cattle, swine)
 - Equine rhinopneumonitis
 - *Escherichia coli* 09:K99 (cattle)
 - *Leptospira borgpetersenii* serovar *hardjobovis* (cattle)
 - *Leptospira* sp. (swine)
 - Lumpy skin disease
 - *Mycobacterium bovis* (cattle)
 - *Mycoplasma* spp. (swine)
 - Ovine epididymitis (*Brucella ovis*)
 - Parainfluenza-3 virus (cattle)
 - Parvovirus (swine)
 - Porcine circovirus (type 2) (pigs)

- Scrapie (goats)
- *Tritrichomonas foetus* (cattle)
- *Ureaplasma/Mycoplasma* spp. (cattle, goats)
- Vesicular stomatitis (cattle, swine).

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- ¹ Based on available research and field information, the Research Subcommittee of the Health and Safety Advisory Committee (HASAC) of the International Embryo Transfer Society (IETS) has categorised some diseases based on their relative risk of dissemination by properly processed and handled *in vivo* derived embryos. This Chapter that contains the complete list of IETS categorised diseases is shown in Article 4.7.14.
- ² Manual of the International Embryo Transfer Society.

CHAPTER 4.8.

COLLECTION AND PROCESSING OF IN VITRO PRODUCED EMBRYOS / OOCYTES FROM LIVESTOCK AND HORSES

Article 4.8.1.

Aims of control

Production of embryos *in vitro* involves the collection of oocytes from the ovaries of donors, *in vitro* maturation and fertilization of the oocytes, then *in vitro* culture to the morula/blastocyst stage at which they are ready for transfer into recipients. The purpose of official sanitary control of *in vitro* produced embryos intended for movement internationally is to ensure that specific pathogenic organisms, which could be associated with such embryos, are controlled and transmission of *infection* to recipient animals and progeny is avoided. The conditions outlined in this chapter are also applicable where the movement of *in vitro* maturing (IVM) oocytes is intended.

Article 4.8.2.

Conditions applicable to the embryo production team

The embryo production team is a group of competent technicians, including at least one *veterinarian*, to perform the collection and processing of ovaries/oocytes and the production and storage of *in vitro* produced embryos. The following conditions should apply:

1. The team should be approved by the *Competent Authority*.
- ~~2.~~ The team should be supervised by a team *veterinarian*.
- ~~2.~~ 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.
- ~~3.~~ ~~The team *veterinarian* should be specifically approved for this purpose.~~
- ~~4.~~ Team personnel should be adequately trained in the techniques and principles of disease control. High standards of hygiene should be practised to preclude the introduction of *infection*.
- ~~5.~~ The production team should have adequate facilities and equipment for:
 - a) collecting ovaries and/or oocytes;
 - b) processing of oocytes and production of embryos at a permanent ~~site~~ or mobile laboratory;
 - c) storing oocytes and/or embryos.

These facilities need not necessarily be at the same location.

Annex XIII (contd)

676. The embryo production team should keep a record of its activities, which should be maintained for inspection by the *Veterinary Authority* for a period of at least 2 years after the embryos have been exported.

787. The embryo production team should be subjected to regular inspection at least once a year by an *Official Veterinarian* to ensure compliance with procedures for the sanitary collection and processing of oocytes and the production and storage of embryos.

Article 4.8.3.

Conditions applicable to the processing laboratories

A processing laboratory used by the embryo production team may be mobile or permanent. It may be contiguous with the oocyte recovery area or at a separate location. It is a facility in which oocytes which have been recovered from ovaries are then matured and fertilised, and where the resulting embryos are further cultured *in vitro*.

Embryos may also be subjected to any required treatments such as washing and storage and quarantine in this laboratory.

Additionally:

1. The laboratory should be under the direct supervision of the team *veterinarian* and regularly inspected by an *Official Veterinarian*.
2. While embryos for export are being produced prior to their storage in ampoules, vials or straws, no oocyte/embryo of a lesser health status should be recovered or processed in the same laboratory.
3. The laboratory should be protected against rodents and insects.
4. The processing laboratory should be constructed with materials which permit its effective cleansing and *disinfection*. This should be done frequently and always before and after each occasion when embryos for export are processed.

Article 4.8.4.

Conditions applicable to donor animals

Oocytes for the *in vitro* production of embryos are obtained from donors basically in two different ways: individual collection or batch collection. The recommended conditions for these differ.

Individual collection usually involves the aspiration of oocytes from the ovaries of individual live *animals* on the farm where the *animal* resides, or at the laboratory. Occasionally oocytes may also be recovered from individual live donors by aspiration from surgically excised ovaries. When oocytes are recovered from individual live *animals*, the conditions for these donors should resemble those set out in Article 4.7.4.

In these cases the cleaning and sterilisation of equipment (e.g. ultrasound guided probes) is especially important and **must should** be carried out between each donor in accordance with the recommendations in the Manual of the International Embryo Transfer Society (IETS)¹.

Batch collection involves the removal of ovaries from batches of donors slaughtered at a slaughterhouse/ *abattoir* (hereafter '*abattoir*'); these ovaries are then transported to the processing laboratory where the oocytes are recovered from the ovarian follicles by aspiration. Batch collection has the disadvantage that it is usually impractical to relate the ovaries which are transported to the laboratory to the donors which were slaughtered at the *abattoir*. Nevertheless, it is critical to ensure that only healthy tissues are obtained and that they are removed from the donors and transported to the laboratory in a hygienic manner.

Additionally:

1. The *Veterinary Authority* should have knowledge of, ~~and authority over,~~ the *herd(s)/ flock(s)* from which the donor animals have been sourced.
2. The donor animals should not originate from *herds / flocks* ~~which that~~ are subject to veterinary restrictions for listed diseases of concern (under study) foot and mouth disease, rinderpest and peste des petits ruminants, and neither should the removal of any tissue or aspiration of oocytes take place in an *infected zone*, or one that is subject to veterinary restrictions for listed diseases of concern (under study) those diseases.
3. In the case of oocyte recovery from live donors, post-collection *surveillance* of the donors and donor *herd(s) / flock(s)* should be conducted based on the recognized *incubation periods* of the *diseases* of concern to determine retrospectively the health status of donors.
4. In the case of oocyte recovery from batches of ovaries collected from an *abattoir*, the *abattoir* should be officially approved and under the supervision of a *veterinarian* whose responsibility is to ensure that ante-mortem and post-mortem inspections of potential donor animals are carried out, and to certify them to be free of clinical or pathological signs of infectious the diseases (under study) listed in point 2 above.
5. Donor animals slaughtered at an *abattoir* should not have been designated for compulsory *slaughter* for a *notifiable disease* and should not be slaughtered at the same time as donors from which ovaries and other tissues will be removed.
6. Batches of ovaries and other tissues collected from an *abattoir* should not be transported to the processing laboratory before confirmation has been obtained that ante- and post-mortem inspection of donors has been satisfactorily completed.
7. Equipment for the removal and transport of ovaries and other tissues should be cleaned and sterilised before use and exclusively used for these purposes.
8. Records of the identities and origins of all donors should be maintained for inspection by the *Veterinary Authority* for a period of at least 2 years after the embryos have been exported. While this may be difficult to achieve in the case of batch collection, it is to be expected that the identities of the *herds/ flocks* from which the donors originated will be maintained.

Article 4.8.5.

Optional tests and treatments

~~The main~~ A supplementary approach for ensuring that *in vitro* produced embryos do not transmit *disease* is by testing various materials to confirm the absence of pathogenic organisms listed in point 2 of Article 4.8.4, which that are of concern to the importing country.

Tests may also be used to assess whether quality control procedures being applied in the processing laboratory are of an acceptable standard.

Annex XIII (contd)

Tests may be carried out on the following materials:

- a) non-viable oocytes/embryos from any stage of the *in vitro* production line from batches intended for export;
- b) samples of *in vitro* maturation medium taken prior to mixing the oocytes with semen for the fertilisation process;
- c) samples of embryo culture medium taken immediately prior to embryo storage.

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

Additionally:

1. Semen used to fertilise oocytes *in vitro* should meet the health requirements and standards set out in Chapter 4.56, as appropriate to the species.

When the donor of the semen used to fertilise the oocytes is ~~no longer living~~ dead, and when the health status of the semen donor concerning a particular infectious *disease* or *diseases* of concern was not known at the time of semen collection, additional tests on the spare embryos may be required to verify that these infectious *diseases* were not transmitted. An alternative may be to test an aliquot of semen from the same collection date.

2. Any biological product of animal origin, including co-culture cells and media constituents, used in oocyte recovery, maturation, fertilisation, culture, washing and storage should be free of living pathogens. Media should be sterilised prior to use by approved methods according to the IETS 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.
3. All equipment used to recover, handle, culture, wash, freeze and store oocytes/embryos should be new or cleaned and sterilised prior to use as recommended in the IETS Manual¹.

Article 4.8.6.

Risk management

With regard to disease transmission, transfer of *in vitro* produced embryos is a low risk method for moving animal genetic material although the risk is not quite as low as for *in vivo* derived embryos. It should be noted that categorisation of *diseases*/disease agents by the IETS, as described for *in vivo* derived embryos in Article 4.7.14., does not apply in the case of *in vitro* produced embryos. Irrespective of the animal species, there are three phases in the embryo production and transfer process that determine the final level of risk. These are as follows:

1. the first phase comprises the risk potential for ovary/oocyte/embryo contamination and depends on:
 - a) the disease situation in the *exporting country* and/or *zone*;
 - b) the health status of the *herds/flocks* and the donors from which the ovaries/oocytes/embryos are collected;
 - c) the pathogenic characteristics of the specified disease agents listed in point 2 of Article 4.8.4. (under study) that are of concern to the Veterinary Authority of the importing country;

2. the second phase covers risk mitigation by the use of internationally accepted procedures for the processing of embryos which are set out in the IETS Manual¹. These include the following:
 - a) after the *in vitro* culture period is finished the embryos should be washed at least ten times with at least 100-fold dilutions between each wash, and a fresh pipette should be used for transferring the embryos through each wash;
 - b) only embryos from the same donor (in the case of individual collection) or from the same batch (in the case of batch collection) should be washed together, and no more than ten embryos should be washed at any one time;
 - c) sometimes, for example when inactivation or removal of certain viruses (e.g. bovine herpesvirus-1, or Aujeszky's disease virus) is required, the standard washing procedure should be modified to include additional washes with the enzyme trypsin, as described in the IETS Manual¹;
 - d) the zona pellucida of each embryo, after washing, should be examined over its entire surface area at not less than 50X magnification to ensure that it is intact and free of adherent material;
3. the third phase, which is applicable to *diseases listed in point 2 of Article 4.8.4. (under study) 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 *herds/ flocks* based on the recognised *incubation periods* of the *diseases* of concern to determine retrospectively the health status of the donors whilst the embryos are stored (in species where effective storage by cryopreservation is possible) in the *exporting country*. Post-collection *surveillance* of donors is not, of course, possible in the case of batch collection from an *abattoir*, although *surveillance* of the *herds/ flocks* of origin may be possible;
 - b) testing of oocytes/embryos, co-culture cells, media and other samples (e.g. blood) (as referred to in Article 4.8.4.) in a laboratory for presence of disease agents.

Article 4.8.7.

Conditions applicable to the storage and transport of embryos

1. Only embryos from the same individual donor or from the same batch collection should be stored together in the same ampoule, vial or straw.
2. The embryos should if possible, depending on the species, be frozen in fresh liquid nitrogen or other cryoprotectant and then stored in fresh cryoprotectant in cleaned and sterilised tanks or containers under strict hygienic conditions at a storage place.
3. Ampoules, vials or straws **must should** be sealed at the time of freezing and should be labelled according to the IETS Manual¹.
4. Liquid nitrogen containers should be sealed prior to shipment from the *exporting country*.
5. Embryos **must should** not be exported until the appropriate veterinary certificates are completed.

Annex XIII (contd)

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.

— text deleted

¹ Manual of the International Embryo Transfer Society.

CHAPTER 4.10.

COLLECTION AND PROCESSING OF LABORATORY
RODENT AND RABBIT EMBRYOS / OVA

Article 4.10.1.

Conditions applicable to the maintenance of laboratory animal colonies

Maintenance of laboratory animal colonies of specific genotypes requires intensive breeding management within specialised premises. They may be kept in a gnotobiotic environment, in either a 'germfree' system or a 'barrier' room (usually with defined flora), in a conventional colony, or under undefined conditions. In both the germfree and barrier systems, the animals are raised in a controlled environment according to protocols that attempt to eliminate potential sources of microbiological contamination. The primary difference is that the barrier maintained animals have been inoculated with known (defined) microbes¹ using a cocktail of non-pathogenic flora, whereas germfree animals are kept free from both pathogenic and non-pathogenic microbes.

A second category is where laboratory animals are kept in closed, conventional colonies within which known pathogens may exist. Here, less rigid colony management protocols are used to control potential sources of contamination, but implementation of simple aseptic precautions (e.g. autoclaving of feed and bedding) should allow animals to be maintained in a microbiologically defined system. Finally, laboratory animals may live in environments with undefined microbiological conditions (e.g. non-restricted colonies, free-ranging animals).

Disease testing and donor animal/embryo handling requirements can therefore be considered as being of three distinct types, depending on the type of colony being dealt with, i.e. defined floral, conventional and undefined. The health status of all colonies should be confirmed quarterly by bacteriological, virological, parasitological, serological and immunohistochemical tests on pre-designated sentinel animals or other representative animals of the colony (e.g. older breeding males which have sired multiple litters).

Microbial status of laboratory animal colonies

Colonies of the various species and genotypes of laboratory animals are usually kept within specialised premises and their microbial status depends largely on the system whereby the colony was formed and is maintained. In this Chapter the microbial status of colonies is considered to be of three main types: 'defined', 'conventional' and 'undefined'. Colonies of defined status are those where, at least initially, the animals are totally free of pathogenic and non-pathogenic micro-organisms (i.e. gnotobiotic), although sometimes a cocktail of known, non-pathogenic micro-organisms has been given subsequently. In either case defined colonies are kept in highly controlled environments in barrier maintained rooms, with strict protocols in place to exclude all potential sources of unwanted microbiological contamination. Colonies of conventional status are those where the animals are kept in closed colonies but where known ('specific') pathogens as well as non-pathogenic micro-organisms may exist. While management protocols for conventional colonies may be less rigid than those for defined colonies, they are designed to control potential sources of microbial contamination. Simple aseptic precautions (e.g. the autoclaving of food and bedding) are taken to ensure that the animals do not become infected with any unwanted microflora. Finally, laboratory animals may be kept in microbiologically undefined colonies which are unrestricted and may include free ranging animals. Details of these different types of colony can be found in the FELASA Report¹.

Annex XIII (contd)

The health status of defined and conventional colonies should be confirmed at least quarterly by bacteriological, virological, parasitological, serological and other tests on pre-designated sentinel animals or other representative members of the colony. Older breeding males which have sired multiple litters are often selected for this purpose.

The purpose of official sanitary control of laboratory rodent and rabbit embryos intended for movement internationally is to ensure that specific pathogenic micro-organisms, which could be associated with such embryos, are controlled and transmission of *infection* to recipient animals, progeny and colonies, is avoided. Requirements for the management of donors and processing of embryos vary depending on the microbial status of the colony, i.e. whether it is defined (including gnotobiotic), conventional, or undefined.

Article 4.10.2.

Conditions applicable to the embryo production collection team/~~laboratory~~

The embryo collection team is a group of competent technicians including at least one experienced professional to perform the collection, processing and storage of embryos/oocytes.

The following conditions should apply:

1. ~~The embryo production team must~~ should be composed of competent technicians supervised by an experienced embryologist team professional holding a graduate academic degree (e.g. M.S., Ph.D., D.V.M.).
2. The team professional is responsible for all team operations which include verification of colony and donor health status, sanitary handling and surgery of donors, *disinfection* and hygienic procedures. The team professional should be responsible to the institute *veterinarian*.
3. The institute *veterinarian* should be certified or accredited in laboratory animal care and should be specifically *approved* for the purpose of embryo collection for export. It is the responsibility of the institute *veterinarian* to ensure that required health profiling procedures appropriate for the colony status are implemented. He/she is responsible for certifying that the embryo handling procedures and laboratory facilities conform to the requirements laid down in this Chapter.
24. Team personnel should be *adequately* trained in the techniques and principles of *disease* control and in the use of aseptic techniques in embryo handling. Laboratory sanitary procedures must conform with requirements in the IETS Manual²The zoonotic potential of specific pathogens affecting the various laboratory animal species should be identified and understood so as to avoid contamination of colonies via human vectors, and vice versa.
35. ~~The embryo production team must~~ should use all necessary precautions to protect the animals, animal facilities, laboratory and equipment against microbiological contamination. In particular, the zoonotic potential of specific pathogens should be identified and understood by staff members to avoid contamination of colonies via human vectors, or vice versa 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 laboratory facilities especially after ~~their exposure~~ 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 site or mobile laboratory;
 - c) storing embryos.
4. Proper records must ~~should~~ be maintained for inspection by the chief embryologist (i.e. supervisor).
- Until standardised record sheets are developed for laboratory animals, it is the responsibility of each laboratory to maintain complete animal and embryo records (i.e. embryo collection, cryopreservation data). Information of the type shown in standard IETS record sheets² for livestock species should be incorporated, where applicable, and data such as embryo quality grading system, morphological stage at cryopreservation and genotypic identification of the donors should be clearly given in the records.
- 5.7. It is the responsibility of the chief embryologist (i.e. laboratory supervisor) ~~institute veterinarian~~ to ensure that the complete animal and embryos are properly stored in sterile, sealed containers (e.g. ampoules or straws) records, including records of collection, processing and storage of embryos are maintained. In addition, the containers must be correctly identified using a standard format which includes embryo species/genotype, cryopreservation date, number and stage of embryos, container number and indication of any specialised procedure (e.g. *in vitro* fertilisation, micromanipulation) or condition (e.g. germfree, microbiologically defined). 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. If appropriate ~~the embryo collection team should keep a record of its activities which should be maintained for inspection by the Veterinary Authority for at least 2 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, preferably annually, by an Official Veterinarian to ensure compliance with procedures for the sanitary collection, processing and storage of embryos.

Article 4.10.2bis.

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 4.10.2tris.**Risk management**

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

1. The first phase comprises the risk potential for embryo contamination and depends on:
 - a) the disease situation in the exporting country and/or zone
 - b) the microbial status of the colony (i.e. defined, conventional or undefined) and the donors from which the embryos are collected;
 - c) the pathogenic characteristics of the specified disease agents that are of concern to the Veterinary Authority of the importing country.
2. The second phase covers risk mitigation by use of internationally accepted procedures for processing of embryos which are set out in the IETS 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 recognized incubation periods of the diseases of concern to determine retrospectively the health status of the colony whilst the embryos are stored (in species where effective storage by cryopreservation is possible) in the exporting country.
 - b) post-mortem testing of the donor(s) or other samples such as blood, embryo-collection (flushing) fluids and non-viable embryos, in a laboratory for presence of specified disease agents

Article 4.10.3.

Conditions applicable to the embryo team/institute veterinarian

1. ~~The veterinarian, certified in laboratory animal care or laboratory animal accredited, must ensure that the required colony health profiling procedures are implemented, and the results are reviewed and properly recorded before shipment of embryos. He/she is also responsible for confirming that proper animal management/sanitation conditions have been maintained.~~ 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 ~~the IETS Manual~~ Articles 4.10.2. and 4.10.2bis.
3. ~~The veterinarian must supervise all quarantine practices to protect against unwanted contamination and spread of disease, and to ensure that valid results are generated.~~ is responsible for the risk management procedures outlined in Article 4.10.2tris.
4. The veterinarian ~~must~~ should authorise all embryo shipments, ensuring that the correct embryo collection records and veterinary certification documents ~~and embryo collection records are~~ have been completed and are included in the shipments.

Article 4.10.4.

Test programmes for donor animals

~~Sentinel animals in each donor colony should be subjected to routine monthly microbial screening. Testing for specific pathogens is species dependent and will undoubtedly also be influenced by geographic location. Recommendations regarding specific microbial agents to be tested for in mice, rats, cotton rats, hamsters, guinea pigs, gerbils and rabbits have been published elsewhere².~~

Article 4.10.5.

Conditions applicable to ~~the embryo/animal handling~~ donors from animal colonies of different microbial status

It should be noted that the conditions applicable to donor animals vary according to the microbial status of the colony from which they originate, i.e. defined, conventional or undefined.

Sentinel animals in each donor colony of defined and conventional status should be subjected to routine microbial screening, preferably monthly, but at least quarterly. Testing for specific pathogens depends on the animal species and may be influenced by geographical location. Recommendations regarding specific microbial agents to be tested for in different laboratory animal species have been published elsewhere¹.

1. Defined microbial ~~conditions~~ status
 - a) ~~Cermfree and m~~Microbiologically defined colonies (Article 4.10.1.), ~~barrier maintained animals~~ represent the cleanest sources of gametes, and the embryos recovered from these animals can be regarded as pathogen free.

Annex XIII (contd)

- b) Since the ~~animals themselves~~ male and female donors are pathogen free ~~or possess defined flora (usually based on random, monthly testing of sentinel animals)~~, dissection of the female reproductive tract and embryo isolation collection procedures ~~can~~ should be performed under aseptic laboratory conditions, ~~and do not require the use of using~~ a biological safety cabinet if appropriate.
- c) ~~Strict aseptic procedures should nevertheless be followed and, while embryo washing is not essential to safeguard against any possible air borne contamination in the laboratory, it is recommended that embryos undergo at least a 3 step washing procedure. In each wash, embryos should be gently agitated in the medium, and the wash volume must constitute at least a one-hundred fold dilution of the volume in which the embryos are transferred. Embryo washed as described in point 2 of Article 4.10.2tris is not necessary but it is recommended that embryos are washed 2 or 3 times. In each wash, embryos should be gently agitated in the medium.~~
- d) ~~Microbial testing of flush or washing media is not required.~~
- ed) ~~Cryopreserved embryos should be designated, in the appropriate records, The embryos should be recorded as coming from a germfree or microbiologically defined, barrier maintained colony, thus indicating that additional safeguards special risk management procedures (Article 4.10.2tris.) for pathogen removal are not necessary. Isolation and health status monitoring of The need to quarantine the embryo recipients should be considered but the need to quarantine them is a decision is a matter for the importing laboratory institute.~~

2. Conventional conditions

- a) ~~Animals maintained under these conditions generally represent closed colonies whose Colonies of conventional microbial status are usually closed and their health status is routinely profiled monitored (Article 4.10.1.). They The animals may have been exposed to various pathogens, resulting in infection the isolation of infectious agents, with positive antibody titres or even active clinical disease. However, prior to embryo collection there should be familiarity with but the pathogen(s) of particular concern in each individual the colony should be well known~~
- b) Reproductive tracts (uteri, oviducts and/or ovaries) should be removed at a separate site and then taken into the embryo processing laboratory. These procedures should be performed by separate different technicians or, at the ~~very~~ minimum, their protective clothing should be changed between locations. If ~~the animals are to~~ should be handled in the laboratory, the tracts should be dissected out within a biological safety cabinet. This will help protect against the possible shedding of pathogens into the laboratory itself.
- c) Once the reproductive tracts have been removed, embryo recovery should be performed under aseptic conditions. ~~Embryos must be inspected (>100x) for the presence of cracks in the zona pellucida and only zona intact embryos should be kept. They must then be washed using the standard 10 step procedure, described Depending on which, if any, pathogens are known to occur in the colony, embryos should be processed according to the risk management procedures, including washing, as described in Article 4.10.2tris, and in the IETS Manual². This recommendation could be waived in the future if sufficient research evidence from embryo pathogen interaction studies warranted it.~~

- d) Embryos derived from animals that have positive antibody titres or other evidence of specific pathogens should only be transferred into a new colony via a *quarantine* system, using microbiologically defined recipient females. ~~As an additional safeguard, Quarantine may also be appropriate if there is any uncertainty about the donor or disease status of the embryos, quarantining of recipients should be applied~~ the microbial status of the donor colony or the donors. In ~~certain~~ situations where ~~the embryos might~~ could have been exposed to bacterial infection (e.g. *mycoplasma*), they should be cultured in a medium containing an appropriate antibiotic for 24 h ~~pre-freezing, or post thawing and prior to transfer~~ before cryopreservation, or in the interval between thawing and transfer into recipients.
- e) ~~If the embryos were not handled in the recommended manner, this must be indicated on the shipment records, and mandatory quarantining of the recipient dam and offspring should be imposed by the recipient institution until their health status is confirmed. The recipient dam should then be tested post weaning for pathogens, and introduction of the progeny into the colony should only take place if test results are satisfactory. If the recipient institution does decide to quarantine the recipient dam and offspring until their health status is confirmed, the recipients should be tested post-weaning for pathogens of concern, and introduction of offspring into the colony should only take place if the test results are satisfactory.~~

3. Undefined microbial conditions

- a) ~~These animals are derived from either the wild~~ Embryos from free ranging animals or from colonies of unknown health status ~~and embryos from them~~ require maximum precautions the full range of risk management procedures that are described in Article 4.10.2tris and in the IETS Manual². The health status of breeder males and donor females should be determined. The procedures resemble those used for embryos of livestock as recommended in Chapter 4.7. and Chapter 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) ~~A~~ Biological safety cabinet should be used for all animal, tissue and embryo handling donors and reproductive tissues, and for processing embryos.
- c) Post-mortem testing of the donor females for diseases or pathogens of concern to the importing country may be appropriate after the embryos/ooocytes have been collected. Alternatively if embryos are collected surgically ~~An aliquot of flush fluid from each donor, or a pooled sample, should be tested for the presence of specific pathogens of concern to the importing country and laboratory.~~
- d) Embryos ~~must~~ should be washed at least 10 times in accordance with the protocols in the IETS Manual² (i.e. the 10 step wash, possibly including trypsin treatment in the case of certain herpesviruses) ~~and an aliquot of media from the last four (pooled) washes should be tested for pathogens~~ trypsin treatment should be used if presence of certain pathogenic herpesviruses is of concern.
- e) Cryopreserved embryos ~~must~~ should be stored in the exporting laboratory until such time as the necessary *disease* screening of colonies, tissues and/or fluids is completed and the certification supporting documents for certification completed and signed by the institute veterinarian.
- f) On arrival in the importing country the ~~All embryos from these animals must~~ should be transferred into a colony via recipients in a quarantine system, ~~as discussed above.~~ Recipients should be tested at intervals appropriate to recognized incubation periods of the diseases of concern. In addition to testing ~~the recipients dam after transfer, all the~~ offspring should be tested at 12 weeks of age and ~~or individuals from successive generations should be tested~~ before their introduction into breeding colonies outside the quarantine facility.

Article 4.10.5.bis.**Conditions applicable to the storage and transport of embryos**

1. Embryos for export should be frozen in fresh liquid nitrogen and then stored in fresh liquid nitrogen in cleaned and disinfected tanks or containers.
2. The embryos should be stored in sealed sterile ampoules, vials or straws under strict hygienic conditions at a storage place approved by the Veterinary Authority of the exporting country. Only embryos from the same donor should be stored together in the same ampoule, vial or straw.
3. Ampoules, vials or straws should be sealed at the time of freezing (or prior to export where cryopreservation is not possible) and they should be clearly identified according to or similar to the system recommended in the IETS Manual². Identification should include details of the species/genotype of the donors, microbial status (e.g. defined, conventional or undefined), collection/cryopreservation date, number and developmental stage of the embryos, container number and details of any specialized procedure such as *in vitro* fertilization, micromanipulation.
4. Liquid nitrogen storage containers should be sealed under the supervision of the Official Veterinarian prior to shipment from the exporting country.
5. Embryos should not be exported until the appropriate veterinary certificates are completed.

Article 4.10.6.

Special experimental circumstances Procedures for *in vitro* fertilization and micromanipulation

If embryos are to be cryopreserved following specialised produced by *in vitro* fertilization of oocytes, it is advised that the washed sperm should be used so as to minimize the risk of possible pathogen exposure. If embryos are to undergo micromanipulation procedures that involve penetration of the zona pellucida, they must undergo the required washing steps (depending on colony status) before treatment. In the case of *in vitro* fertilisation, to minimise possible pathogen exposure, it is also advised that only washed sperm should be used. Embryos should be washed again before cryopreservation any required risk management steps (including washing) should be carried out first, as described in Chapter 4.9.

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¹ **Recommendations for the health monitoring of mouse, rat, hamster, guinea pig 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).

³ Schiewe M.C., Hollifield V.M., Kasbohm L.A. & Schmidt P.M. (1995) — Embryo importation and cryobanking strategies for laboratory animals and wildlife species. *Theriogenology*, **43**, 97-104.

CHAPTER 4.12.

DISPOSAL OF DEAD ANIMALS

Article 4.12.1.

Introduction

The mass disposal of dead *animals* associated with an animal *disease outbreak* is often subject to intense public and media scrutiny thereby obligating the *Veterinary Authority* of a Member to not only conduct disposal operations within acceptable scientific principles to destroy the causative pathogen but also to address public and environmental concerns.

The recommendations in this chapter are general in nature. The choice of one or more of the recommended methods should be in compliance with relevant local and national legislation and be attainable with the resources available. The recommendations should also be applied in conjunction with the procedures described for the *killing of animals* in Chapter 7.6.

Strategies for the disposal of dead *animals* (entire *animals* or parts thereof) should be prepared well in advance of any emergency. Major issues related to the disposal of dead *animals* include the number of *animals* involved, biosecurity concerns over the movement of infected or exposed *animals*, people and equipment, environmental concerns, and the psychological distress experienced by farmers and *animal handlers*.

Article 4.12.2.

Regulations and jurisdiction

The legislation regulating animal health and the organisation of the *Veterinary Authority* should give the *Veterinary Services* the authority and the legal powers to carry out the activities necessary for the efficient and effective disposal of dead *animals*. Cooperation between the *Veterinary Service* and other relevant government bodies is necessary to developing a coherent set of legal measures for the disposal of dead *animals* in advance of any emergency. In this context the following aspects should be regulated:

1. Powers of *Veterinary Services* (inspectors, veterinary officers, etc.) to effect controls and direct persons as well as the right of entry to an *establishment* for the *Veterinary Services* and associated personnel;
2. movement controls and the authority to make exemptions under certain biosecurity conditions, for example for transport of dead *animals* to another location for disposal;
3. the obligation on the involved farmer and *animal handlers* to cooperate with the *Veterinary Services*;
4. any need to transfer the ownership of *animals* to the competent authority;
5. the determining of the method and location of disposal, and the necessary equipment and facilities, by the *Veterinary Services*, in consultation with other involved authorities including national and local governmental organisations competent for the protection of human health and of the environment.

Should the chosen option for the disposal of dead *animals* be applied near the border of a neighbouring country, the competent authorities of that country should be consulted.

Annex XIV (contd)

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 **must** **should** proceed with the minimum delay. The success is determined by the structures, policies and infrastructure established in advance:

1. Relationship with industry

A relationship with industry organisations, such as farmer associations, commodity representatives, *animal welfare* organisations, security services, media and consumer representatives is essential to obtain compliance with animal health policies.

2. Standard operating procedures

Standard operating procedures should be developed (including documented decision-making processes, training of staff).

3. Financial preparedness

Financial preparedness means a compensation or insurance mechanism, an access to emergency funding and an access to personnel through agreements with private veterinarians.

4. Communication plan

Information sharing with officials involved in the *outbreak*, affected farmers, professional organizations, politicians and the media is essential. A well informed spokesperson should be available at all times to answer enquiries.

5. Resources

The management of resources should address such items as personnel, transport, storage facilities, equipment (such as mobile handling facilities for *animals*, *disinfection* equipment), fuel, protective and disposable material and logistical support.

6. Special equipment

Special equipment such as trucks, tractors, bulldozers, and front-end loaders should be available.

Article 4.12.4.

Critical elements

Critical elements which need to be considered in planning and implementation include:

1. Timeliness

Early detection of new *infections*, immediate *killing* of infected *animals* and rapid removal of the dead *animals* with inactivation of the pathogen are important. Spread of the pathogen from the dead *animals* and their surroundings should be blocked as soon and as effectively as possible.

2. Occupational health and safety

Disposal should be organised in such a way that the workers are safeguarded against the risks of handling decomposing dead *animals*. Special attention should be given to zoonotic aspects. Workers should receive appropriate training and be sufficiently protected against *infection* with protective clothing, gloves, face masks, effective respirators, goggles, vaccination, and effective anti viral medicines. Workers should also receive regular health checks.

3. Pathogen inactivation

The disposal procedure should be selected to result in inactivation of the pathogen.

4. Environmental concerns

Different methods of the disposal of dead *animals* have different effects on the environment. For instance, pyre burning will produce smoke and smells; burial might lead to gas and leachate production resulting in potential contamination of air, soil, surface and sub surface water.

5. Availability of capacity

An assessment of capacities of different methods of disposal should be made prior to any emergency. Temporary storage of dead *animals* in cold stores may relieve a lack of processing capacity.

6. Adequate funding

Adequacy of funding for the options chosen **must** 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.

Annex XIV (contd)11. Scavengers and vectors

When disposing of dead *animals*, full attention should be given to preventing scavengers and vectors gaining access to dead *animals*, which might cause spread of *disease*.

12. Economic impact (short and long term including recovery)

The method of disposal used has a significant bearing on economic impact.

Article 4.12.5.

Practical considerations1. Selection of disposal site

Sufficient top soil to cover the site; soil type; water drainage; prevailing wind conditions; easy access to transport; availability of meteorological data; separation from sensitive public sites, and the effect on future use.

2. Contractors

Contractors — availability of manpower, materials and equipment including transport *vehicles*; can they supply in all the needs; exclusive use of *vehicles* or would they also be used for other purposes (risk of *disease* transmission); access to available roads; suitable for the purpose to be used.

3. Logistical preparedness for the appropriate technology

Availability of fuel; sufficient manual labour available; sites and availability of *disinfection* tents for personnel; storage and disposal of protective clothing; housing for personnel to minimise the spread of *infection*; facilities for entry and exit control; availability of electricity for night operations; personal facilities for personnel such as toilets, drinking water; availability of communication – mobile phone reception; protection (e.g. vaccination) of personnel; rendering capacity at rendering plants; arms and ammunition, additional cold storage and holding facilities at rendering plants and *abattoirs*.

4. Procedures and policies for disposal of other possibly contaminated products

Animal products such as litter, manure, wool, eggs and milk; animal feed; non-animal products such as protective clothing.

5. Wildlife

Need to minimise the risks posed by wildlife, including by excluding or repelling them from the disposal site.

Article 4.12.6.

Recommended methods for the disposal of dead animals

The method(s) chosen should be based on local conditions and the required capacity and speed of outcome and on the conditions required for the inactivation of the causative agent.

Some of the methods below may require on-farm pre-processing prior to transportation of dead *animals* to central facilities for rendering or incineration. Preprocessing could include the grinding of dead *animals* which can then be transported in sealed *containers*, or be subjected to fermentation, composting or freezing.

1. Rendering

This is a closed system for mechanical and thermal treatment of animal tissues leading to stable, sterilized products, e.g. animal fat and dried animal protein. The technology exists in dedicated facilities. It produces an effective inactivation of all pathogens with the exception of prions where infectivity is reduced. The availability of the capacity should be determined in advance.

2. Incineration in a dedicated facility

In such a facility, whole dead *animals* or parts of *animals* can be completely burned and reduced to ash, often in conjunction with other substances (such as municipal waste, hazardous waste or hospital waste). Effective inactivation of pathogens, including spores, occurs. Fixed facility incineration is wholly contained and has some advantages from the environmental viewpoint as the exhausts may be fitted with afterburner chambers to completely burn hydrocarbon gases and particulate matter from the main combustion chamber.

3. Rendering and incineration

These may be combined for improved security and to provide additional fuel for furnaces in facilities used for other purposes such as in cement kilns and electricity generation plants.

4. Air curtain incineration

This process fan-forces a mass of air through a manifold, thereby creating a turbulent environment in which incineration is accelerated up to six times for example in a burn-pit. The equipment can be mobile and, because it can be used on site, there is no requirement for transportation of the animal material. It also produces effective inactivation of pathogens.

5. Pyre burning

This open system of burning dead *animals* is a well established procedure that can be conducted on site with no requirement for transportation of animal material. However, it takes an extended period of time and has no way of verifying pathogen inactivation, and there may be particulate dissemination from incomplete combustion. Further, because the process is open to view, there may be a lack of acceptance by the public.

6. Composting

Composting is a natural biological decomposition process that takes place in the presence of oxygen. In the first phase, the temperature of the compost pile increases, organic materials break down into relatively small compounds, soft tissue decomposes, and bones soften partially. In the second phase, the remaining materials, mainly bones, break down fully to a dark brown or black humus containing primarily non-pathogenic bacteria and plant nutrients. However, some viruses and spore forming bacteria, such as *Bacillus anthracis*, and other pathogens such as *Mycobacterium tuberculosis* may survive.

Annex XIV (contd)7. Burial

In this method, whole dead *animals* are buried and covered by soil. Burial is an established procedure which may be conducted on site. It may not inactivate all pathogens. In some circumstances, dead *animals* may be disposed of by mounding whereby they are covered by a layer of soil above ground.

8. Biogas production

This is a closed system of anaerobic fermentation which would require for the disposal of dead *animals* or their parts prior mechanical and thermal treatment of the input material (such as the liquid product of rendering plants). This process may not inactivate all pathogens.

9. Alkaline hydrolysis

This method uses sodium hydroxide or potassium hydroxide to catalyse the hydrolysis of biological material into a sterile aqueous solution consisting of small peptides, amino acids, sugars, and soaps. Heat is applied (150°C) to accelerate the process. The only solid byproducts are the mineral constituents of bones and teeth. This residue (2% 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

This Bio-refining is a process of high pressure, high temperature hydrolytic process, thermal hydrolysis conducted in a sealed pressurised vessel chamber. The waste material is treated with high-pressure saturated steam at 180°C at 12 bar pressure for 40 minutes, heated by the indirect application of steam kj, other compostable material, paper and comparable materials, and cereal straws either alone or in combination. The process inactivates all microbiological agents 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. The process produces no environmental pollutants but yields renewable energy from bio-methane and thermal energy, as well as mineral and protein end-products suitable as fertilizers for soil remediation and animal feed additives. All microbiological agents are inactivated and the infectivity of the infectious agents causing transmissible spongiform encephalopathies (prions) 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 must 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, must should total 100.
3. Step 3 - Identify and list all disposal options under consideration. Rate each disposal option against each factor and assign a Utility Rating of between 1 to 10 to each comparison. The Utility Rating (U) is a number between 1 and 10 which is allocated according to how well the option achieves the ideal with respect to each factor (eg 1 = the worst possible fit, and 10 = the best fit).
4. Step 4 - For each factor and each disposal option, multiply the Factor Weight (F) x Utility Rating (U) to yield a numeric Balanced Value (V), (eg $V = F \times U$).
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	Weight	Rendering		Fixed Incineration		Pyre Burning		Composting		Mass Buntal		On-Farm Buntal		Commercial Landfill	
		Utility	Value	Utility	Value	Utility	Value	Utility	Value	Utility	Value	Utility	Value	Utility	Value
Factors															
Operator Safety	20	7	140	4	60	6	160	3	60	7	140	6			
Speed of Resolution	20	8	160	8	160	2	40	5	100	5	100	6			
Pathogen Inactivation	15	10	150	10	150	6	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	6	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	6	6	25	3	15	9	45	9	45	9	45	9			
Total Weight to Equal 100 Units	100	sum	785	sum	660	sum	535	sum	595	sum	515	sum	sum	sum	sum

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CHAPTER 5.1.

GENERAL OBLIGATIONS RELATED TO CERTIFICATION

Article 5.1.1.

Safety of *international trade* in *animals* and animal products depends on a combination of factors which should be taken into account to ensure unimpeded trade, without incurring unacceptable *risks* to human and animal health.

Because of differences between countries in their animal health situations, various options are offered by the *Terrestrial Code*. The animal health situation in the *exporting country*, in the *transit country* or *countries* and in the *importing country* should be considered before determining the requirements for trade. To maximise harmonisation of the sanitary aspects of *international trade*, *Veterinary Authorities* of OIE Members should base their import requirements on the OIE standards.

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

Certification requirements should be exact and concise, and should clearly convey the wishes of the *importing country*. For this purpose, prior consultation between *Veterinary Authorities* of *importing* and *exporting countries* may be necessary. It enables the setting out of the exact requirements so that the signing *veterinarian* can, if necessary, be given a note of guidance explaining the understanding between the *Veterinary Authorities* involved.

The certification requirements should not include conditions for *diseases* that are not transmitted by the *commodity* concerned. There should only be one signing *veterinarian* for one certificate. The certificate should be signed in accordance with the provisions of Chapter 5.2.

When officials of a *Veterinary Authority* wish to visit another country for matters of professional interest to the *Veterinary Authority* of the other country, the latter should be informed.

Article 5.1.2.

Responsibilities of the importing country

1. The import requirements included in the *international veterinary certificate* should assure that *commodities* introduced into the *importing country* comply with the OIE standards. *Importing countries* should restrict their requirements to those necessary to achieve the national appropriate level of protection. If these are stricter than the OIE standards, they should be based on an import *risk analysis*.
2. The *international veterinary certificate* should not include requirements for the exclusion of pathogens or animal *diseases* which are present in the *importing country* and are not subject to any *official control programme*. The measures imposed on imports to manage the *risks* posed by a specific pathogen or *disease* should not require a higher level of protection than that provided by measures applied as part of the *official control programme* operating within the *importing country*.
3. The *international veterinary certificate* should not include measures against pathogens or *diseases* which are not OIE listed, unless the *importing country* has demonstrated through import *risk analysis*, carried out in accordance with Section 2., that the pathogen or *disease* poses a significant *risk* to the *importing country*.

Annex XV (contd)

4. The transmission by the *Veterinary Authority* of certificates or the communication of import requirements to persons other than the *Veterinary Authority* of another country, necessitates that copies of these documents are also sent to the *Veterinary Authority*. This important procedure avoids delays and difficulties which may arise between traders and *Veterinary Authorities* when the authenticity of the certificates or permits is not established.

This information is the responsibility of *Veterinary Authorities*. However, it can be issued by private sector *veterinarians* at the place of origin of the *commodities* when this practice is the subject of appropriate approval and authentication by the *Veterinary Authority*.

5. Situations may arise which result in changes to the consignee, identification of the means of transportation, or *border post* after a certificate is issued. Because these do not change the animal or public health status of the consignment, they should not prevent the acceptance of the certificate.

Article 5.1.3.

Responsibilities of the exporting country

1. An *exporting country* should, on request, supply the following to *importing countries*:
 - a) information on the animal health situation and national animal health information systems to determine whether that country is free or has *zones* or *compartments* free from *listed diseases*, including the regulations and procedures in force to maintain its free status;
 - b) regular and prompt information on the occurrence of *notifiable diseases*;
 - c) details of the country's ability to apply measures to control and prevent the relevant *listed diseases*;
 - d) information on the structure of the *Veterinary Services* and the authority which they exercise according to Chapters 3.1. and 3.2.;
 - e) technical information, particularly on biological tests and vaccines applied in all or part of the national territory.
2. *Veterinary Authorities* of *exporting countries* should:
 - a) have official procedures for authorisation of certifying veterinarians, defining their functions and duties as well as conditions of oversight and accountability, covering including possible suspension and termination of the ~~appointment~~ 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. ~~Equally, if~~ if a *disease* condition appears in imported *commodities* within a time period after importation consistent with the recognised *incubation period* of the *disease*, the *Veterinary Authority* of the *exporting country* should be informed so as to enable an investigation to be made, since this may be the first available information on the occurrence of the *disease* in a previously free *herd*. The *Veterinary Authority* of the *importing country* should be informed of the result of the investigation since the source of *infection* may not be in the *exporting country*.
3. In case of suspicion, on reasonable grounds, that an official certificate may be fraudulent, the *Veterinary Authority* of the *importing country* and *exporting country* should conduct an investigation. Consideration should also be given to notifying any third country(ies) that may have been implicated. All associated consignments should be kept under official control, pending the outcome of the investigation. The *Veterinary Authorities* of all countries involved should fully cooperate with the investigation. If the certificate is found to be fraudulent, every effort should be made to identify those responsible so that appropriate action can be taken according to the relevant legislation.

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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 ~~must~~ should be respected and safeguarded according to Chapters 3.1. and 3.2.

It is essential ~~not~~ to include in ~~the~~ any requirements ~~additional specific matters which cannot~~ only those specific statements that can be accurately and honestly signed by a *veterinarian*. For example, these requirements should not include certification of an area as being free from diseases that are not non-notifiable, diseases or the occurrence of which the signing veterinarian is not necessarily informed about. ~~Equally, It is unacceptable to ask for certification for events which will take place after the document is signed is unacceptable~~ when these events are not under the direct control and supervision of the signing veterinarian.

Certification of freedom from *diseases* based on purely clinical freedom and *herd* history is of limited value. This is also true of *diseases* for which there is no specific diagnostic test, or the value of the test as a diagnostic aid is limited.

The note of guidance referred to in Article 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 authorised by the *Veterinary Authority*;
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:

Annex XV (contd)

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 ~~They~~ should be written ~~in~~ using terms that are ~~as~~ simple, unambiguous and as easy to understand as possible, without losing their legal meaning.
3. If so required, certificates ~~they~~ should be written in the language of the *importing country*. In such circumstances, they should also be written in a language understood by the certifying veterinarian.
4. Certificates ~~They~~ should require appropriate identification of *animals* and animal products except where this is impractical (e.g. *day-old birds*).
5. Certificates ~~They~~ should not require a *veterinarian* to certify matters that are outside his/her knowledge or which he/she cannot ascertain and verify.
6. Where appropriate, when presented to the certifying veterinarian, certificates ~~they~~ should be accompanied, ~~when presented to the certifying veterinarian,~~ by notes of guidance indicating the extent of enquiries, tests or examinations expected to be carried out before the certificate is signed.
7. ~~Their~~ text of a certificate should not be amended except by deletions which must should be signed and stamped by the certifying veterinarian.
8. The signature and stamp must should be in a colour different from that of the printing of the certificate. The stamp may be embossed instead of being a different colour.
9. Replacement certificates may be issued by a *Veterinary Authority* to replace certificates that have been, for example, lost, damaged, contain errors, or where the original information is no longer correct. These replacements should be provided by the issuing authority and be clearly marked to indicate that they are replacing the original certificate. A replacement certificate should reference the number and the issue date of the certificate that it supersedes. The superseded certificate should be cancelled and where possible, returned to the issuing authority.
10. Only original certificates are acceptable.

Article 5.2.4.

Electronic certification

1. Certification may be provided by electronic documentation sent directly from the *Veterinary Authority* of the *exporting country* to the *Veterinary Authority* of the *importing country*. Such systems also normally provide an interface with the commercial organisation marketing the *commodity* for provision of information to the certifying authority. The certifying veterinarian must should have access to all information such as *laboratory* results and *animal identification* data.
2. Electronic certificates may be in a different format but should carry the same information as conventional paper certificates.

Annex XV (contd)

3. The *Veterinary Authority* ~~must~~ should have in place systems for the security of electronic certificates against access by unauthorised persons or organisations.
4. The certifying veterinarian ~~must~~ should be officially responsible for the secure use of his/her electronic signature.

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CHAPTER 6.3.

**THE CONTROL OF HAZARDS OF
ANIMAL HEALTH AND
PUBLIC HEALTH IMPORTANCE IN ANIMAL FEED**

Article 6.3.1.

Introduction

Animal feed is a critical component of the food-chain that has a direct impact on animal health and *welfare* and also on food safety and public health.

Historically, the OIE primarily addressed animal feed as an important pathway for the entry and spread of contagious epidemic *diseases*, such as foot and mouth disease, swine vesicular disease and avian influenza. In recent years, the role of feed as a *vector* for disease agents, including zoonotic organisms, was a focus of standards development in regards to bovine spongiform encephalopathy. Animal feed and feed ingredients are widely traded internationally and trade disruptions have the potential to impact economies in both developed and developing countries. Since 2002 the OIE has expanded its zoonotic disease mandate to encompass animal production food safety, working in collaboration with the Codex Alimentarius Commission (CAC) and other international organisations. In 2006 the International Committee resolved that the OIE should develop guidance on foodborne *zoonoses* and animal feeding, complementing relevant CAC texts.

Article 6.3.2.

Objective and scope

The objective of this chapter is to provide guidance on animal feeding in relation to animal health and to complement the guidance provided by the Codex Code of Practice on Good Animal Feeding (CAC/RCP 54-2004) which deals primarily with food safety, and related other Codex texts covering animal feeding, e.g. Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals (CAC/RCP 49-2001).

This chapter aims at ensuring the control of animal and public health hazards through adherence to recommended practices during the production (growing procurement, handling, storage, processing and distribution) and use of both commercial and on-farm produced animal feed and feed ingredients for terrestrial animals.

This chapter applies to the production and use of all products destined for animal feed and feed ingredients at all levels whether produced commercially or on farm. It also includes grazing or free-range feeding, forage crop production and water for drinking. Swill feeding is a particular aspect of on-farm practice that is specifically addressed because of its recognised role in disease transmission.

This chapter deals with feed for terrestrial *animals* (except bees).

Annex XVI (contd)

Article 6.3.3.

Definitions

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, ~~health of the animal or the characteristics of products of the animal~~ 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.

Contamination: means the unwanted presence of a material or product in a feed or feed ingredient potentially harmful ~~for~~ to animal or public health or restricted under current regulations.

Article 6.3.4.

General principles1. Roles and responsibilities

The *Competent Authority* has the legal power to set and enforce regulatory animal feeding requirements, and has final responsibility for verifying that these requirements are met. The *Competent Authority* may establish regulatory requirements for relevant parties to provide it with information and assistance. Refer to Chapters 3.1. and 3.2. of the *Terrestrial Code*.

Those involved in the production and use of animal feed and feed ingredients have the responsibility to ensure that these products meet regulatory requirements. 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. In defining limits and tolerances for hazards, ~~s~~Scientific evidence, including the sensitivity of analytical methods and on the characterisation of risks, should be taken into account in defining limits and tolerances for hazards.

3. Risk analysis (risk assessment, risk management and risk communication)

Internationally accepted principles and practices on risk analysis (Section 2 of the *Terrestrial Code* and relevant Codex texts) should be used in developing and applying the regulatory framework.

Application of a generic framework should provide a systematic and consistent process for managing all biosecurity risks, while recognising the different *risk assessment* methodologies used in animal and public health.

4. Good practices

Where national guidelines exist, good agricultural practices and good manufacturing practices (including good hygienic practices) should be followed. Countries without such guidelines are encouraged to develop them or adopt suitable international standards or recommendations.

Where appropriate, Hazard Analysis and Critical Control Point (HACCP) principles should be followed to control hazards that may occur in the manufacture, distribution and feeding of feed and feed additives and feed ingredients.

5. Geographic and environmental considerations

Epidemiological links between potential sources of hazards for animal health or food safety should be considered when assessing water sources, land or facilities for suitability for the production of animal feed and feed ingredients. Animal health considerations include factors such as disease status, location of quarantined premises and existence of *zones/ compartments* of specified health status. Food safety considerations include factors such as industrial operations that generate pollutants and waste treatment plants.

6. Zoning and compartmentalisation

Feed is an important component of biosecurity and needs to be considered when defining a *compartment* or *zone* in accordance with Chapter 4.3. of the *Terrestrial Code*.

7. Sampling and analysis

Sampling and analysis should be based on scientifically recognised principles and procedures.

8. Labelling

Labelling should be informative, unambiguous, legible and conspicuously placed on the package if sold in package form and on the waybill and other sales documents if sold in bulk, un-packaged form, and should comply with regulatory requirements and Section 4.2.10 Labelling of Codex Code of Practice on Good Animal Feeding (CAC/RCP 54-2004), including listing of ingredients and instructions on the handling, storing and use.

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.

Annex XVI (contd)

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 the primary full responsibility for implementing systems for process quality control. The *Competent Authority* should verify that process control systems and safety standards achieve all regulatory requirements.

10. Assurance and certification

Feed business operators are responsible for demonstrating the safety of the establishments under their control. *Competent Authorities* are responsible for providing assurances domestically and to trading partners that regulatory safety standards have been met. For *international trade* in animal product-based feeds, *Veterinary Services* are required to provide *international veterinary certificates*.

11. Hazards associated with animal feed

a) Biological hazards

Biological hazards that may occur in feed and feed ingredients include agents such as bacteria, viruses, prions, fungi and parasites.

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

~~It is important to avoid~~ ~~necessary that the prevention of~~ Procedures to minimise the risk of contamination during the manufacture, storage, distribution (including transport) and the use of feed and feed ingredients ~~and relevant provisions should~~ 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 ~~avoid~~ reduce the likelihood of contamination between batches of feed or feed ingredients.

13. Antimicrobial resistance

Concerning the use of antimicrobials in animal feed refer to Chapters 6.7. to 6.11. of the *Terrestrial Code*.

14. Management of information

The *Competent Authority* should establish clear requirements for the provision of information by the private sector as this relates to regulatory requirements.

Records should be maintained in a readily accessible form regarding the production, distribution and use of feed and feed ingredients. These records are required to facilitate the prompt trace-back of feed and feed ingredients to the immediate previous source, and trace-forward to the next subsequent recipients, to address identified animal health or public health concerns (see Section 4.3. of CAC/RCP 54-2004).

Animal identification and *animal traceability* are tools for addressing animal health (including *zoonoses*), and food safety risks arising from animal feed (see Chapters 4.1. and 4.2. of the *Terrestrial Code*).

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CHAPTER 6.5.

PREVENTION, DETECTION AND CONTROL OF
SALMONELLA IN POULTRY

Article 6.5.1.

Introduction

This Chapter provides recommendations on the prevention, detection and control of *Salmonella* in *poultry*.

Salmonellosis is one of the most common foodborne bacterial *diseases* in the world. The great majority of *Salmonella infections* in humans are foodborne with *Salmonella* Enteritidis and *Salmonella* Typhimurium accounting for a major part of the problem. *Salmonella* serotypes and prevalence may vary considerably between localities, districts, regions and countries and therefore, *surveillance* and identification of the prevalent *Salmonella* serotypes in humans and *poultry* should be carried out in order to develop a control programme for the area.

In most food animal species, *Salmonella* can establish a clinically inapparent *infection* of variable duration, which is significant as a potential *zoonosis*. Such animals may be important in relation to the spread of *infection* between *flocks* and as causes of human foodborne *infection*. In the latter case, this can occur when *meat* and eggs, or their products, enter the food chain thus producing contaminated food.

Article 6.5.2.

Purpose and scope

This Chapter deals with methods for on farm prevention, detection and control of *Salmonella* in *poultry*, and complements the Codex Alimentarius Code of Hygiene Practice for Meat (CAC/RCP 58-2005) and Code of Hygienic Practice for Eggs and Egg Products (CAC/RCP 15-1976 ~~Revision 2007~~). A pathogen reduction strategy at the farm level is seen as the first step in a continuum that will assist in reducing the presence of foodborne pathogens in eggs and *meat*.

Hygiene and biosecurity procedures to be implemented in *poultry flocks* and hatcheries are described in Chapter 6.4. Hygiene and Biosecurity Procedures in Poultry Production.

The recommendations presented in this Chapter are relevant to the control of all *Salmonella* with special attention to *S. Enteritidis* and *S. Typhimurium*, as these are common *Salmonella* serotypes in many countries. It should be noted that the epidemiology of animal and human salmonellosis in a particular locality, district, region or country is important for effective control of *Salmonella*.

Article 6.5.3.

Definitions (for this Chapter only)

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

Competitive exclusion: means the administration of defined or undefined bacterial flora to *poultry* to prevent gut colonisation by enteropathogens, including *Salmonella*.

Annex XVII (contd)

Culling: means the depopulation of a *flock* before the end of its normal production period.

Layers: means *poultry* during the period of laying eggs for human consumption.

Article 6.5.4.

Surveillance of poultry flocks for *Salmonella*

Where justified by *risk assessment*, *surveillance* should be carried out to identify infected *flocks* in order to take measures that will reduce the prevalence in *poultry* and the risk of transmission of *Salmonella* to humans. Sampling methods, frequency and type of samples required should be determined by the *Veterinary Services* based on a *risk assessment*. Microbiological testing is preferred to serological testing because of its higher sensitivity in broilers *flocks* and higher specificity in breeders 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 ensure that decisions are soundly based exclude false positive or negative results.

Sampling

1. Available methods for sampling

Drag swabs: sampling is done by dragging swabs throughout the *poultry* building.

Boot swabs: sampling is done by walking throughout the *poultry* building 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* building.

Faecal samples: multiple fresh faecal/caecal samples collected from different areas in the *poultry* building.

Meconium, chick box papers, dead in shell and culled chicks at the hatchery.

Hatchery samples: throughout the hatchery, including the inside inner liner of the incubators.

~~Additional sampling of equipment and surfaces may be performed to increase sensitivity.~~

2. Sample size

Refer to the *Terrestrial Manual* (under development).

3. Laboratory methods

Refer to the *Terrestrial Manual* (under development).

4. Time and frequency of testing

Time and frequency of sampling for each *poultry* type are listed below:

a) Breeders and hatcheries

i) Breeder *flocks* before lay

- Before the end of the first week of life when the status of the breeding farm and 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 animals 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 may 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 breeding farm and 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 animals 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 by commercial considerations.

ii) *Layer flocks*

- At expected peak of lay for each production cycle (the period of time in the laying cycle when the production of the *flock* is highest).
- One or more times if there is a culling policy in place or if eggs are diverted to processing for the inactivation of the pathogen. The minimal frequency should be determined by the *Veterinary Services*.

Annex XVII (contd)

- c) Poultry for the production of *meat*
- i) *Flocks* should be sampled at least once before slaughter.
 - ii) When re sampling occurs on farms and when re there is a long period (2 weeks or more) between thinning and final depopulation, further testing should be considered.
 - iii) When re sampling occurs on farms, *flocks* should be sampled as late as possible before the first birds are transported to the slaughter house. ~~Where this is done~~ In order to allow for the implementation of control measures during processing, this must 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 that allows for investigation of the source of positive flocks.

- d) Empty building testing
- i) 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 building 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:

- a) 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*.
- b) In *layer flocks* control measures will reduce and may eliminate contamination of eggs with *Salmonella*.
- c) In *poultry* for *meat* production, control measures may be implemented at *slaughter* or further down the food chain.

Article 6.5.5.

Prevention and Control measures

Salmonella prevention and control may be achieved by adopting Good Agricultural Practices and Hazard Analysis Critical Control Point (HACCP), and general measures detailed in Chapter 6.4. Hygiene and Biosecurity Procedures in Poultry Production, in combination with the following additional measures, where appropriate. No single measure used alone will achieve effective *Salmonella* control.

Additional prevention and control measures include: vaccination, competitive exclusion, *flock* culling, organic acids and product diversion to processing.

Antimicrobials 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. Antimicrobials may also reduce normal flora in the gut and increase the likelihood of colonisation with *Salmonella*. In special circumstances antimicrobials may be used to salvage animals birds with high genetic value.

1. ~~Day-old chicks~~ Day-old birds used to stock a *poultry* house should be obtained from breeding *flocks* and hatcheries that ~~are free from at least *S. Enteritidis* and *S. Typhimurium* and~~ have been monitored according to this Chapter and in which no evidence of *S. Enteritidis* and *S. Typhimurium* has been detected.
2. *Layer* and breeder *flocks* should be stocked from *flocks* that ~~are free from at least *S. Enteritidis* and *S. Typhimurium* (under study) and~~ have been monitored according to this chapter and in which no evidence of *S. Enteritidis* and *S. Typhimurium* has been detected.
3. Feed contamination with *Salmonella* is known to be a source of *infection* for *poultry*. Therefore, it is recommended to monitor the *Salmonella* status of *poultry* feed, and if found positive to take corrective measures. The use of heat treated feeds or feeds subjected to other bacteriostatic or bactericidal treatment (~~e.g. organic acids~~) is recommended (e.g. organic acids). Feed should be stored in clean closed containers to prevent access by wild birds and rodents. Spilled feed should be cleaned up immediately to remove attractants for wild birds and rodents.
4. Competitive exclusion may be used in ~~day-old chicks~~ day-old birds to reduce colonisation by *Salmonella*.

When used, competitive exclusion should be administered according to the instructions provided by the manufacturer and in accordance with the standards and recommendations of the *Veterinary Services*.

5. Vaccines are used against *Salmonella* infections caused by different serotypes in various *poultry* species, including single or combined vaccines. Vaccines produced according to the *Terrestrial Manual* should be used.

If live vaccines are used it is important that field and vaccine strains be easily differentiated in the laboratory. If serology is used as the *surveillance* method, it may not be possible to distinguish between vaccination and *infection* with a field strain.

Vaccination can be used as part of an overall *Salmonella* control programme. It is recommended that vaccination not be used as the sole control measure.

When the status of the breeding farm and the hatchery from which the *flock* originates is not known or does not comply with this Chapter, vaccination of *flocks*, starting with ~~day-old chicks~~ 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 chicks~~ day-old birds to a previously contaminated shed so as to minimise the risk of the birds contracting *Salmonella* infection.

When used, vaccines should be administered according to the instructions provided by the manufacturer and in accordance with the standards and recommendations of the *Veterinary Services*.

Vaccination against *S. Enteritidis* can cause a ~~positive~~ cross reactions in *Salmonella* Pullorum/S. Gallinarum serological tests and needs to be considered when implementing measures for these pathogens.

6. Depending on animal health, *risk assessment*, and public health policies, culling is an option to manage infected breeder and *layer* *flocks*. Infected *flocks* should be destroyed or slaughtered and processed to minimise human exposure to *Salmonella*.

If *poultry* are not culled, eggs for human consumption should be diverted for processing for inactivation of *Salmonella*.

Annex XVII (contd)

7. *S. Enteritidis* is characterised by its ovarian transmission pattern. Countries should set targets for eradicating (or significantly reducing) *S. Enteritidis* from egg-producing flocks through a guided policy for eradication from the top of the production pyramid, i.e. from grandparent *flocks* through breeder *flocks* to *layer flocks*.
8. ~~As far as the veterinary involvement is concerned,~~ The responsible *veterinarian* should evaluate ~~monitor~~ the results of *surveillance* testing for *Salmonella* and supervise the implementation of appropriate control measures. This information 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 ~~authorised~~ person responsible for notification should notify the *Competent Authority* if the presence of *Salmonella* of the relevant serotype is confirmed.

Article 6.5.6.

Prevention of *Salmonella* spread from infected flocks

If a *flock* is found infected with specific *Salmonella* serotypes of concern, the following actions should be taken in addition to general measures detailed in Chapter 6.4. Hygiene and Biosecurity Procedures in Poultry Production:

1. According to the epidemiological situation, investigations should be carried out to determine the origin of the *infection*.
2. Movement of *poultry flocks* at the end of the production cycle should only be allowed for *slaughter* or destruction. Special precautions should be taken in the transport, *slaughter* and processing of the birds, e.g. they could be sent to a separate slaughterhouse or processed at the end of a shift before cleaning and *disinfection* of the equipment.
3. Litter should not be reused. *Poultry* litter/faeces and other potentially contaminated farm waste should be disposed of in a safe manner to prevent the direct or indirect exposure of humans, livestock and wildlife to *Salmonella*. Particular care needs to be taken in regard to *poultry* litter/faeces used to fertilise plants intended for human consumption. If litter is not removed then it should be treated in a manner to inactivate infectious agents, to prevent the spread from one *flock* to the next.
4. Particular care should be taken in cleaning and *disinfection* of the *poultry* house and equipment.
5. Before restocking the facility, a bacteriological examination should be carried out as detailed in this Chapter and the *Terrestrial Manual*.

Article 6.5.7.**Recommendations for importation of live poultry (other than day-old birds)**

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

1. the *poultry* originated from an *establishment* that participates in a *Salmonella surveillance* programme in accordance with the recommendations in Article 6.5.4.;
2. the *poultry* originated from an *establishment* in which no evidence of *S. Enteritidis* and *S. Typhimurium* has been detected **prior to shipment** and have had no contact with birds or other material from *establishments* that do not comply with this chapter;
3. the *poultry* originated from an *establishment* that complies with the recommendations of Chapter 6.4.

Article 6.5.8**Recommendations for importation of day-old birds**

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

1. the *day-old birds* showed no clinical signs of salmonellosis on the day of shipment;
2. the *day-old birds* originated from a breeder *establishment* and hatchery that participate in a *Salmonella surveillance* programme in accordance with the recommendations in Article 6.5.4.;
3. the *day-old birds* originated from a breeder *establishment* and 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 **an establishment poultry** that do not comply with this chapter;
4. the *day-old birds* originated from a breeder *establishment* and hatchery that complies with the recommendations of Chapter 6.4.;
5. the *day-old birds* were shipped in new and clean *containers*.

Article 6.5.9**Recommendations for importation of hatching eggs**

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

1. the *hatching eggs* originated from a breeder *establishment* that participates in a *Salmonella surveillance* programme in accordance with the recommendations in Article 6.5.4.;
2. the *hatching eggs* originated from a breeder *establishment* in which no evidence of *S. Enteritidis* and *S. Typhimurium* has been detected and have had no contact with *poultry* or other material from *establishments* that do not comply with this Chapter;
3. the *hatching eggs* originated from a breeder *establishment* that complies with the recommendations of Chapter 6.4.;
4. the *hatching eggs* were shipped in new and clean packaging materials.

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~~CHAPTER 6.6.~~~~SALMONELLA ENTERITIDIS AND
SALMONELLA TYPHIMURIUM
IN POULTRY~~~~Article 6.6.1.~~~~Veterinary Authorities of importing countries should require:~~~~for breeding birds~~~~the presentation of an international veterinary certificate attesting that the birds:~~

- ~~1. come from an establishment which has been regularly monitored for the presence of Salmonella in conformity with the provisions of Chapter 6.4. (see Article 6.4.9.);~~
- ~~2. come from a flock of birds within the establishment in which no evidence of Salmonella enteritidis and Salmonella typhimurium has been detected and have had no contact with birds or other material from poultry flocks which do not comply with this standard;~~
- ~~3. come from an establishment which complies with the hygiene and disease security procedures referred to in Chapter 6.4.~~

~~Article 6.6.2.~~~~Veterinary Authorities of importing countries should require:~~~~for day old birds~~~~the presentation of an international veterinary certificate attesting that the day old birds:~~

- ~~1. showed no clinical sign of salmonellosis on the day of shipment;~~
- ~~2. come from an establishment and a hatchery which are regularly monitored for the presence of Salmonella in conformity with the provisions of Chapter 6.4. (see Article 6.4.9.);~~
- ~~3. come from a flock of birds within the establishment in which no evidence of Salmonella enteritidis or Salmonella typhimurium has been detected and have had no contact during setting, incubation or hatching with hatching eggs or other material from poultry flocks which do not comply with this standard;~~
- ~~4. come from an establishment and a hatchery which comply with the hygiene and disease security procedures referred to in Chapter 6.4.;~~
- ~~5. were shipped in clean and unused packages.~~

Annex XVII (contd)

~~Article 6.6.3.~~

~~Veterinary Authorities of importing countries should require:~~

~~for hatching eggs~~

~~the presentation of an international veterinary certificate attesting that the hatching eggs:~~

- ~~1. come from an *establishment* which is regularly monitored for the presence of *Salmonella* in conformity with the provisions of Chapter 6.4. (see Article 6.4.9.);~~
- ~~2. come from a *flock* of birds within the *establishment* in which no evidence of *Salmonella enteritidis* or *Salmonella typhimurium* has been detected and have had no contact with *hatching eggs* or material from *poultry flocks* which do not comply with this standard;~~
- ~~3. come from an *establishment* which complies with the hygiene and disease security procedures referred to in Chapter 6.4.;~~
- ~~4. were shipped in clean and unused packages.~~

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CHAPTER 6.7.

INTRODUCTION TO THE RECOMMENDATIONS FOR
CONTROLLING ANTIMICROBIAL RESISTANCE

Article 6.7.1.

Objective

The purpose of ~~this e~~ Chapters 6.8., 6.9., 6.10. and 6.11. is to provide methodologies for OIE Members to appropriately address the emergence or spread of resistant bacteria from the use of antimicrobial agents in animal husbandry and to contain antimicrobial resistance through controlling the use of antimicrobial agents.

Antimicrobial agents are essential drugs for human and animal health and welfare. The OIE recognises the need for access to antimicrobial agents in veterinary medicine: antimicrobial agents are essential for treating, controlling and preventing infectious diseases in animals. The OIE therefore considers that ensuring continued access to effective antimicrobial agents is a priority important.

The OIE recognises that antimicrobial resistance is a global public and animal health concern that is influenced by the usage of antimicrobial agents in humans, animals and elsewhere. Those working in the human, animal and plant sectors have a shared responsibility to prevent or minimise pressures for the selection of antimicrobial resistance factors in humans and animals. Arising from its mandate for the protection of animal health and food safety, the OIE developed these chapters to provide guidance to Members in regard to risks in the animal sector.

The application of *risk management* measures should be based on relevant international standards on ~~microbiological~~ *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.

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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, feral and partly domesticated *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 ~~herds~~ 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*.

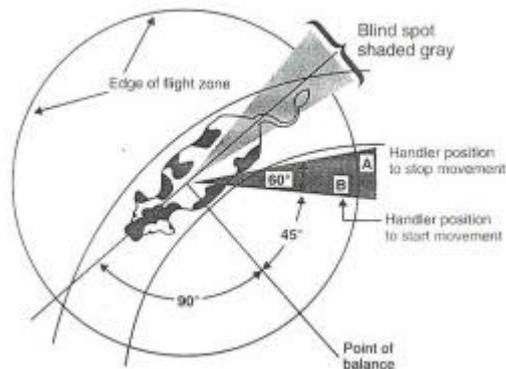
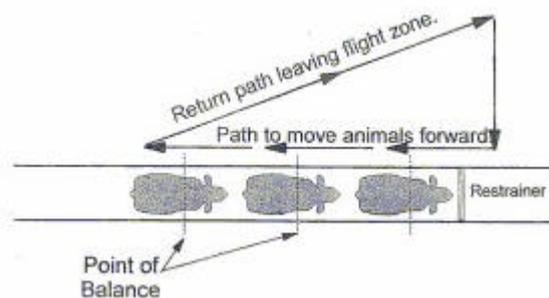
Animal handlers should use the point of balance at the *animal's* shoulder to move *animals*, adopting a position behind the point of balance to move an *animal* forward and in front of the point of balance to move it backward.

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 ~~all~~ most 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*.

Annex XIX (contd)

Domestic *animals* can hear over a greater range of frequencies than humans and are more sensitive to higher frequencies. They tend to be alarmed by constant loud noises and by sudden noises, which may cause them to panic. Sensitivity to such noises should also be taken into account when handling *animals*.

An example of a flight zone (cattle)**Handler movement pattern to move cattle forward**2. Distractions and their removal

Design of new *loading* and *unloading* facilities or modification of existing facilities should aim to minimise the potential for distractions that may cause approaching *animals* to stop, baulk or turn back. Below are examples of common distractions and methods for eliminating them:

- reflections on shiny metal or wet floors - move a lamp or change lighting;
- dark entrances — illuminate with indirect lighting which does not shine directly into the eyes of approaching *animals*;
- animals* seeing moving people or equipment up ahead — install solid sides on chutes and races or install shields;
- dead ends — avoid if possible by curving the passage, or make an illusory passage;

- e) chains or other loose objects hanging in chutes or on fences — remove them;
- f) uneven floors or a sudden drop in floor levels — avoid uneven floor surfaces or install a solid false floor to provide an illusion of a solid and continuous walking surface;
- g) sounds of air hissing from pneumatic equipment — install silencers or use hydraulic equipment or vent high pressure to the external environment using flexible hosing;
- h) clanging and banging of metal objects — install rubber stops on gates and other devices to reduce metal to metal contact;
- i) air currents from fans or air curtains blowing into the face of *animals* — redirect or reposition equipment.

Article 7.3.3.

Responsibilities

Once the decision to transport the *animals* has been made, the *welfare* of the *animals* during their *journey* is the paramount consideration and is the joint responsibility of all people involved. The individual responsibilities of persons involved will be described in more detail in this Article.

The roles of each of those responsible are defined below:

1. The owners and managers of the *animals* are responsible for:
 - a) the general health, overall *welfare* and fitness of the *animals* for the *journey*;
 - b) ensuring compliance with any required veterinary or other certification;
 - c) the presence of an *animal handler* competent for the species being transported during the *journey* with the authority to take prompt action; in case of transport by individual trucks, the truck driver may be the sole *animal handler* during the *journey*;
 - d) the presence of an adequate number of *animal handlers* during *loading* and *unloading*;
 - e) ensuring that equipment and veterinary assistance are provided as appropriate for the species and the *journey*.
2. Business agents or buying/selling agents are responsible for:
 - a) selection of *animals* that are fit to travel;
 - b) availability of suitable facilities at the start and at the end of the *journey* for the assembly; *loading*, transport, *unloading* and holding of *animals*, including for any stops at *resting points* during the *journey* and for emergencies.
3. *Animal handlers* are responsible for the humane handling and care of the *animals*, especially during *loading* and *unloading*, and for maintaining a *journey* log. To carry out their responsibilities, they should have the authority to take prompt action. In the absence of a separate *animal handler*, the driver is the *animal handler*.
4. Transport companies, *vehicle* owners and drivers are responsible for planning the *journey* to ensure the care of the *animals*; in particular they are responsible for:

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- a) choosing appropriate *vehicles* for the species transported and the *journey*;
 - b) ensuring that properly trained staff are available for *loading/unloading* of *animals*;
 - c) ensuring adequate competency of the driver in matters of *animal welfare* for the species being transported in case a separate *animal handler* is not assigned to the truck;
 - d) developing and keeping up-to-date contingency plans to address emergencies (including adverse weather conditions) and minimise stress during transport;
 - e) producing a *journey* plan which includes a *loading* plan, *journey* duration, itinerary and location of resting places;
 - f) *loading* only those *animals* which are fit to travel, for their correct *loading* into the *vehicle* and their inspection during the *journey*, and for appropriate responses to problems arising; if its fitness to travel is in doubt, the *animal* should be examined by a *veterinarian* in accordance with point 3a) of Article 7.3.7.;
 - g) *welfare* of the *animals* during the actual transport.
5. Managers of facilities at the start and at the end of the *journey* and at *resting points* are responsible for:
- a) providing suitable premises for *loading, unloading* and securely holding the *animals*, with water and feed when required, and with protection from adverse weather conditions until further transport, sale or other use (including rearing or slaughter);
 - b) providing an adequate number of *animal handlers* to load, unload, drive and hold *animals* in a manner that causes minimum stress and injury; in the absence of a separate *animal handler*, the driver is the *animal handler*;
 - c) minimising the opportunities for disease transmission;
 - d) providing appropriate facilities, with water and feed when required;
 - e) providing appropriate facilities for emergencies;
 - f) providing facilities for washing and disinfecting *vehicles* after *unloading*;
 - g) providing facilities and competent staff to allow the humane *killing* of *animals* when required;
 - h) ensuring proper rest times and minimal delay during stops.
6. The responsibilities of *Competent Authorities* include:
- a) establishing minimum standards for *animal welfare*, including requirements for inspection of *animals* before, during and after their travel, defining 'fitness to travel' and appropriate certification and record keeping;
 - b) setting standards for facilities, *containers* and *vehicles* for the transport of *animals*;
 - c) setting standards for the competence of *animal handlers*, drivers and managers of facilities in relevant issues in *animal welfare*;

- d) ensuring appropriate awareness and training of *animal handlers*, drivers and managers of facilities in relevant issues in *animal welfare*;
 - e) implementation of the standards, including through accreditation of / interaction with other organisations;
 - f) monitoring and evaluating the effectiveness of standards of health and other aspects of *welfare*;
 - g) monitoring and evaluating the use of veterinary medications;
 - h) giving animal consignments priority at frontiers in order to allow them to pass without unnecessary delay.
7. All individuals, including *veterinarians*, involved in transporting *animals* and the associated handling procedures should receive appropriate training and be competent to meet their responsibilities.
 8. The receiving *Competent Authority* should report back to the sending *Competent Authority* on significant *animal welfare* problems which occurred during the *journey*.

Article 7.3.4.

Competence

1. All people responsible for *animals* during *journeys*, should be competent according to their responsibilities listed in Article 7.3.3. Competence may be gained through formal training and/or practical experience.
2. The assessment of the competence of *animal handlers* should at a minimum address knowledge, and ability to apply that knowledge, in the following areas:
 - a) planning a *journey*, including appropriate *space allowance*, and feed, water and ventilation requirements;
 - b) responsibilities for *animals* during the *journey*, including *loading* and *unloading*;
 - c) sources of advice and assistance;
 - d) animal behaviour, general signs of *disease*, and indicators of poor *animal welfare* such as stress, pain and fatigue, and their alleviation;
 - e) assessment of fitness to travel; if fitness to travel is in doubt, the *animal* should be examined by a *veterinarian*;
 - f) relevant authorities and applicable transport regulations, and associated documentation requirements;
 - g) general disease prevention procedures, including cleaning and *disinfection*;
 - h) appropriate methods of animal handling during transport and associated activities such as assembling, *loading* and *unloading*;
 - i) methods of inspecting *animals*, managing situations frequently encountered during transport such as adverse weather conditions, and dealing with emergencies, including humane *killing*;

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- 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 according to factors such as:

- a) the ability of the *animals* to cope with the stress of transport (such as very young, old, lactating or pregnant *animals*);
- b) the previous transport experience of the *animals*;
- c) the likely onset of fatigue;
- d) the need for special attention;
- e) the need for feed and water;
- f) the increased susceptibility to injury and *disease*;
- g) *space allowance*, *vehicle* design, road conditions and driving quality;
- h) weather conditions;
- i) *vehicle* type used, terrain to be traversed, road surfaces and quality, skill and experience of the driver.

4. Vehicle and container design and maintenance

- a) *Vehicles* and *containers* used for the transport of *animals* should be designed, constructed and fitted as appropriate for the species, size and weight of the *animals* to be transported. Special attention should be paid to avoid injury to *animals* through the use of secure smooth fittings free from sharp protrusions. The avoidance of injury to drivers and *animal handlers* while carrying out their responsibilities should be emphasised.
- b) *Vehicles* and *containers* should be designed with the structures necessary to provide protection from adverse weather conditions and to minimise the opportunity for *animals* to escape.
- c) In order to minimise the likelihood of the spread of infectious *disease* during transport, *vehicles* and *containers* should be designed to permit thorough cleaning and *disinfection*, and the containment of faeces and urine during a *journey*.
- d) *Vehicles* and *containers* should be maintained in good mechanical and structural condition.
- e) *Vehicles* and *containers* should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported; the ventilation system (natural or mechanical) should be effective when the *vehicle* is stationary, and the airflow should be adjustable.

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- 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 eages/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*. However, under tropical and subtropical conditions *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*.
- b) If the *animals* are in crates or on multi-tiered *vehicles* which do not allow free access for observation, for example where the roof of the tier is too low, *animals* cannot be inspected adequately, and serious injury or *disease* could go undetected. In these circumstances, a shorter *journey* duration should be allowed, and the maximum duration will vary according to the rate at which problems arise in the species and under the conditions of transport.

9. Control of disease

As animal transport is often a significant factor in the spread of infectious *diseases*, *journey* planning should take the following into account:

- a) mixing of *animals* from different sources in a single consignment should be minimised;
- b) contact at *resting points* between *animals* from different sources should be avoided;
- c) when possible, *animals* should be vaccinated against *diseases* to which they are likely to be exposed at their destination;
- d) medications used prophylactically or therapeutically should be approved by the *Veterinary Authority* of the *exporting country* and the *importing country* and should only be administered by a *veterinarian* or other person who has been instructed in their use by a *veterinarian*.

Annex XIX (contd)10. Emergency response procedures

There should be an emergency management plan that identifies the important adverse events that may be encountered during the *journey*, the procedures for managing each event and the action to be taken in an emergency. For each important event, the plan should document the actions to be undertaken and the responsibilities of all parties involved, including communications and record keeping.

11. Other considerations

- a) Extreme weather conditions are hazardous for *animals* undergoing transport and require appropriate *vehicle* design to minimise risks. Special precautions should be taken for *animals* that have not been acclimatised or which are unsuited to either hot or cold conditions. In some extreme conditions of heat or cold, *animals* should not be transported at all.
- b) In some circumstances, transportation during the night may reduce thermal stress or the adverse effects of other external stimuli.

Article 7.3.6.

Documentation

1. *Animals* should not be loaded until the documentation required to that point is complete.
2. The documentation accompanying the consignment should include:
 - a) *journey* travel plan and emergency management plan;
 - b) date, time and place of *loading* and *unloading*;
 - c) veterinary certification, when required;
 - d) *animal welfare* competencies of the driver (under study);
 - e) *animal identification* to allow *animal traceability* to the premises of departure and, where possible, to the premises of origin;
 - f) details of any *animals* considered at particular risk of suffering poor *welfare* during transport (point 3e) of Article 7.3.7.);
 - g) documentation of the period of rest, and access to feed and water, prior to the *journey*;
 - h) *stocking density* estimate for each load in the consignment;
 - i) the *journey log* - daily record of inspection and important events, including records of morbidity and mortality and actions taken, climatic conditions, rest stops, travel time and distance, feed and water offered and estimates of consumption, medication provided, and mechanical defects.
3. When veterinary certification is required to accompany consignments of *animals*, it should address:
 - a) fitness of *animals* to travel;
 - b) *animal identification* (description, number, etc.);

- c) health status including any tests, treatments and vaccinations carried out;
- d) when required, details of *disinfection* carried out.

At the time of certification, the *veterinarian* should notify the *animal handler* or the driver of any factors affecting the fitness of *animals* to travel for a particular *journey*.

Article 7.3.7.

Pre-journey period

1. General considerations

- a) Pre-*journey* rest is necessary if the *welfare* of *animals* has become poor during the collection period because of the physical environment or the social behaviour of the *animals*. The need for rest should be judged by a *veterinarian* or other competent person.
- b) Pre-*journey* assembly/holding areas should be designed to:
 - i) securely hold the *animals*;
 - ii) maintain a safe environment from hazards, including predators and *disease*;
 - iii) protect *animals* from exposure to severe weather conditions;
 - iv) allow for maintenance of social groups;
 - v) allow for rest, and appropriate water and feed.
- c) Consideration should be given to the previous transport experience, training and conditioning of the *animals*, if known, as these may reduce fear and stress in *animals*.
- d) Feed and water should be provided pre-*journey* if the *journey* duration is greater than the normal inter-feeding and drinking interval for the *animal*. Recommendations for specific-species are described in detail in Article 7.3.12.
- e) When *animals* are to be provided with a novel diet or method of feed or water provision during the *journey*, an adequate period of adaptation should be allowed.
- f) Before each *journey*, *vehicles* and *containers* should be thoroughly cleaned and, if necessary, treated for animal health and public health purposes, using methods approved by the *Competent Authority*. When cleaning is necessary during a *journey*, this should be carried out with the minimum of stress and risks to the *animals*.
- g) Where an *animal handler* believes that there is a significant risk of *disease* among the *animals* to be loaded or significant doubt as to their fitness to travel, the *animals* should be examined by a *veterinarian*.

2. Selection of compatible groups

Compatible groups should be selected before transport to avoid adverse *animal welfare* consequences. The following recommendations should be applied when assembling groups of *animals*:

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- 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.

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- 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.

Travel1. General considerations

- a) Drivers and *animal handlers* should check the load immediately before departure to ensure that the *animals* have been properly loaded. Each load should be checked again early in the trip and adjustments made as appropriate. Periodic checks should be made throughout the trip, especially at rest or refuelling stops or during meal breaks when the *vehicle* is stationary.
- b) Drivers should utilise smooth, defensive driving techniques, without sudden turns or stops, to minimise uncontrolled movements of the *animals*.

2. Methods of restraining or containing animals

- a) Methods of restraining *animals* should be appropriate to the species and age of *animals* involved and the training of the individual *animal*.
- b) Recommendations for specific species are described in detail in Article 7.3.12.

3. Regulating the environment within vehicles or containers

- a) *Animals* should be protected against harm from hot or cold conditions during travel. Effective ventilation procedures for maintaining the environment within *vehicles* or *containers* will vary according to whether conditions are cold, hot and dry or hot and humid, but in all conditions a build-up of noxious gases should be prevented.
- b) The environment within *vehicles* or *containers* in hot and warm weather can be regulated by the flow of air produced by the movement of the *vehicle*. In warm and hot weather, the duration of *journey* stops should be minimised and *vehicles* should be parked under shade, with adequate and appropriate ventilation.
- c) To minimise slipping and soiling, and maintain a healthy environment, urine and faeces should be removed from floors when necessary and disposed of in such a way as to prevent the transmission of *disease* and in compliance with all relevant health and environmental legislation.

4. Sick, injured or dead animals

- a) A driver or an *animal handler* finding sick, injured or dead *animals* should act according to a predetermined emergency response plan.
- b) Sick or injured animals should be segregated.
- c) Ferries (roll-on roll-off) should have procedures to treat sick or injured *animals* during the *journey*.
- d) In order to reduce the likelihood that animal transport will increase the spread of infectious *disease*, contact between transported *animals*, or the waste products of the transported *animals*, and other farm *animals* should be minimised.
- e) During the *journey*, when disposal of a dead *animal* becomes necessary, this should be carried out in such a way as to prevent the transmission of *disease* and in compliance with all relevant health and environmental legislation.

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- f) When *killing* is necessary, it should be carried out as quickly as possible and assistance should be sought from a *veterinarian* or other person(s) competent in humane *killing* procedures. Recommendations for specific species are described in Chapter 7.6. on killing of *animals* for disease control purposes.

5. Water and feed requirements

- a) If *journey* duration is such that feeding or watering is required or if the species requires feed or water throughout, access to suitable feed and water for all the *animals* (appropriate for their species and age) carried in the *vehicle* should be provided. There should be adequate space for all *animals* to move to the feed and water sources and due account taken of likely competition for feed.
- b) Recommendations for specific species are described in detail in Article 7.3.12.

6. Rest periods and conditions

- a) *Animals* that are being transported should be rested at appropriate intervals during the *journey* and offered feed and water, either on the *vehicle* or, if necessary, unloaded into suitable facilities.
- b) Suitable facilities should be used en route, when resting requires the *unloading* of the *animals*. These facilities should meet the needs of the particular animal species and should allow access of all *animals* to feed and water.

7. In-transit observations

- a) *Animals* being transported by road should be observed soon after a *journey* is commenced and whenever the driver has a rest stop. After meal breaks and refuelling stops, the *animals* should be observed immediately prior to departure.
- b) *Animals* being transported by rail should be observed at each scheduled stop. The responsible rail transporter should monitor the progress of trains carrying *animals* and take all appropriate action to minimise delays.
- c) During stops, it should be ensured that the *animals* continue to be properly confined, have appropriate feed and water, and their physical condition is satisfactory.

Article 7.3.10.

Unloading and post-journey handling1. General considerations

- a) The required facilities and the principles of animal handling detailed in Article 7.3.8. apply equally to *unloading*, but consideration should be given to the likelihood that the *animals* will be fatigued.
- b) *Unloading* should be supervised and/or conducted by an *animal handler* with knowledge and experience of the behavioural and physical characteristics of the species being unloaded. *Animals* should be unloaded from the *vehicle* into appropriate facilities as soon as possible after arrival at the destination but sufficient time should be allowed for *unloading* to proceed quietly and without unnecessary noise, harassment or force.

- c) Facilities should provide all *animals* with appropriate care and comfort, adequate space and ventilation, access to feed (if appropriate) and water, and shelter from extreme weather conditions.
- d) For details regarding the *unloading* of *animals* at a *slaughterhouse*, see Chapter 7.5. on slaughter of animals for human consumption.

2. Sick or injured animals

- a) An *animal* that has become sick, injured or disabled during a *journey* should be appropriately treated or humanely killed (see Chapter 7.6. on killing of *animals* for disease control purposes). If necessary, veterinary advice should be sought in the care and treatment of these *animals*. In some cases, where *animals* are non-ambulatory due to fatigue, injury or sickness, it may be in the best *welfare* interests of the *animal* to be treated or killed aboard the *vehicle*. Assistance should be sought from a *veterinarian* or other person(s) competent in humane *killing* procedures.
- b) At the destination, the *animal handler* or the driver during transit should ensure that responsibility for the *welfare* of sick, injured or disabled *animals* is transferred to a *veterinarian* or other suitable person.
- c) If treatment or humane *killing* is not possible aboard the *vehicle*, there should be appropriate facilities and equipment for the humane *unloading* of *animals* that are non-ambulatory due to fatigue, injury or sickness. These *animals* should be unloaded in a manner that causes the least amount of suffering. After *unloading*, separate pens and other appropriate facilities should be available for sick or injured *animals*.
- d) Feed, if appropriate, and water should be available for each sick or injured *animal*.

3. Addressing disease risks

The following should be taken into account in addressing the greater risk of *disease* due to animal transport and the possible need for segregation of transported *animals* at the destination:

- a) increased contact among *animals*, including those from different sources and with different disease histories;
- b) increased shedding of pathogens and increased susceptibility to infection related to stress and impaired defences against disease, including immunosuppression;
- c) exposure of *animals* to pathogens which may contaminate *vehicles*, *resting points*, *markets*, etc.

4. Cleaning and disinfection

- a) *Vehicles*, crates, *containers*, etc. used to carry the *animals* should be cleaned before re-use through the physical removal of manure and bedding by scraping, washing and flushing with water and detergent. This should be followed by *disinfection* when there are concerns about disease transmission.
- b) Manure, litter, bedding and the bodies of any *animals* which die during the *journey* should be disposed of in such a way as to prevent the transmission of *disease* and in compliance with all relevant health and environmental legislation.

Annex XIX (contd)

- c) Establishments like livestock *markets, slaughterhouses*, resting sites, railway stations, etc. where *animals* are unloaded should be provided with appropriate areas for the cleaning and *disinfection* of *vehicles*.

Article 7.3.11.

Actions in the event of a refusal to allow the completion of the journey

1. The *welfare* of the *animals* should be the first consideration in the event of a refusal to allow the completion of the *journey*.
2. When the *animals* have been refused import, the *Competent Authority* of the *importing country* should make available suitable isolation facilities to allow the *unloading* of *animals* from a *vehicle* and their secure holding, without posing a risk to the health of national herd or flock, pending resolution of the situation. In this situation, the priorities should be:
 - a) the *Competent Authority* of the *importing country* should provide urgently in writing the reasons for the refusal;
 - b) in the event of a refusal for animal health reasons, the *Competent Authority* of the *importing country* should provide urgent access to a *veterinarian*, where possible an OIE *veterinarian(s)* appointed by the Director General, to assess the health status of the *animals* with regard to the concerns of the *importing country*, and the necessary facilities and approvals to expedite the required diagnostic testing;
 - c) the *Competent Authority* of the *importing country* should provide access to allow continued assessment of the health and other aspects of the *welfare* of the *animals*;
 - d) if the matter cannot be promptly resolved, the *Competent Authorities* of the *exporting* and *importing countries* should call on the OIE to mediate.
3. In the event that a *Competent Authority* requires the *animals* to remain on the *vehicle*, the priorities should be:
 - a) to allow provisioning of the *vehicle* with water and feed as necessary;
 - b) to provide urgently in writing the reasons for the refusal;
 - c) to provide urgent access to an independent *veterinarian(s)* to assess the health status of the *animals*, and the necessary facilities and approvals to expedite the required diagnostic testing in the event of a refusal for animal health reasons;
 - d) to provide access to allow continued assessment of the health and other aspects of the *welfare* of the *animals*, and the necessary actions to deal with any animal issues which arise.
4. The OIE should utilise its informal procedure for dispute mediation to identify a mutually agreed solution which will address animal health and any other *welfare* issues in a timely manner.

Article 7.3.12.

Species-specific issues

Camelids of the new world in this context comprise llamas, alpacas, guanaco and vicuna. They have good eyesight and, like sheep, can negotiate steep slopes, though ramps should be as shallow as possible. They load most easily in a bunch as a single *animal* will strive to rejoin the others. Whilst they are usually docile, they have an unnerving habit of spitting in self-defence. During transport, they usually lie down. They frequently extend their front legs forward when lying, so gaps below partitions should be high enough so that their legs are not trapped when the *animals* rise.

Cattle are sociable *animals* and may become agitated if they are singled out. Social order is usually established at about two years of age. When groups are mixed, social order has to be re-established and aggression may occur until a new order is established. Crowding of cattle may also increase aggression as the *animals* try to maintain personal space. Social behaviour varies with age, breed and sex; *Bos indicus* and *B. indicus*-cross *animals* are usually more temperamental than European breeds. Young bulls, when moved in groups, show a degree of playfulness (pushing and shoving) but become more aggressive and territorial with age. Adult bulls have a minimum personal space of six square metres. Cows with young calves can be very protective, and handling calves in the presence of their mothers can be dangerous. Cattle tend to avoid “dead end” in passages.

Goats should be handled calmly and are more easily led or driven than if they are excited. When goats are moved, their gregarious tendencies should be exploited. Activities which frighten, injure or cause agitation to *animals* should be avoided. Bullying is particularly serious in goats and can reflect demands for personal space. Housing strange goats together could result in fatalities, either through physical violence, or subordinate goats being refused access to food and water.

Horses in this context include donkeys, mules and hinnies. They have good eyesight and a very wide angle of vision. They may have a history of *loading* resulting in good or bad experiences. Good training should result in easier *loading*, but some horses can prove difficult, especially if they are inexperienced or have associated *loading* with poor transport conditions. In these circumstances, two experienced *animal handlers* can load an *animal* by linking arms or using a strop below its rump. Blindfolding may even be considered. Ramps should be as shallow as possible. Steps are not usually a problem when horses mount a ramp, but they tend to jump a step when descending, so steps should be as low as possible. Horses benefit from being individually stalled, but may be transported in compatible groups. When horses are to travel in groups, their shoes should be removed. Horses are prone to respiratory *disease* if they are restricted by period by tethers that prevent the lowering and lifting of their heads.

Pigs have poor eyesight, and may move reluctantly in unfamiliar surroundings. They benefit from well lit loading bays. Since they negotiate ramps with difficulty, these should be as level as possible and provided with secure footholds. Ideally, a hydraulic lift should be used for greater heights. Pigs also negotiate steps with difficulty. A good ‘rule-of-thumb’ is that no step should be higher than the pig’s front knee. Serious aggression may result if unfamiliar *animals* are mixed. Pigs are highly susceptible to heat stress. Pigs are susceptible to motion sickness when in transit. Feed deprivation prior to loading may be beneficial to prevent motion sickness.

Annex XIX (contd)

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.

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CHAPTER 7.4.

TRANSPORT OF ANIMALS BY AIR

Article 7.4.1.

Livestock containers1. Design

a) General principles of design

The *container* should:

- conform to the size of the standard pallet of the aircraft that will be used to transport *animals*; the common sizes are: 224 x 318 cm (88 x 125 in.) and 244 x 318 cm (96 x 125 in.);
- not be constructed of material that could be harmful to the *animals* health or *welfare*;
- allow observation of the *animals* and be marked on opposite sides with the International Air Transport Association (IATA) symbols which indicate *animals* and the upright position;
- allow emergency access to *animals*;
- allow the *animal* to stand in its normal position without touching the roof of the *container* or, in the case of open *containers*, the restraining nets, and provide at least 10 cm (4 in.) clearance above the *animals* head when standing in its normal position; in the case of horses, provide sufficient space above the horses head (21 cm, 8 in. recommended) to allow for the movement required to maintain the horses balance;
- protect the *animals* from adverse weather;
- ensure *animals* stand on a suitable floor to prevent slipping or injury;
- have adequate strength to ensure the safety of the *animals* and to prevent the *animals* from escaping;
- ensure doors can be opened and closed easily, but be secured so that they cannot be opened accidentally;
- be free of any nails, bolts and other protrusions or sharp edges that could cause injuries;
- be designed to minimise the risk of any opening or space entrapping any portion of the *animals* body;
- if reusable, crates should be constructed of impermeable material that is easily cleaned and disinfected;
- ensure faeces and urine cannot escape from the crate; this requires a minimum upturn of 20 cm but it ~~must~~ should not block any ventilation openings;

Annex XIX (contd)

- if designated for stacking be stable, not block any ventilation space and prevent urine and faeces from leaking into the *containers* below when stacked;
- allow for a facility for provision of water and possibly food during transportation of longer than 6 hours duration.

b) Ventilation

The *container* design should:

- provide adequate ventilation taking into consideration the species stocking density, maximum temperature and humidity of the points of departure, destination, and any interim technical stops;
- allow the normal resting or sleeping position to be assumed for certain species and juvenile *animals*;
- ensure there is no dead air space in the *container*;
- provide ventilation openings on the walls equal to at least 16% of the wall area; this may be reduced if the *container* has an open top;
- in the case of two-tiered *containers*, ventilation in the sides should be for cattle equivalent to not less than 20% of the floor area of each deck, and for pigs and sheep up to 40% of the floor area of each deck;
- have ventilation openings on all four sides of the crate except that two walls may have reduced ventilation space and the other walls have increased space where required by the positioning of the crates during transportation and/or the ventilation pattern of the aircraft;
- ensure that any internal supports or dividers do not block the cross ventilation;
- not have a solid wall above the height of the animal's head in normal resting position;
- in those species where the mouth is normally held near the floor, have at least 25 cm (10 in.) of ventilation space at the level of the *animals* 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.

Annex XIX (contd)

- In order to reduce fighting, swine shipped in group pens should be housed together as a group prior to shipment and not be mixed with other swine before *loading* on the aircraft.
- Mature boars and incompatible females should be shipped in individual crates.
- Individual crates should be 20 cm (8 in.) longer than the body, 15 cm (6 in.) higher than the loin of the pig and of sufficient width, to allow the pigs to lie on their side.

c) Cattle

Crates used to transport cattle should:

- if multi-tiered or roofed, have at least 33% of the roof and four walls as open space;
- have at least one ventilation opening 20-25 cm (8-10 in.) above the floor which is of such width that it will not cause injuries to the feet.

Adult bulls should be transported separately unless they have been accustomed to each other. Cattle with and without horns should be separated from each other.

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 ~~w~~ 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:

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.

Females	Maximum number of days since the last service or successful mating
Horses	300
Cows	250
Deer (axis, fallow and sika)	170
(red deer, reindeer)	185
Ewes (sheep)	115
Nannies (goats)	115
Sows (pigs)	90

Article 7.4.3.

Stocking density

The current *stocking densities* agreed by the International Air Transport Association (IATA) should continue to be accepted. However, the graphs giving the space requirements should be extended to take into account *animals* larger and smaller than those dealt with currently.

1. General considerations

When calculating stocking rates, the following should be taken into account:

- a) it is essential that accurate weights of *animals* are obtained in view of the limitations imposed by the load capabilities of the aircraft and the space required per *animal*;
- b) in narrow bodied aircraft, there is a loss of floor area in the upper tier of two-tier penning due to the contours of the aircraft;
- c) space available should be calculated on the inside measurements of the crates or penning system used, not on the floor space of the aircraft;
- d) multi-tiered crates, high outdoor temperatures at departure, arrival or stopover points, or extreme length of the trip will require an increase in the amount of space per *animal*; a 10% 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;

Annex XIX (contd)

- 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		
					10 m ²	214x264 cm	214x308 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 livestock1. 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 **must 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 **must 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 **must should** be done far enough in advance of the departure date to allow for immunity to develop.

Veterinary certification and serological testing **must 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 **must 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.

Annex XIX (contd)

- 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 **must 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 slaughter

Emergency *slaughter* of *animals* in aircraft should, in general, only occur when the safety of the aircraft, crew or other *animals* are involved.

Every aircraft transporting *animals* should have a method of killing the *animals* with minimum pain and someone trained in that method.

In all cases when horses or other large *animals* are to be carried, the method of killing should be discussed with the airline during the planning stages. Suitable methods are:

1. Captive bolt stunner, followed by an injection of a lethal chemical
 - a) Operator should be trained to use the captive bolt stunner on the species or type of *animal* being transported.
 - b) An expert should determine that the type of captive bolt pistol is adequate for all the *animals* being transported.
 - c) Some airlines and countries may prohibit the carriage of captive bolt pistols.
 - d) The user should recognise that the noise associated with the captive bolt may excite other *animals*.
 - e) The requirement that the captive bolt pistol is accurately centered may be difficult to achieve with an excited *animal*.

Annex XIX (contd)2. Injection of a chemical

- a) Various chemicals may be used to sedate, immobilize or kill *animals*.
- b) Central nervous system depressants such as barbiturate euthanasia solutions **must should** be injected directly into a vein to be effective. This is not normally practical for anyone but an experienced *veterinarian* or an especially trained and experienced attendant, where the *animal* is sufficiently fractious to require euthanasia.
- c) Sedatives such as promazine and its derivatives may make the *animal* more fractious (see Article 7.4.7.).
- d) Immobilizing solutions such as succinylcholine are not humane.

3. Firearms

Airlines do not permit the use of firearms which discharge a free bullet because of the danger to the aircraft.

Article 7.4.10.

Handling of food and waste material

Waste material which contains anything of animal origin including food, litter, manure, or animal feed should be handled, collected and disposed of in a manner that ensures it will not be fed to livestock. It should be collected in specified areas, and stored and transported in closed, leakproof *containers*.

Some *importing countries* legislation may prohibit or restrict the use of hay or straw during the transportation period. Unloading of hay, straw, other animal feed and litter may be restricted or prohibited by in *transit countries*.

Article 7.4.11.

Disposal of food and waste material

Recommended methods of disposal are:

- a) incineration to an ash;
- b) heating at an internal temperature of at least of 100°C for 30 minutes, then disposal in a land fill site;
- c) controlled burial in a land fill site.

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CHAPTER 7.5.

SLAUGHTER OF ANIMALS

Article 7.5.1.

General principles1. Object

These recommendations address the need to ensure the *welfare* of food *animals* during pre-slaughter and slaughter processes, until they are dead.

These recommendations apply to the *slaughter* in *slaughterhouses* of the following domestic *animals*: cattle, buffalo, bison, sheep, goats, camelids, deer, horses, pigs, ratites, rabbits and *poultry*. ~~Many of the recommendations do not apply to rabbits and *poultry* because of the specific manner of handling these *animals*.~~ Other *animals*, wherever they have been reared, and all *animals* slaughtered outside *slaughterhouses* should be managed to ensure that their *transport*, *lairage*, *restraint* and *slaughter* is carried out without causing undue stress to the *animals*, the principles underpinning these recommendations apply also to these *animals*.

2. Personnel

Persons engaged in the *unloading*, *moving*, *lairage*, *care*, *restraint*, *stunning*, *slaughter* and *bleeding* of *animals* play an important role in the *welfare* of those *animals*. For this reason, there should be a sufficient number of personnel, who should be patient, considerate, competent and familiar with the recommendations outlined in the present Chapter and their application within the national context.

Competence may be gained through formal training and/or practical experience. This competence should be demonstrated through a current certificate from the *Competent Authority* or from an independent body accredited by the *Competent Authority*.

The management of the *slaughterhouse* and the *Veterinary Services* should ensure that *slaughterhouse* staff are competent and carry out their tasks in accordance with the principles of *animal welfare*.

3. Animal behaviour

Animal handlers should be experienced and competent in handling and moving farm livestock, and understand the behaviour patterns of *animals* and the underlying principles necessary to carry out their tasks.

The behaviour of individual *animals* or groups of *animals* will vary, depending on their breed, sex, temperament and age and the way in which they have been reared and handled. Despite these differences, the following behaviour patterns which are always present to some degree in domestic *animals*, should be taken into consideration in handling and moving the *animals*.

Most domestic livestock are kept in ~~herds~~ groups and follow a leader by instinct.

Animals which are likely to harm each other in a group situation should not be mixed at *slaughterhouses*.

The desire of some *animals* to control their personal space should be taken into account in designing facilities.

Annex XIX (contd)

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.

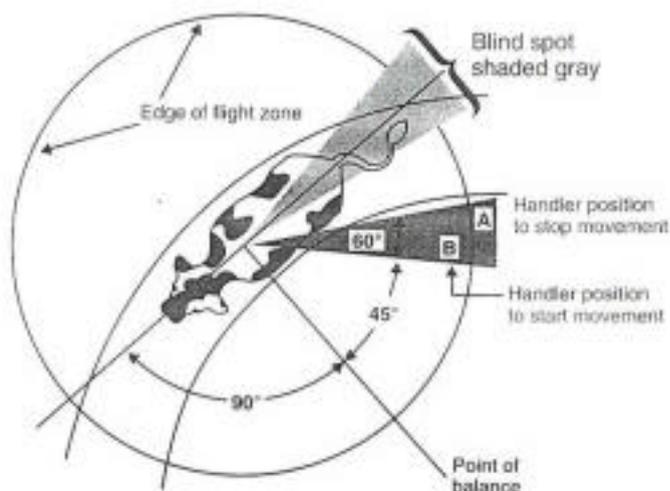
Animal handlers should use the point of balance at the *animal's* shoulder to move *animals*, adopting a position behind the point of balance to move an *animal* forward and in front of the point of balance to move it backward.

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.

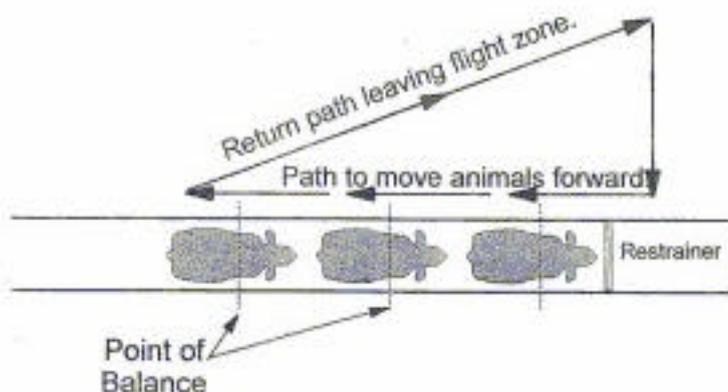
Although ~~all~~ most domestic *animals* have a highly sensitive sense of smell, they react in different ways to the smells of *slaughterhouses*. Smells which cause fear or other negative responses should be taken into consideration when managing *animals*.

Domestic *animals* can hear over a greater range of frequencies than humans and are more sensitive to higher frequencies. They tend to be alarmed by constant loud noise and by sudden noises, which may cause them to panic. Sensitivity to such noises should also be taken into account when handling *animals*.

An example of a flight zone (cattle)



Handler movement pattern to move cattle forward



4. Distractions and their removal

Distractions that may cause approaching *animals* to stop, baulk or turn back should be designed out from new facilities or removed from existing ones. Below are examples of common distractions and methods for eliminating them:

- a) reflections on shiny metal or wet floors — move a lamp or change lighting;
- b) dark entrances to chutes, races, stun boxes or conveyor restrainers — illuminate with indirect lighting which does not shine directly into the eyes of approaching *animals*;
- 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. These lairage conditions may not apply to poultry.
- 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. These conditions may not apply to poultry.

Moving and handling animals

1. General considerations

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. These conditions may not apply to poultry.
- 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, 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.
- viii) Performance standards should be established to evaluate the use of such instruments. Numerical scoring may be used to measure the percentage of *animals* moved with an electric instrument and the percentage of *animals* slipping or falling at a point in the *slaughterhouse*. Any risk of compromising *animal welfare*, for example slippery floor, should be investigated immediately and the defect rectified to eliminate the problem. In addition to resource-based measures, outcome-based measures (e.g. bruises, lesions, behaviour, and mortality) should be used to monitor the level of welfare of the *animals*.

2. Specific considerations for poultry

Stocking density in transport crates should be optimum to suit climatic conditions and to maintain species-specific thermal comfort within containers.

Care is especially necessary during loading and unloading to avoid wings or legs being caught on crates, leading to dislocated or broken wing 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 the poorly designed and/or constructed 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.

Annex XIX (contd)

All birds should have sufficient space to so that all can lie down at the same time without being on top of each other.

Birds with broken bone(s) and/or dislocated joint(s) 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 joint(s) and/or broken bone(s) should be recorded verifiably in a manner that allows for verification. For poultry, the percentage of chickens with broken or dislocated wings should not exceed 2%. A frequency of, with less than 1% should be being the goal.

3.2. 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.

4.3. Provisions relevant to restraining and containing animals

- a) Provisions relevant to *restraining animals* for *stunning* or *slaughter* without *stunning*, to help maintain *animal welfare* include:
 - i) provision of a non-slippery floor;
 - ii) avoidance of excessive pressure applied by *restraining* equipment that causes struggling or vocalisation in *animals*;
 - iii) equipment engineered to reduce noise of air hissing and clanging metal;
 - iv) absence of sharp edges in *restraining* equipment that would harm *animals*;
 - v) avoidance of jerking or sudden movement of *restraining* device.
- b) Methods of *restraint* causing avoidable suffering should not be used in conscious *animals* because they cause severe pain and stress:
 - i) suspending or hoisting *animals* (other than *poultry*) by the feet or legs;
 - ii) indiscriminate and inappropriate use of *stunning* equipment;
 - iii) mechanical clamping of the legs or feet of the *animals* (other than shackles used in *poultry* and ostriches) as the sole method of *restraint*;

- iv) breaking legs, cutting leg tendons or blinding *animals* in order to immobilise them;
- v) severing the spinal cord, for example using a puntilla or dagger, to immobilise *animals* using electric currents to immobilise *animals*, except for proper *stunning*.

Article 7.5.3.

Lairage design and construction

1. General considerations

The *lairage* should be designed and constructed to hold an appropriate number of *animals* in relation to the throughput rate of the *slaughterhouse* without compromising the *welfare* of the *animals*.

In order to permit operations to be conducted as smoothly and efficiently as possible without injury or undue stress to the *animals*, the *lairage* should be designed and constructed so as to allow the *animals* to move freely in the required direction, using their behavioural characteristics and without undue penetration of their flight zone.

The following recommendations may help to achieve this. Some of these conditions may not apply to poultry.

2. Design of lairage

- a) The *lairage* should be designed to allow a one-way flow of *animals* from *unloading* to the point of *slaughter*, with a minimum number of abrupt corners to negotiate.
- b) In red meat *slaughterhouses*, pens, passageways and races should be arranged in such a way as to permit inspection of *animals* at any time, and to permit the removal of sick or injured *animals* when considered to be appropriate, for which separate appropriate accommodation should be provided.
- c) Each *animal* should have room to stand up and lie down and, when confined in a pen, to turn around, except where the *animal* is reasonably restrained for safety reasons (e.g. fractious bulls). Fractious *animals* should be slaughtered as soon as possible after arrival at the *slaughterhouse* to avoid *welfare* problems. The *lairage* should have sufficient accommodation for the number of *animals* intended to be held. Drinking water should always be available to the *animals*, and the method of delivery should be appropriate to the type of *animal* held. Troughs should be designed and installed in such a way as to minimise the risk of fouling by faeces, without introducing risk of bruising and injury in *animals*, and should not hinder the movement of *animals*.
- d) Holding pens should be designed to allow as many *animals* as possible to stand or lie down against a wall. Where feed troughs are provided, they should be sufficient in number and feeding space to allow adequate access of all *animals* to feed. The feed trough should not hinder the movement of *animals*.
- e) Where tethers, ties or individual stalls are used, these should be designed so as not to cause injury or distress to the *animals* and should also allow the *animals* to stand, lie down and access any food or water that may need to be provided.
- f) Passageways and races should be either straight or consistently curved, as appropriate to the animal species. Passageways and races should have solid sides, but when there is a double race, the shared partition should allow adjacent *animals* to see each other. For pigs and sheep, passageways should be wide enough to enable two or more *animals* to walk side by side for as long as possible. At the point where passageways are reduced in width, this should be done by a means which prevents excessive bunching of the *animals*.

Annex XIX (contd)

- 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) 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 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. 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. If *animals* are not to be slaughtered as soon as possible, 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.

Annex XIX (contd)

13. Poultry awaiting slaughter should be protected from adverse weather conditions and provided with adequate ventilation.
14. Laying duration for poultry waiting time should be kept to the minimum minimised and it should not exceed 12 hours.
15. Poultry in transport containers should be examined at the time of arrival. Containers should be stacked with sufficient gap space between the columns so as stacks to facilitate inspection of birds and air movement of air through them.
16. Forced ventilation or other cooling systems may be necessary under certain conditions to avoid build up of temperature and humidity.

Recommendations for specific species are described in detail in Articles 7.5.5. to 7.5.8.

Article 7.5.5.

Management of fetuses 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* 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 fetuses 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 fetuses should be left inside the unopened uterus until they are dead. When uterine, placental or foetal tissues are to be collected, where practical, fetuses 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 fetuses 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
	Head restraint, upright	Neck yoke	Captive bolt Electrical-head only Free bullet Slaughter without stunning	Stress of loading and neck capture; stress of prolonged restraint, horn configuration; unsuitable for fast line speeds, animals struggling and falling due to slippery floor, excessive pressure	Equipment; competent animal handlers, prompt stunning or slaughter	Cattle
	Leg restraint	Single leg tied in flexion (animal standing on 3 legs)	Captive bolt Free bullet	Ineffective control of animal movement, misdirected shots	Competent animal handler	Breeding pigs (boars and sows)
	Upright restraint	Beak holding	Captive bolt Electrical-head only	Stress of capture	Sufficient competent animal handlers	Ostriches
		Head restraint in electrical stunning box	Electrical-head only	Stress of capture and positioning	Competent animal handler	Ostriches
	Holding body upright- manual	Manual restraint	Captive bolt Electrical-head only Slaughter without stunning	Stress of capture and restraint; accuracy of stunning/ slaughter	Competent animal handlers	Sheep, goats, calves, ratites, small camelids, poultry
	Holding body upright mechanical	Mechanical clamp / crush / squeeze/ V-restrainer (static)	Captive bolt Electrical methods Slaughter without stunning	Loading of animal and overriding; excessive pressure	Proper design and operation of equipment	Cattle, buffalo, sheep, goats, deer, pigs, ostriches
	Lateral restraint – manual or mechanical	Restrainer/ cradle/crush	Slaughter without stunning	Stress of restraint	Competent animal handlers	Sheep, goats, calves, camelids, cattle

Annex XIX (contd)

	Presentation of animals	Specific procedure	Specific purpose	Animal welfare concerns/ implications	Key animal welfare requirements	Applicable species
Restraining methods (contd)	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-upright	Mechanical straddle – band restrainer (moving)	Electrical methods Captive bolt Slaughter without stunning	Loading of animal and overriding, size mismatch between restrainer and animal	Competent animal handlers, proper design and layout of restraint	Cattle, calves, sheep, goats, pigs
	Mechanical upright	Flat bed/deck - Tipped out of containers on to conveyors	Presentation of birds for shackling prior to electrical stunning Gas stunning	Stress and injury due to tipping in dump-module systems height of tipping conscious poultry broken bones and dislocations	Proper design and operation of equipment	Poultry
	Suspension and/or inversion	Poultry shackle	Electrical stunning Slaughter without stunning	Inversion stress; pain from compression on leg bones; Keep restraint as short as possible	Competent animal handlers; proper design and operation of equipment; birds should be hung by both legs	Poultry
	Suspension and/or inversion	Cone	Electrical head-only Captive bolt Slaughter without stunning	Inversion stress	Competent animal handlers; proper design and operation of equipment	Poultry
	Upright restraint	Mechanical leg clamping	Electrical head-only	Stress of resisting restraint in ostriches	Competent animal handlers; proper equipment design and operation	Ostriches
Restraining by inversion	Rotating box	Fixed side(s) (e.g. Weinberg pen)	Slaughter without stunning	Inversion stress; stress of resisting restraint, prolonged restraint, inhalation of blood and ingesta Keep restraint as brief as possible	Proper design and operation of equipment	Cattle
		Compressible side(s)	Slaughter without stunning	Inversion stress, stress of resisting restraint, prolonged restraint Preferable to rotating box with fixed sides Keep restraint as brief as possible	Proper design and operation of equipment	Cattle

	Presentation of animals	Specific procedure	Specific purpose	Animal welfare concerns/ implications	Key animal welfare requirements	Applicable species
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
Leg restraints		Rope casting	Mechanical stunning methods Slaughter without stunning	Stress of resisting restraint; prolonged restraint, animal temperament; bruising. Keep restraint as short as possible	Competent animal handlers	Cattle, camelids
		Tying of 3 or 4 legs	Mechanical stunning methods Slaughter without stunning	Stress of resisting restraint; prolonged restraint, animal temperament; bruising. Keep restraint as short as possible	Competent animal handlers	Sheep, goats, small camelids, pigs

Article 7.5.7.

Stunning methods

1. General considerations

The competence of the operators, and the appropriateness, and effectiveness of the method used for *stunning* and the maintenance of the equipment are the responsibility of the management of the *slaughterhouse*, and should be checked regularly by a *Competent Authority*.

Persons carrying out *stunning* should be properly trained and competent, and should ensure that:

- a) the *animal* is adequately restrained;
- b) *animals* in *restraint* are stunned as soon as possible;
- c) the equipment used for *stunning* is maintained and operated properly in accordance with the manufacturer's recommendations, in particular with regard to the species and size of the *animal*;
- d) the ~~instrument~~ 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 neck captive bolt and 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.

Annex XIX (contd)2. Mechanical stunning

A mechanical device should be applied usually to the front of the head and perpendicular to the bone surface. For a more detailed explanation on the different methods for mechanical stunning, see Chapter 7.6. and Articles 7.6.6., 7.6.7. and 7.6.8. The following diagrams illustrate the proper application of the device for certain species.

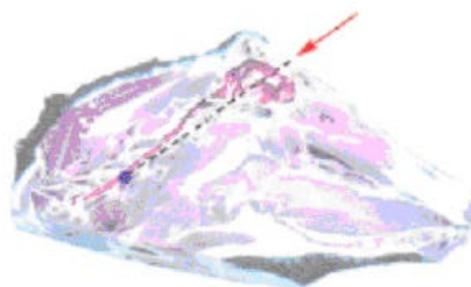
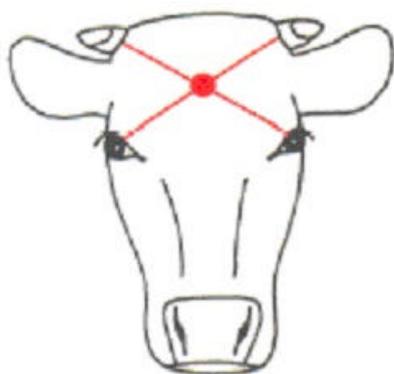
Cattle

Figure source: Humane Slaughter Association (2005) Guidance Notes No.3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

The optimum position for cattle is at the intersection of two imaginary lines drawn from the rear of the eyes to the opposite horn buds.

Pigs

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

The optimum position for pigs is on the midline just above eye level, with the shot directed down the line of the spinal cord.

Sheep

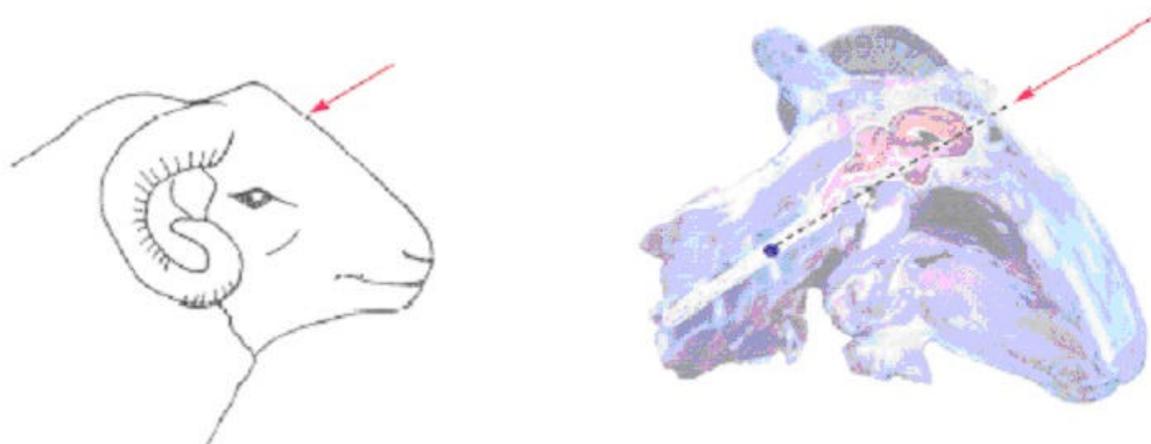


Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

The optimum position for hornless sheep and goats is on the midline.

Goats

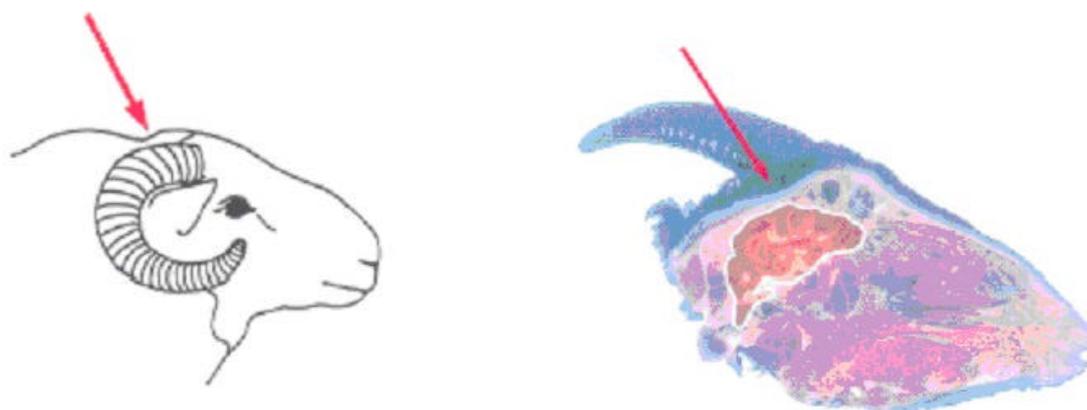


Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

The optimum position for heavily horned sheep and horned goats is behind the poll, aiming towards the angle of the jaw.

Annex XIX (contd)**Horses**

Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

The optimum position for horses is at right angles to the frontal surface, well above the point where imaginary lines from eyes to ears cross.

Signs of correct *stunning* using a mechanical instrument are as follows:

- a) the *animal* collapses immediately and does not attempt to stand up;
- b) the body and muscles of the *animal* become tonic (rigid) immediately after the shot;
- c) normal rhythmic breathing stops; and
- d) the eyelid is open with the eyeball facing straight ahead and is not rotated.

Poultry

Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).



Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Captive bolts powered by cartridges, compressed air or spring can be used for *poultry*. The optimum position for *poultry* species is at right angles to the frontal surface.

Firing of a captive bolt according to **the manufacturers' instructions** should lead to immediate destruction of the skull and the brain and, as a result, immediate *death*.

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*.

Annex XIX (contd)

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 required for electrical *stunning* should be provided with adequate power to achieve continuously the minimum current level recommended for *stunning* as indicated in the table below.

In all cases, the correct current level shall be attained within one second of the initiation of stun and maintained at least for between one and three seconds and in accordance with the manufacturer's instructions. Minimum current levels for head-only *stunning* are shown in the following table.

Species	Minimum current levels for head-only stunning
Cattle	1.5 amps
Calves (bovines of less than 6 month of age)	1.0 amps
Pigs	1.25 amps
Sheep and goats	1.0 amps
Lambs	0.7 amps
Ostriches	0.4 amps

b) Electrical stunning of birds using a waterbath

There should be no sharp bends or steep gradients in the shackle line and the shackle line should be as short as possible consistent with achieving acceptable line speeds, and ensuring that birds have settled by the time they reach the water bath. A breast comforter can be used effectively to reduce wing flapping and calm birds. The angle at which the shackle line approaches the entrance to the water bath, and the design of the entrance to the water bath, and the draining of excess 'live' water from the bath are all important considerations in ensuring birds are calm as they enter the bath, do not flap their wings, and do not receive pre-stun electric shocks.

In the case of birds suspended on a moving line, measures should be taken to ensure that the birds are not wing flapping at the entrance of the stunner. The birds should be secure in their shackle, but there should not be undue pressure on their shanks. The shackle size should be appropriate to fit the size of the shanks (Meta tarsal metatarsal bones) of birds.

Birds should be hung on shackles by both legs.

Birds with dislocated or broken legs and or wings should be humanely killed rather than shackled.

The duration between hanging on shackles and *stunning* should not be shackled, instead 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 soft water, it is recommended that salt be added in the waterbath as necessary. Additional salt should be added regularly as a solution to maintain suitable constant concentrations in the waterbath.

Using waterbaths, birds are stunned in groups and different birds will have different impedances. The voltage should be adjusted so that the total current is the required current per bird as shown in the table hereafter, multiplied by the number of birds in the waterbath at the same time. The following values have been found to be satisfactory when employing a 50 Hertz sinusoidal alternating current.

Birds should receive the current for at least 4 seconds.

While a lower current may also be satisfactory, the current shall in any case be such as to ensure that unconsciousness occurs immediately and lasts until the bird has been killed by cardiac arrest or by bleeding. When higher electrical frequencies are used, higher currents may be required.

Every effort shall be made to ensure that no conscious or live birds enter the scalding tank.

In the case of automatic systems, until fail-safe systems of *stunning* and bleeding have been introduced, a manual back-up system should be in place to ensure that any birds which have missed the waterbath stunner and/or the automatic neck-cutter are immediately stunned and/or killed immediately, and they are dead before entering scald tank.

To lessen the number of birds that have not been effectively stunned reaching neck cutters, steps should be taken to ensure that small birds do not go on the line amongst bigger birds and that these small birds are stunned separately. The height of the waterbath stunner should be adjusted according to the size of birds being stunned and slaughtered to ensure even the small birds are immersed in the water bath up to the base of the wings.

Waterbath stunning equipment should be fitted with a device which displays and records the details of the electrical key parameter.

Minimum currents for *stunning poultry* when using 50Hz is as follows:

Species	Minimum currents (milliamperes per bird)
Broilers	100
Layers (spent hens)	100
Turkeys	150
Ducks and geese	130

Annex XIX (contd)

Minimum currents for stunning poultry when using high frequencies Minimum current for stunning poultry when using high frequencies is as follows:

Frequency (Hz)	Minimum current (milliamperes) per bird	
	Chickens	Turkeys
< 200 Hz	100 mA	250 mA
From 200 to 400 Hz	150 mA	400 mA
From 400 to 1500 Hz	200 mA	400 mA

High frequency electrical stunning seldom induces cardiac arrest, and so it is potentially suitable as an alternative to slaughter without stunning.

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 others.

The conveyor and the chamber shall be adequately lit to allow the *animals* to see their surroundings and, if possible, each other.

It should be possible to inspect the 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 dead or 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 water bath *stunning* and *killing* systems. Therefore, gas *stunning* should be limited to birds contained in crates or on conveyors only. Inhalation of high concentrations (40% or more) of carbon dioxide can be aversive to birds and ideally (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 or sensibly during bleeding.

Gas *stunning* of *poultry* in their transport *containers* will eliminate the need for live birds' handling at the processing plant and all the problems associated with the electrical *stunning*. Gas *stunning* of *poultry* on a conveyor eliminates the problems associated with the electrical water bath *stunning*.

Live *poultry* should be conveyed into the gas mixtures either in transport crates or on conveyor belts.

The following gas procedures have been properly documented for chickens and turkeys but do not necessarily apply for other domestic birds. In any case the procedure should be designed as to ensure that all *animals* are properly stunned without unnecessary suffering. Some monitoring points for gas *stunning* could be the following:

- ensure smooth entry and passage of crates or birds through the system;
- avoid **bunching** **crowding** of birds in crates or conveyors;
- **monitor and maintain** gas concentrations ~~should be~~ continuously **monitored and maintained** during operation;
- provide visible and audible alarm systems if gas concentrations are inappropriate to the species;
- calibrate ~~of~~ gas monitors and maintain verifiable records;
- **ensure that** duration of exposure ~~should be~~ **is** adequate to prevent recovery of consciousness **in birds**;
- **make** provision to monitor and deal with recovery of consciousness;
- **ensure that** blood vessels are cut ~~should to~~ induce *death* in unconscious birds;
- **ensure that** all birds ~~should be~~ **are** dead before entering scalding tank;
- **provide** emergency procedures in the event of system failure.

i) Gas mixtures used for stunning *poultry* ~~could~~ 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

Annex XIX (contd)

- 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* 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.

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.

Stunning method	Maximum delay for bleeding to be started
Electrical methods and non-penetrating captive bolt	20 seconds
CO ₂	60 seconds (after leaving the chamber)

Article 7.5.8.

Summary analysis of stunning methods and the associated animal welfare issues

Method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements applicable	Species	Comment
Mechanical	Free bullet	Inaccurate targeting and inappropriate ballistics	Operator competence; achieving outright kill with first shot	Cattle, calves, buffalo, deer, horses, pigs (boars and sows)	Personnel safety
	Captive bolt - penetrating	Inaccurate targeting, velocity and diameter of bolt	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, buffalo, sheep, goats, deer, horses, pigs, camelids, ratites, <u>poultry</u>	(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, <u>poultry</u>	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	
	Inert gases	Recovery of consciousness	Concentration; duration of exposure; design, maintenance and operation of equipment; stocking density management	Pigs, poultry	

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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	
	Neck skin cut followed by stick wound; 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

Annex XIX (contd)

Slaughter methods	Specific method	Animal welfare concerns/ implications	Key requirements	Species	Comments
Bleeding with prior stunning (contd)	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 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.

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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, aesthetics of the method of euthanasia and cost of the method.
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 done 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 and should not cause anxiety, pain, distress or suffering in *animals*. 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.

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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 team1. 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;

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- 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
- ii) specific knowledge of his/her *animals* and their environment.

Article 7.6.4.

Considerations in planning the humane killing of animals

Many activities will need to be conducted on affected premises, including the humane *killing of animals*. The team leader should develop a plan for humanely *killing animals* on the premises which should include consideration of:

1. minimising handling and movement of *animals*;
2. *killing* the *animals* on the affected premises; however, there may be circumstances where the *animals* may need to be moved to another location for *killing*; when the *killing* is conducted at an *abattoir*, the recommendations in Chapter 7.5. on the *slaughter of animals* should be followed;
3. the species, number, age and size of *animals* to be killed, and the order of *killing* them;
4. methods of *killing* the *animals*, and their cost;
5. housing, husbandry, location of the *animals* as well as accessibility of the farm;
6. the availability and effectiveness of equipment needed for *killing* of the *animals*, as well as the time necessary to kill the required number of *animals* using such methods;
7. the facilities available on the premises that will assist with the *killing* including any additional facilities that may need to be brought on and then removed from the premises;
8. biosecurity and environmental issues;
9. the health and safety of personnel conducting the *killing*;
10. any legal issues that may be involved, for example where restricted veterinary drugs or poisons may be used, or where the process may impact on the environment;
11. the presence of other nearby premises holding *animals*;
12. possibilities for removal, disposal and destruction of carcasses.

The plan should minimise the negative *welfare* impacts of the *killing* by taking into account the different phases of the procedures to be applied for *killing* (choice of the *killing* sites, *killing* methods, etc.) and the measures restricting the movements of the *animals*.

Competences and skills of the personnel handling and *killing animals*.

In designing a *killing* plan, it is essential that the method chosen be consistently reliable to ensure that all *animals* are humanely and quickly killed.

Article 7.6.5.

Table summarising killing methods described in Articles 7.6.6.-7.6.18.

The methods are described in the order of mechanical, electrical and gaseous, not in an order of desirability from an *animal welfare* viewpoint.

Annex XIX (contd)

Species	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
Cattle	all	free bullet	no	non-lethal wounding	7.6.6.
	all except neonates	penetrating captive bolt - followed by pithing or bleeding	yes	ineffective stunning	7.6.7.
	adults only	non-penetrating captive bolt, followed by bleeding	yes	ineffective stunning, regaining of consciousness before killing	7.6.8.
	calves only	electrical, two-stage application	yes	pain associated with cardiac arrest after ineffective stunning	7.6.10.
	calves only	electrical, single application (method 1)	yes	ineffective stunning	7.6.11.
	all	injection with barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	7.6.15.
Sheep and goats	all	free bullet	no	non-lethal wounding	7.6.6.
	all except neonates	penetrating captive bolt, followed by pithing or bleeding	yes	ineffective stunning, regaining of consciousness before death	7.6.7.
	all except neonates	non-penetrating captive bolt, followed by bleeding	yes	ineffective stunning, regaining of consciousness before death	7.6.8.
	neonates	non-penetrating captive bolt	yes	non-lethal wounding	7.6.8.
	all	electrical, two-stage application	yes	pain associated with cardiac arrest after ineffective stunning	7.6.10.
	all	electrical, single application (method 1)	yes	ineffective stunning	7.6.11.
	neonates only	CO ₂ / air mixture	yes	slow induction of unconsciousness, aversiveness of induction	7.6.12.
	neonates only	nitrogen and/or inert gas mixed with CO ₂	yes	slow induction of unconsciousness, aversiveness of induction	7.6.13.
	neonates only	nitrogen and/or inert gases	yes	slow induction of unconsciousness	7.6.14.
	all	injection of barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	7.6.15.
Pigs	all, except neonates	free bullet	no	non-lethal wounding	7.6.6.
	all except neonates	penetrating captive bolt, followed by pithing or bleeding	yes	ineffective stunning, regaining of consciousness before death	7.6.7.
	neonates only	non-penetrating captive bolt	yes	non-lethal wounding	7.6.8.
	all ¹	electrical, two-stage application	yes	pain associated with cardiac arrest after ineffective stunning	7.6.10.
	all	electrical, single application (method 1)	yes	ineffective stunning	7.6.11.
	neonates only	CO ₂ / air mixture	yes	slow induction of unconsciousness, aversiveness of induction	7.6.12.
	neonates only	nitrogen and/or inert gas mixed with CO ₂	yes	slow induction of unconsciousness, aversiveness of induction	7.6.13.
	neonates only	nitrogen and/or inert gases	yes	slow induction of unconsciousness	7.6.14.
	all	injection with barbiturates and other	yes	non-lethal dose, pain associated with injection site	7.6.15.
Poultry	adults only	non penetrating captive bolt	yes	ineffective stunning	7.6.8.
	day-olds and eggs only	maceration	no	non-lethal wounding, non- immediacy	7.6.9.
	adults only	electrical, single application (method 2)	yes	ineffective stunning	7.6.11.
	adults only	electrical, single application, followed by killing (method 3)	yes	ineffective stunning; regaining of consciousness before death	7.6.11.

Annex XIX (contd)

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	7.6.12.
	all	nitrogen and/or inert gas mixed with CO ₂	yes	slow induction of unconsciousness, aversiveness of induction	7.6.13.
	all	nitrogen and/or inert gases	yes	slow induction of unconsciousness	7.6.14.
	all	injection of barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	7.6.15.
	adults only	addition of anaesthetics to feed or water, followed by an appropriate killing method	no	ineffective or slow induction of unconsciousness	7.6.16.

Article 7.6.6.

Free 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.

Annex XIX (contd)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 and pigs, including large *animals* in open spaces.

Figure 1. The optimum shooting position for cattle is at the intersection of two imaginary lines drawn from the rear of the eyes to the opposite horn buds.

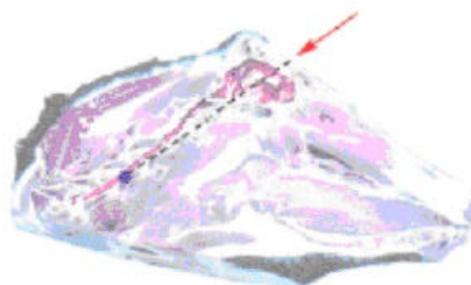
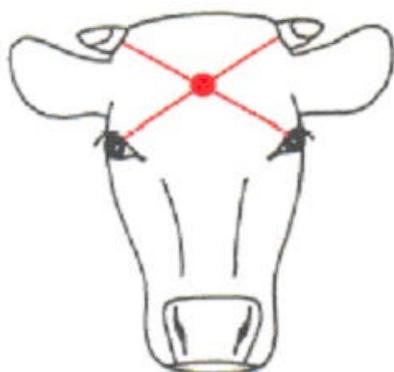


Figure source: Humane Slaughter Association (2005) Guidance Notes No.3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Figure 2. The optimum position for hornless sheep and goats is on the midline.

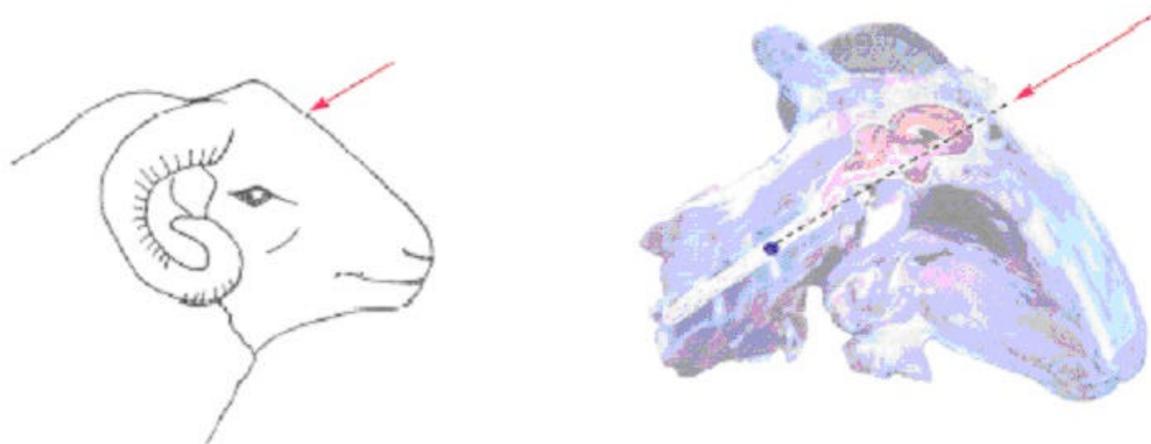


Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Figure 3. The optimum shooting position for heavily horned sheep and horned goats is behind the poll aiming towards the angle of the jaw.

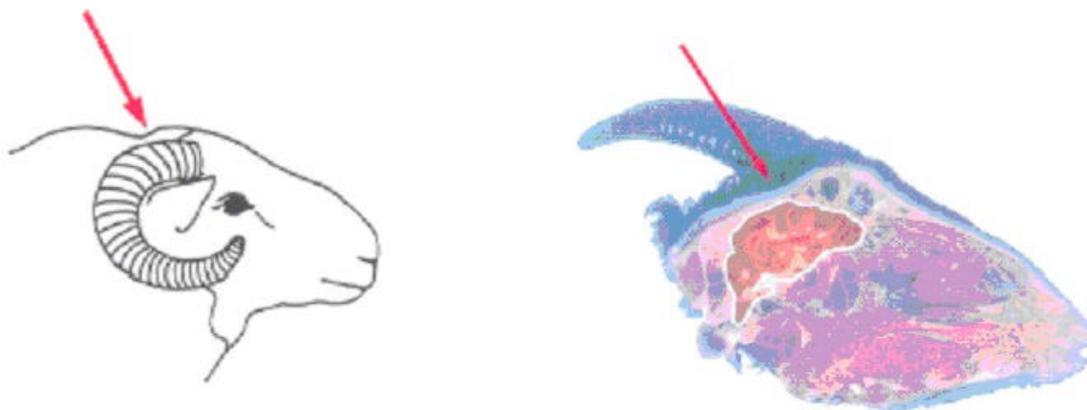


Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Annex XIX (contd)

Figure 4. The optimum shooting position for pigs is just above eye level, with the shot directed down the line of the spinal cord.



Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Article 7.6.7.

Penetrating captive bolt

1. Introduction

A penetrating captive bolt is fired from a gun powered by either compressed air or a blank cartridge. There is no free projectile.

The captive bolt should be aimed on the skull in a position to penetrate the cortex and mid-brain of the *animal*. The impact of the bolt on the skull produces unconsciousness. Physical damage to the brain caused by penetration of the bolt may result in *death*, however, pithing or bleeding should be performed as soon as possible after the shot to ensure the *death* of the *animal*. Shooting poultry species with the captive bolts results in immediate destruction of the skull and brain, causing death. For a detailed description on the use this method see Chapter 7.5. of the Terrestrial Code.

2. Requirements for effective use

- a) For cartridge powered and compressed air guns, the bolt velocity and the length of the bolt should be appropriate to the species and type of *animal*, in accordance with the recommendations of the manufacturer.
- b) Captive bolt guns should be frequently cleaned and maintained in good working condition.
- c) More than one gun may be necessary to avoid overheating, and a back-up gun should be available in the event of an ineffective shot.
- d) Animals should be restrained; at a minimum, they should be penned for cartridge powered guns and in a race for compressed air guns.
- e) The operator should ensure that the head of the *animal* is accessible.
- f) The operator should fire the captive bolt at right angles to the skull in the optimal position (see figures 1, 3 & 4. The optimum shooting position for hornless sheep is on the highest point of the head, on the midline and aim towards the angle of the jaw).

- g) To ensure the *death* of the *animal*, pithing or bleeding should be performed as soon as possible after *stunning*.
- h) *Animals* should be monitored continuously after *stunning* until *death* to ensure the absence of brain stem reflexes.

3. Advantages

- a) Mobility of cartridge powered equipment reduces the need to move *animals*.
- b) The method induces an immediate onset of a sustained period of unconsciousness.

4. Disadvantages

- a) Poor gun maintenance and misfiring, and inaccurate gun positioning and orientation may result in poor *animal welfare*.
- b) Post stun convulsions may make pithing difficult and hazardous.
- c) The method is difficult to apply in agitated *animals*.
- d) Repeated use of a cartridge powered gun may result in over-heating.
- e) Leakage of bodily fluids may present a biosecurity risk.
- f) Destruction of brain tissue may preclude diagnosis of some *diseases*.

5. Conclusions

The method is suitable for poultry, cattle, sheep, goats and pigs (except neonates), when followed by pithing or bleeding.

Article 7.6.8.

Non-penetrating captive bolt

1. Introduction

A non-penetrating captive bolt is fired from a gun powered by either compressed air or a blank cartridge. There is no free projectile.

The gun should be placed on the front of the skull to deliver a percussive blow which produces unconsciousness in cattle (adults only), sheep, goats and pigs, and *death* in *poultry* and neonate sheep, goats and pigs. Bleeding should be performed as soon as possible after the blow to ensure the *death* of the *animal*.

2. Requirements for effective use

- a) For cartridge powered and compressed air guns, the bolt velocity should be appropriate to the species and type of *animal*, in accordance with the recommendations of the manufacturer.
- b) Captive bolt guns should be frequently cleaned and maintained in good working condition.

Annex XIX (contd)

- c) More than one gun may be necessary to avoid overheating, and a back-up gun should be available in the event of an ineffective shot.
- d) *Animals* should be restrained; at a minimum mammals should be penned for cartridge powered guns and in a race for compressed air guns; birds should be restrained in cones, shackles, crushes or by hand.
- e) The operator should ensure that the head of the *animal* is accessible.
- f) The operator should fire the captive bolt at right angles to the skull in the optimal position (figures 1-4).
- g) To ensure *death* in non-neonate mammals, bleeding should be performed as soon as possible after *stunning*.
- h) *Animals* should be monitored continuously after *stunning* until *death* to ensure the absence of brain stem reflexes.

3. Advantages

- a) The method induces an immediate onset of unconsciousness, and *death* in birds and neonates.
- b) Mobility of equipment reduces the need to move *animals*.

4. Disadvantages

- a) As consciousness can be regained quickly in non-neonate mammals, they should be bled as soon as possible after *stunning*.
- b) Laying hens in cages have to be removed from their cages and most birds have to be restrained.
- c) Poor gun maintenance and misfiring, and inaccurate gun positioning and orientation may result in poor *animal welfare*.
- d) Post stun convulsions may make bleeding difficult and hazardous.
- e) Difficult to apply in agitated *animals*; such *animals* may be sedated in advance of the *killing* procedure.
- f) Repeated use of a cartridge powered gun may result in over-heating.
- g) Bleeding may present a biosecurity risk.

5. Conclusions

The method is suitable for *killing poultry*, and neonate sheep, goats and pigs up to a maximum weight of 10 kg.

Article 7.6.9.

Maceration1. Introduction

Maceration, utilising a mechanical apparatus with rotating blades or projections, causes immediate fragmentation and *death* in ~~day-old~~ newly hatched 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.

Annex XIX (contd)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 3seconds; 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 **must 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.

Annex XIX (contd)

c) Disadvantages

- i) Method 1 requires individual mechanical animal *restraint*.
- ii) The electrodes **must** **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 ~~must~~ should be applied and maintained in the correct position to produce an effective stun.
- iii) Birds ~~must~~ should be individually restrained.
- iv) It ~~must~~ should be followed by a *killing* method.

d) Conclusion

Method 3 is suitable for small numbers of *poultry*.

CO₂ / air mixture (under study)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 the gas being introduced into a poultry house (Method 2) or by placing transport modules or crates containing birds in a gas tight container and introducing a gas mixture (Method 32) or by the gas being introduced into a poultry house (Method 3). Method 2 should be used whenever possible, as it eliminates *welfare* issues resulting from the need to manually remove live birds. Although Method 32 requires handling and crating of the birds, it benefits overall bird welfare overall (in comparison with Method 1) as it eliminate chances reduces the risk of causing death by smothering or suffocation when compared with Method 1.

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 aversiveness nature of various gas mixtures containing high concentrations of CO₂ and the respiratory distress occurring during the induction phase are important considerations for animal welfare consideration.

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 outdoors, 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. But CO₂ is likely to cause a period of distress in the *animals* before they lose consciousness.

3. Method 2

In this method, the crates or modules full of holding the birds are loaded into a chamber and into which gas is introduced into a chamber. As shown illustrated in the example below, each a containerised gassing unit (CGU) typically consists of 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 which in turn 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 during filling when the container is filling with gas.

Procedures involved in The procedures for the operation of CGU includes (a) position the container on a level, solid, open ground; (b) connect the gas cylinder to the container (c) load a module full of birds into the container (d) shut and secure the door, (e) deliver the gas until a concentration of 40-45% by volume of carbon dioxide was 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 surviving birds survivors (j) humanely kill any survivors, if any; and (k) dispose of carcasses appropriately.



Figure source: Department of Clinical Veterinary Science, University of Bristol, United Kingdom.

Annex XIX (contd)

Figure source: Department of Clinical Veterinary Science, University of Bristol, United Kingdom.



Figure source: Department of Clinical Veterinary Science, University of Bristol, Langford, Bristol, United Kingdom.

- 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 40% carbon dioxide is achieved ~~on~~ at the top of the crates.
 - iv) An appropriate gas meter should be used to ~~monitor and maintain~~ ensure the level appropriate concentration of carbon dioxide continuously during is achieved and maintained until it can be confirmed that the ~~operation~~ 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 couple of metres away from near the container, can be used to determine that the presence of unconsciousness birds are unconscious and that death will be is imminent. Remove the crates or modules out of from the container and leave them in atmospheric 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 movement under this situation 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 time to die.
- b) Advantages
- i) The gas is introduced quickly and quietly resulting in less turbulence and disturbance to the birds.
- ii) Gradual rising of CO₂ increase in the concentration of CO₂ minimises the aversiveness nature of the introduction of this method for inducing unconsciousness with this gas.
- 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 but such. However, this equipment is usually available and suitable areas with hard surfaces are usually available.
- ii) The main limiting factors are speed of catching and availability of gas birds.
- iii) It is difficult to visually confirm In the absence of a viewing window, visual confirmation of death while the birds are still in the container is difficult. However, cessation of vocalisations and convulsive wing flapping sounds can be used to determine onset of death.

Annex XIX (contd)d) Conclusion

- i) Method 32 is suitable for use in poultry in a wide range of poultry systems which have, providing there is access to vehicles to carry the containers and handling equipment.
- ii) ~~Animals~~ Birds should be introduced into the container or apparatus, which is then sealed and filled as quickly as possible thereafter with the required gas concentrations, i.e. more than 40% CO₂ and. Birds are held in this atmosphere until death is confirmed.
- iii) Method 32 is suitable for use in poultry, and neonatal sheep, goats and pigs. But However, CO₂ is likely to cause a period of distress in the animals before they lose consciousness.

24. Method 2-3

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, will have to should only be switched off immediately prior to gas administration.

The mains 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 will have to 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 the very cold gas delivered at high pressures. It may be necessary that to exclude birds are excluded at 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 vaporiser may be required to prevent freezing.
- iv) Devices should be used to accurately measure the gas concentration at the maximum height accommodation of birds.

b) Advantages

- i) Applying gas to birds *in situ* eliminates the need to manually remove live birds.
- ii) CO₂ is readily available.
- iii) Gradual raising of CO₂ concentration minimises the aversiveness of the induction of unconsciousness.

c) Disadvantages

- i) It is difficult to determine volume of gas required to achieve adequate concentrations of CO₂ in some *poultry* houses.
- ii) It is difficult to verify *death* while the birds are in the *poultry* house.

The extremely low temperature of liquid CO₂ entering the house and formation of solid CO₂ (dry ice) are also may cause concern for bird welfare concerns.

d) Conclusion

Method 2 is suitable for use in *poultry* in closed-environment sheds. This method could be developed for killing pigs. But However, CO₂ is likely to cause a period of distress in the birds animals before they lose consciousness.

Article 7.6.13.

Nitrogen and/or inert gas mixed with CO₂

1. Introduction

CO₂ may be mixed in various proportions with nitrogen or an inert gas (e.g. argon), and the inhalation of such mixtures leads to hypercapnic-hypoxia and *death* when the oxygen concentration by volume is <2%. Various mixtures of CO₂ and nitrogen or an inert gas can be administered to kill birds using Methods 1 and 3 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 complexity of 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.
- ii) *Animals* should be introduced into the *container* or apparatus after it has been filled with the required gas concentrations (with <2% O₂), and held in this atmosphere until *death* is confirmed.

Annex XIX (contd)

- 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.

~~5.~~ b) Advantages

Low concentrations of CO₂ cause little aversiveness and, in combination with nitrogen or an inert gas, produces a fast induction of unconsciousness.

~~4.~~ c) 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.~~ 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 full of holding the birds are loaded into a container and gas is introduced into the container (refer to Figures under Article 7.6.12.). As shown in the example below, each containerised gassing unit (CGU) typically consists of 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 during 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 full of birds into the container, (d) shut and secure the door, (e) deliver the gas until < to the point where less than 2% by volume of oxygen was achieved 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 full 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 on at the top of the crates.

- iv) An appropriate gas meter should be used to monitor and maintain the level ensure a concentration of oxygen continuously during the operation <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, which can be listened to observed by standing couple of meters away from close to the container can be and used to determine the onset of death in birds. Remove the crates or modules out of from the container and leave them in atmospheric 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 under this situation 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 uniformity 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 outdoors 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 but. However, such equipment is usually available and suitable area outdoor areas with a hard surface are usually available.
 - ii) The main limiting factors are speed of catching birds and availability of gas mixtures.

Annex XIX (contd)

iii) It is difficult to visually confirm death. In the absence of a viewing window, visual confirmation of death while the birds are still in the container (however is difficult. However, cessation of localisations 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 for in neonatal sheep, goats and pigs.

ii) Method 2 is suitable for use in poultry in a wide range of poultry systems which providing that these have access to vehicles to carry containers and handling equipment.

iii) Animals should be introduced into the container or apparatus, which is then sealed and filled as quickly as possible thereafter with the gas mixtures and a 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 and/or inert gases**1. Introduction**

This method involves the introduction of *animals* into a container or apparatus containing nitrogen or an inert gas such as argon. The controlled atmosphere produced leads to unconsciousness and *death* from hypoxia.

Research has shown that hypoxia is not aversive to pigs and *poultry*, and it does not induce any signs of respiratory distress prior to loss of consciousness.

2. Requirements for effective use

- a) *Containers* or apparatus should allow the required gas concentrations to be maintained, and the O₂ concentration accurately measured.
- b) When *animals* are exposed to the gases individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the *animals* and allow them to be observed.
- c) *Animals* should be introduced into the *container* or apparatus after it has been filled with the required gas concentrations (with <2% 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.

~~Whole house gassing of *poultry* with nitrogen has been tested in Denmark and Sweden. Nitrogen can also be used on containerised gassing systems however evidence is lacking. Therefore, these two methods of administration could be described as under development.~~

Article 7.6.15.

Lethal injection

1. Introduction

A lethal injection using high doses of anaesthetic and sedative drugs causes CNS depression, unconsciousness and *death*. In practice, barbiturates in combination with other drugs are commonly used.

2. Requirements for effective use

- a) Doses and routes of administration that cause rapid loss of consciousness followed by *death* should be used.
- b) Prior sedation may be necessary for some *animals*.
- c) Intravenous administration is preferred, but intraperitoneal or intramuscular administration may be appropriate, especially if the agent is non-irritating.
- d) *Animals* should be restrained to allow effective administration.
- e) *Animals* should be monitored to ensure the absence of brain stem reflexes.

3. Advantages

- a) The method can be used in all species.
- b) *Death* can be induced smoothly.

4. Disadvantages

- a) *Restraint* and/or sedation may be necessary prior to injection.
- b) Some combinations of drug type and route of administration may be painful, and should only be used in unconscious *animals*.
- c) Legal requirements and skill/training required may restrict use to veterinarians.
- d) Contaminated carcasses may present a risk to other wild or domestic *animals*.

Annex XIX (contd)5. Conclusion

The method is suitable for *killing* small numbers of cattle, sheep, goats, pigs and *poultry*.

Article 7.6.16.

Addition of anaesthetics to feed or water1. 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) **Must 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 **provided. However, a back-up method is should be** available to kill birds that are **only anaesthetised anaesthetized but not killed.**

Article 7.6.17.

Cervical dislocation and decapitation1. Cervical dislocation (manual and mechanical)

a) Introduction

Unconscious *poultry* may be killed by either manual cervical dislocation (stretching the neck) ~~or mechanical neck crushing with a pair of pliers. Both methods. 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, ~~or are impracticable~~, conscious birds ~~of less than 3 kilograms~~ 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~~ 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 or by using mechanical pliers to crush the cervical vertebrae 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

- i) Decapitation results in *death* by cerebral ischaemia using a guillotine or knife.

Annex XIX (contd)

- b) Requirements for effective use
 - i) The required equipment should be kept in good working order.
- c) Advantages
 - i) 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 due to loss of consciousness is not being immediate lost immediately.

Article 7.6.18.

Pithing and bleeding1. Pithing

a) Introduction

Pithing is a method of *killing animals* which have been stunned by a penetrating captive bolt, without immediate *death*. Pithing results in the physical destruction of the brain and upper regions of the spinal cord, through the insertion of a rod or cane through the bolt hole.

b) Requirements for effective use

- i) Pithing cane or rod is required.
- ii) An access to the head of the *animal* and to the brain through the skull is required.
- iii) *Animals* should be monitored continuously until *death* to ensure the absence of brain stem reflexes.

c) Advantages

The technique is effective in producing immediate *death*.

d) Disadvantages

- i) A delayed and/or ineffective pithing due to convulsions may occur.
- ii) The working area is contaminated with body fluids, which increases biosecurity risks.

2. Bleeding

a) Introduction

Bleeding is a method of *killing animals* through the severance of the major blood vessels in the neck or chest that results in a rapid fall in blood pressure, leading to cerebral ischaemia and *death*.

- b) Requirements for effective use
- i) A sharp knife is required.
 - ii) An access to the neck or chest of the *animal* is required.
 - iii) *Animals* should be monitored continuously until *death* to ensure the absence of brain stem reflexes.
- c) Advantages
- The technique is effective in producing *death* after an effective *stunning* method which does not permit pithing.
- d) Disadvantages
- i) A delayed and/or ineffective bleeding due to convulsions may occur.
 - ii) The working area is contaminated with body fluids, which increases biosecurity risks.

Article 7.6.19 (under study)

Foam as a killing method for poultry

1. Introduction

In fire fighting terms, foam is usually defined, on the basis of volume of foam produced to the volume of liquid used as low (20:1), medium (up to 200:1) and high (over 200:1) expansion foam. Medium expansion fire fighting foam made using air bubble has been used to create a blanket over live birds in order to deprive them of oxygen, and causing death. It was concluded that birds died due to occlusion of the upper respiratory tract with the foam. A physiological definition of suffocation is the physical separation of the upper respiratory tract from the atmospheric air, and therefore, occlusion of the upper respiratory tract with foam or water would amount to death due to suffocation or asphyxiation, which are unacceptable from animal welfare point of view.

Therefore, high expansion foam made with 100% carbon dioxide or nitrogen has been tested for killing poultry. Research has shown that birds do not show any aversive reactions to high expansion foam with large diameter (10 to 50 mm) made using gases. Therefore, high expansion foam with large diameter and made using industrial gases such as carbon dioxide or nitrogen has potential to be an acceptable method of killing poultry.

2. Requirements for effective use

- a) Foam expansion ratio should be at least 300:1.
- b) Diameter of foam should be at least 10mm.
- c) Foam should be made using 100% carbon dioxide, nitrogen or inert gases (argon) or mixtures of these gases.
- d) Surfactant used in foam making should be non irritant, non corrosive and the surfactant and water mixture should be buffered adequately to avoid causing discomfort to birds.
- v) Foam should be administered into poultry houses as rapidly as possible in a calm manner, without causing distress or panic among the birds.

Annex XIX (contd)3. Advantages

- a) Foam can be administered without entering poultry houses.
- b) Administration of a gas in foam will minimise disturbances to live birds.
- c) Poultry houses may not have to be sealed for the purpose containing gases.
- d) Standard firefighting foam makers can be deployed.

4. Disadvantages

- i) Availability of foam making devices, surfactants and gas in large quantities.
- ii) Surface run-off and its consequences for biosecurity.

4. Conclusion

High expansion foam with large diameter and made using industrial gases such as carbon dioxide or nitrogen has potential to be an acceptable method of killing poultry.

Article 7.6.20 (under study)

Use of carbon monoxide for killing poultry.1. Introduction

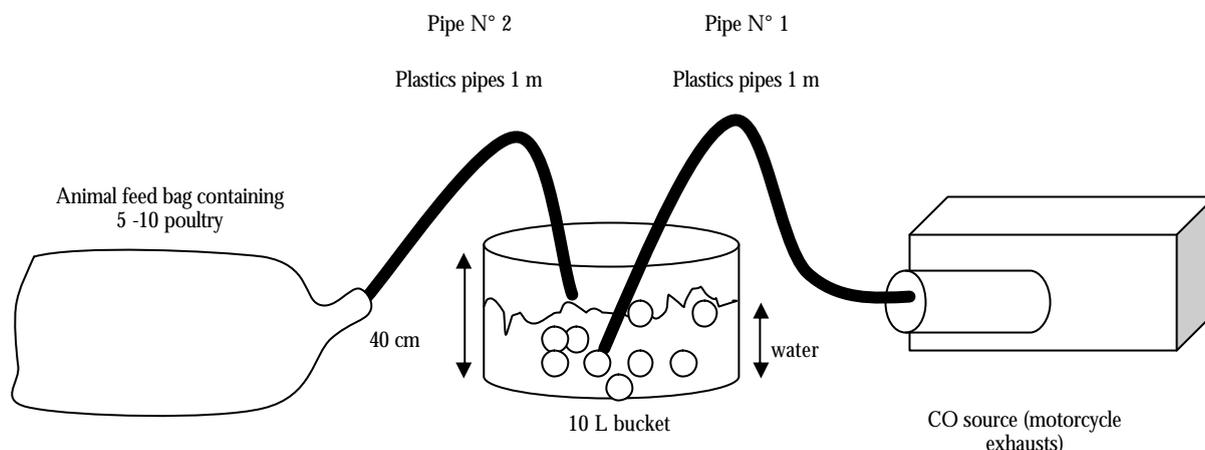
Inhalation of carbon monoxide leads to unconsciousness and death. However some argue that convulsions may occur prior to loss of consciousness. It is also lethal at low concentrations and highly explosive at concentrations above 12.5% by volume.

There are two methods of application: Method 1 involves the introduction of poultry into a container or apparatus containing carbon monoxide; Method 2 involves administration of carbon monoxide into poultry houses.

Carbon monoxide could be delivered from a pure (100%) source or as a mixture of gases generated by using a petrol engine. The concentration required to killing poultry has been estimated to be 1.5 to 2.0% in air.

Method 1:

Exhaust gas from a badly tuned motorcycle engines has been used to generate carbon monoxide, however in low concentrations. An example is presented in the schematic diagram below.

Schema of Method 1Method 2 : Administration into poultry houses

Carbon monoxide can be delivered using a pure source and it is being lighter than air may diffuse very rapidly throughout the house.

2. Requirements for effective use

Carbon monoxide concentration should be measured in both Methods.

a) Method 1:

- i) The time to attain a lethal concentration of this gas in the container (or bag) will depend upon the generator or engine.
- ii) The exhaust gas should be cooled and filtered prior to administration.
- iii) Poultry should be introduced into the container or apparatus after it has been filled with the required gas concentration, and held in this atmosphere until death is confirmed.
- iv) Team members should ensure that there is sufficient time allowed for each batch of poultry to die before subsequent ones are introduced into the container or apparatus.
- v) Containers or apparatus should not be overcrowded.
- vi) Operators' health and safety should not be compromised.

b) Method 2

An exclusion zone of several meters around the vicinity of the house may ensure human safety and the explosive nature of the gas require the presence of fire brigade.

- i) Carbon monoxide should be delivered using a pure source.

Annex XIX (contd)

3. Conclusion

Carbon monoxide is suitable for poultry.

Article 7.6.21

Prohibited methods include ventilation shut down as a sole method of killing poultry.

— text deleted

¹ The only preclusion against the use of this method for neonates is the design of the stunning tongs that may not facilitate their application across such a small-sized head/body.

CHAPTER 7.7.

~~GUIDELINES ON~~ STRAY DOG POPULATION CONTROL

Preamble: The scope of these recommendations is to deal with stray and feral dogs, which pose serious human health, animal health and *welfare* problems and have a socio-economic, political, and religious problems in many countries. Whilst acknowledging human health is a priority including the prevention of zoonotic diseases notably rabies, the OIE recognises the importance of controlling dog populations without causing unnecessary or avoidable 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

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 for successful reproduction.

Owned dog

means a dog with a person that claims responsibility.

Person

this can include more than one individual, and could comprise family/household members or an organisation.

Responsible dog ownership

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

Annex XIX (contd)**Euthanasia**

means the act of inducing *death* in a humane manner.

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).

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.

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 (NGOs)

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 programs 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.

Annex XIX (contd)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 **must 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 disease, as appropriate;
- c) veterinary procedures (e.g. surgical procedures);
- d) control of dog movement (national and international);

- e) control of dangerous dogs;
- f) regulations on the breeding and sale of dogs;
- g) environmental controls (e.g. *abattoirs*, rubbish dumps, dead stock facilities);
- h) regulations for dog shelters;
- i) *animal welfare* obligations of owners and authorities.

4. Resources available to authorities

- a) Human resources;
- b) financial resources;
- c) technical tools;
- d) infrastructure;
- e) cooperative activities;
- f) public-private-NGO partnerships;
- g) central-state or province-local partnerships.

Article 7.7.6.

Control measures

The following control measures could be implemented according to the national context and local circumstances. Measures may be used in combination. Euthanasia of dogs, used alone, is not an effective control measure. If used, it should be done humanely (see point 11 of Article 7.7.6.) and in combination with other measures to achieve effective long term control. It is also important that authorities gain an understanding of people's attitudes towards dog ownership so that they can develop a cooperative approach to the control of dog populations.

1. Education and legislation for responsible ownership

Encouraging dog owners to be more responsible will reduce the number of dogs allowed to roam, improve the health and *welfare* of dogs, and minimise the risk that dogs pose to the community. The promotion of responsible dog ownership through legislation and education is a necessary part of a dog population control programme. Collaboration with local government authorities, *animal welfare* NGOs, kennel clubs, private veterinarians and veterinary organisations will assist *Veterinary Authorities* in establishing and maintaining programmes.

Education on responsible dog ownership (for the currently owned dog and any offspring it produces) should address the following elements:

- a) the importance of proper selection **for behaviour** and care to ensure the *welfare* of the dog and any offspring; the latter may include preparing the dog to cope with its environment through attention to socialisation and training;
- b) registration and identification of dogs (see point 2 of Article 7.7.6.);
- c) disease prevention, in particular zoonotic disease, 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.

Annex XIX (contd)

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 programs, for example, mandatory rabies vaccination and traceability.

Registration of animals in a centralised database can be used to support the enforcement of legislation and the reuniting of lost animals with owners. The control of dog reproduction by sterilisation can be encouraged through financial incentives presented by differential licensing fees.

3. Reproductive control

Controlling reproduction in dogs prevents the birth of unwanted puppies and can help address the balance between demand for dogs and the size of the population. It is advisable to focus efforts to control reproduction on those individuals or groups in the dog population identified as the most productive and the most likely to be the sources of unwanted and stray dogs, to ensure best use of resources. Methods of controlling reproduction will require direct veterinary input to individual animals. Involvement of both private and public veterinary sectors may be required to meet demand for services. Subsidisation of sterilisation programmes by government or other organisations may be considered to encourage uptake. The control of reproduction is essentially the responsibility of owners and can be incorporated into education on responsible ownership (see point 1 of Article 7.7.6.). Methods for controlling reproduction in dogs include:

- a) surgical sterilisation;
- b) chemical sterilisation;
- c) chemical contraception;
- d) separation of female dogs during oestrus from unsterilised males.

Surgical sterilisation should be carried out by a veterinarian and include appropriate anaesthesia and pain management.

Any chemicals or drugs used in controlling reproduction should be shown to have appropriate safety, quality and efficacy for the function required and used according to the manufacturer's and *Competent Authority's* regulations. In the case of chemical sterilants and contraceptives, research and field trials may need to be completed before use.

4. Removal and handling

The *Competent Authority* should collect dogs that are not under direct supervision and verify their ownership. Capture, transport, and holding of the dogs should be done humanely. The *Competent Authority* should develop and implement appropriate legislation and training to regulate these activities. Capture should be achieved with the minimum force required and equipment should be used that supports humane handling. Uncovered wire loops should not be used for capture.

5. Capture and return, rehoming or release

Competent Authorities have the responsibility to develop minimum standards for the housing (physical facilities) and care of these dogs. There should be provision for holding the dogs for a reasonable period of time to allow for reunion with the owner and, as appropriate, for rabies observation.

- a) Minimum standards for housing should include the following provisions:
 - i) site selection: Access to drainage, water and electricity are essential and environmental factors such as noise and pollution should be taken into account;
 - ii) kennel size, design and occupancy taking exercise into account;
 - iii) *disease* control measures including isolation and quarantine facilities.
- b) Management should address:
 - i) adequate fresh water and nutritious food;
 - ii) regular hygiene and cleaning;
 - iii) routine inspection of the dogs;
 - iv) monitoring of health and provision of required veterinary treatments;
 - v) policies and procedures for rehoming (adoption), sterilisation and euthanasia;
 - vi) training of staff in safe and appropriate handling of dogs;
 - vii) record keeping and reporting to authorities.

Dogs that are removed from a community may be reunited with the owner or offered to new owners for rehoming. This provides an opportunity to promote responsible ownership and good animal health care (including rabies vaccination). Prior to rehoming, authorities may consider sterilisation of dogs as a population control measure. The suitability of new owners to adopt dogs should be assessed and owners matched with available animals. The effectiveness of rehoming may be limited due to the suitability and number of dogs.

Dogs that are removed from a community may in some cases be provided with health care (including rabies vaccination), sterilised, and released to their local community at or near the place of capture. This method is more likely to be accepted in the situation where the presence of stray dogs is considered to be inevitable and is well tolerated by the local community.

This method is not applicable in all situations and may be illegal in countries or regions where legislation prohibits the abandonment of dogs. Problems caused by dogs, such as noise, faecal pollution, bite injuries and traffic accidents, would not be alleviated as dogs are returned to the local community and their movements are not restricted. If the local community has owned dogs, and sterilised dogs are released, consideration should be given to the risk that this could encourage abandonment of unwanted dogs. In the situation where many dogs are owned, a population control programme that focuses on neutering and responsible ownership may be more appropriate.

It is recommended that before adopting this approach, a cost-benefit analysis is conducted. Factors such as the monetary costs, impact on culture of ownership and public safety should be assessed as well as the benefits for *disease* control and *animal welfare* as well as any societal benefits.

Annex XIX (contd)

- c) If this method is adopted, the following factors should be addressed:
- i) raising awareness of the programme within the local community to ensure understanding and support;
 - ii) use of humane methods for catching, transporting and holding dogs;
 - iii) correct surgical technique, anaesthesia and analgesia, followed by post-operative care;
 - iv) *disease* control may include blanket vaccination (e.g. rabies) and treatments and testing for *diseases* (e.g. leishmaniasis) followed, as appropriate by treatment or euthanasia of the dog;
 - v) behavioural observation may be used to assess if dogs are suitable for release; if not suitable for release or rehoming, euthanasia should be considered;
 - vi) permanent marking (e.g. tattoo or microchip) to indicate that the animal has been sterilised. Individual identification also allows for tracking of vaccination status and treatment history and identification of a level of 'ownership' by the organisation/authority responsible for carrying out this intervention. A visible identification (e.g. collar) may also be used to prevent unnecessary recapture;
 - vii) the dog should be returned to a place that is as near as possible to the place of capture;
 - viii) the *welfare* of dogs after release should be monitored and action taken if required.

Dogs that are removed from a community may be too numerous or may be unsuitable for any rehoming scheme. If euthanasia of these unwanted animals is the only option, the procedure should be conducted in accordance with the regulations of the *Competent Authority* (see point 11 of Article 7.7.6.)

6. Environmental controls

Steps should be taken to exclude dogs from sources of food (e.g. rubbish dumps and *abattoirs*, and installing animal-proof rubbish containers).

This should be linked to a reduction in the dog population by other methods, to avoid *animal welfare* problems.

7. Control of dog movement – international (export/import)

Chapter 8.10. provides recommendations on the international movement of dogs between rabies free countries and countries considered to be infected with 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 *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 List of methods for the euthanasia of dogs.

Table 1: Summary analysis List 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 lost of consciousness if injection given rapidly	Use slow IV injection with sedation to permit slow rate of injection.	Correct restraint is needed. To be administered under veterinary supervision and by trained personnel.	Quite low cost.	Unavailable/unlicensed in some countries
Chemical -via injection (contd)	Anaesthetic agent overdose (thiopentone or propofenol)	Underdosing may lead to recovery	IV injection of a sufficient dose	Correct restraint is needed. To be administered under veterinary supervision and by trained personnel.	Generally quick action and minimal discomfort to animal.	Large volume required (cost implications)
	Potassium chloride (KCl)	K ⁺ is cardiotoxic and very painful if used without anaesthetic agent.	Only use on anaesthetised animals, IV injection	Requires trained personnel.	Readily available without veterinary control.	Prior need for anaesthetic (cost and availability implications)

Table 1: Summary analysis List of methods for the euthanasia of dogs (contd)

Mechanical	Free bullet	Can be inhumane if shot is inaccurate and dog is only wounded; dog may also escape.	Skilled operator essential.	Risk of injury to operators and spectators.	Not necessary to handle or capture dog.	Brain tissue may be unavailable for rabies diagnosis. Risk of injury to bystanders. Legal constraints on use of firearms.
	Penetrating captive bolt followed by pithing where necessary to ensure death	Can be inhumane if shot is inaccurate and dog is only wounded.	Skilled operator essential.	Animal must should be restrained. Skilled operator essential.	No risk to operator (cf 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.	Should Must be done on unconscious animal. Aesthetically objectionable

Annex XIX (contd)

Table 1: Summary analysis List of methods for the euthanasia of dogs (contd)

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 must <u>should</u> be used to achieve and maintain adequate concentration, which must <u>should</u> be monitored. Note: fumes from gasoline engines are an irritant and this source of CO is not recommended.	Very hazardous for operator - gas is odourless and causes toxicity at both acute high levels and chronic low levels	Dog dies quite rapidly if concentration of 4 to 6% used. No odour (therefore no aversive effect). Gas is not flammable or explosive except at concentration greater than 10%.	

Table 1: Summary analysis List of methods for the euthanasia of dogs (contd)

Euthanasia method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements	Considerations relating to operator security	Advantages	Disadvantages
	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.
Gaseous	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% must should be achieved rapidly and maintained. Properly designed equipment must 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.

Annex XIX (contd)

Table 1: Summary analysis List of methods for the euthanasia of dogs (contd)

Euthanasia method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements	Considerations relating to operator security	Advantages	Disadvantages
Gaseous	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 2ppm to avoid narcosis.	Gas is not flammable or explosive. Valuable for use with small animals (<7kgs) and animals that are already anesthetised with gas.	High cost. Anaesthetic and euthanasia properties of the gas used must should be known. Isoflurane has a pungent odour. Methoxyflurane's action is slow and dog may become agitated.
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.	Dogs must should be unconscious before being electrocuted. 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.	Inhumane if performed on conscious dog. May raise aesthetic objections.

KEY to abbreviations used in Table 1: IV: intravenous; IP: Intraperitoneal; IC: Intracardiac

a) Comments on methods for the euthanasia of dogs:

i) 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 **must** **should** be used in association with sedation or anaesthesia in order to be considered humane.

ii) 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*.

iii) The following methods, procedures and practices are unacceptable on *animal welfare* grounds:

- 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.
- Mechanical methods:
 - Air embolism on conscious animal
 - Burning
 - Exsanguination of conscious animal
 - Decompression: expansion of gas trapped in body cavities may be very painful
 - Drowning
 - Hypothermia, rapid freezing
 - Stunning: stunning is not a euthanasia method, it should always be followed by a method which ensures death.
 - Kill-trapping
 - Electrocution of conscious animal.

Annex XIX (contd)

Because neonatal *animals* and adults with impaired breathing or low blood pressure are resistant to hypoxia, methods that depend upon achieving a hypoxic state (e.g. CO₂, CO, N₂, Ar) should not be used. These methods should not be used in *animals* aged less than 2 months, except to produce loss of consciousness and should be followed by another method to cause death. Concussion and cervical dislocation may be used in very small neonatal dogs and only in cases of emergency.

Operators **must should** be well trained in the use of physical techniques to ensure that they are correctly and humanely carried out. The dog **must should** be exsanguinated immediately after concussion or cervical dislocation.

iv) Confirmation of death

For all methods of euthanasia used, death **must should** be confirmed before *animals* are disposed of or left unattended. If an animal is not dead, another method of euthanasia **must should** be performed.

v) Carcass disposal

Carcasses should be disposed of in a manner that complies with legislation. Attention **must should** be paid to the risk of residues occurring in the carcass. Incineration is generally the safest way of carcass disposal.

Article 7.7.7

Monitoring and evaluation of dog population control programmes

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:

1. to help improve performance, by highlighting both problems and successful elements of interventions;
2. for accountability, to demonstrate that the programme is achieving its aims;
3. assuming methods are standardised, to compare the success of strategies used in different locations and situations.

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.

4. Elements that should generally be monitored and evaluated include:
 - a) dog population size, separated ~~by~~ into sub-populations according to ownership and restriction of movement (i.e. roaming unrestricted or restricted by an owner);≡

- b) dog *welfare*, in the target population (e.g. body condition score, skin conditions and injuries or lameness) and as a result of the programme (if interventions involve direct handling of dogs, the *welfare* of the dogs as result of this handling should be monitored);
 - c) prevalence of zoonotic diseases, such as rabies, in both the animal and human population;
 - d) responsible animal ownership, including measures of attitudes and understanding of responsible ownership and evidence that this is translating into responsible behaviour.
5. 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).

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. Sample questionnaires can be found in the "Guidelines for Dog Population Management" (WHO/WSPA 1990). Standard polling principles **must** should be applied.

Annex XIX (contd)

If the proportion of ownerless dogs is high or difficult to assess, then one must should resort to more experimental approaches. Methods borrowed from wildlife biology can be applied. These methods are described WHO/WSPA's "Guidelines for Dog Population Management" (1990), and in more detail in numerous professional publications and handbooks, such as Bookhout (1994) and Sutherland (2006). 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 must 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 must 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 must 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 (Peterson-Jackson, Lincoln indices). 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. Examples for the two methods are given in WHO/WSPA's "Guidelines for Dog Population Management" (1990).

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.

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Annex XIX (contd)

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CHAPTER 7.X.

USE OF ANIMALS IN RESEARCH AND EDUCATION

Preamble

The purpose of this chapter is to provide advice and assistance for OIE Members to follow when formulating regulatory requirements, or other form of oversight, for the use of live *animals* in research, and education¹. A system of animal use oversight should be implemented in each country. The system will, in practice, vary from country to country and according to cultural, economic, religious and social factors. However, the OIE recommends that Members address all the essential elements identified in these standards 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 at the level of the country, the region and/or the institution and both public sector and private sector responsibilities should be clearly defined.

The OIE recognises the vital role played by the use of live *animals* in research and education. The OIE Guiding Principles for Animal Welfare state that such use makes a major contribution to the wellbeing of people and *animals* and emphasise the importance of the Three Rs (see Article 7.X.3.) of Russell and Burch (1959). Most scientists and members of the public agree that the *animals* should only be used when necessary, and 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 sentient *animals* and that good quality science depends upon good *animal welfare*. It is the responsibility of all involved in the use of *animals* to ensure that they give due regard to these recommendations. In keeping with the overall approach to *animal welfare* detailed in the Guiding Principles, the OIE stresses the importance of standards based on outcomes for the *animal*.

The OIE recognises the significant role of *veterinarians* in animal based research. Given their unique training and skills, they are essential members of a team including scientists and animal care technicians. This team approach is based on the concept that everyone involved in the use of *animals* has an ethical responsibility for the *animals' welfare*. The approach also ensures that animal use leads to high quality scientific and educational outcomes and optimum *welfare* for the *animals* used.

The OIE recommends that records on animal use should be maintained at an institutional level, as appropriate to the institution and project proposals and species used. Key events should be recorded to aid decision making and promote good science and welfare. A summary of these records may be gathered on a regional or national basis. These records may and be used published to provide a degree of public transparency, without compromising personnel or animal safety, or releasing proprietary information.

¹ Wherever the term "research" is used, it includes basic and applied research, testing and the production of biological materials; "education" includes teaching and training.

Definitions

Biological safety or biosafety

means the application of knowledge, techniques and equipment to prevent personal, laboratory and environmental exposure to potentially infectious agents or biohazards.

Biological containment or Biocontainment

means the system and procedures designed to prevent the accidental release of biological material including allergens. The objective of biocontainment is to confine biohazards and to reduce the potential exposure of the laboratory worker, animals on other studies, persons outside of the laboratory, and the environment to potentially infectious agents.

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. A comprehensive biosecurity programme not only seeks to prevent contamination but also to minimise the loss of animals and scientific data, and to limit the spread of unwanted microorganisms should contamination occur.

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 completely to stressors, and that manifests as abnormal physiological or behavioural responses. It can be acute or chronic and may result in pathological conditions.

Environmental enrichment

means increasing the complexity (e.g. with toys, cage furniture, foraging opportunities, social housing, etc.) in a captive animal's environment to foster the expression of non-injurious species-typical behaviours and reduce the expression of maladaptive behaviours, as well as provide cognitive stimulation.

Euthanasia

means the act of inducing death using a method that results in rapid loss of consciousness without recovery and minimum pain or distress to the animal.

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 staff personnel training. Ethical judgements are influenced by prevailing societal attitudes.

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.

Genetically altered animal (GA animal) (also genetically modified animal and genetically engineered animal)

means an *animal* that has had a random or targeted change in its nuclear or mitochondrial DNA, or the progeny of such an *animal(s)*, where they have inherited the change, achieved through a deliberate human technological intervention, 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

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*. 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.

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. The benefits should be maximised and the harms, in terms of pain and distress, should be minimised.

The Three Rs

means the internationally accepted tenet, first described by of Russell and Burch (1959), for the use of *animals* in research and education. The Three Rs comprise the following alternatives:

- replacement which refers to the use of methods utilizing cells, tissues or organs of vertebrate *animals* (relative replacement), as well as those that do not require the use of vertebrate *animals* to achieve the scientific aims (absolute replacement);
- reduction which 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*;
- refinement which refers to the use of methods that prevent, alleviate or minimise known and potential 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.

Operant (Instrumental) 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).

Annex XIX (contd)**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. The purpose of the Project Proposal is to enable assessment of the quality of, and justification for, the study, work or activity.

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.

Suffering

means an unpleasant, undesired state of being which 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.X.2.

Scope

These standards chapter applies to *animals* as defined in the *Terrestrial Code* (excluding bees) bred, supplied and/or used in research, (including testing) and higher education. *Animals* to be used for production of biologicals and/or humanely killed for harvesting their cells, tissues and organs for scientific purposes are also covered. Members should consider both the species and the developmental stage of the *animal* in implementing these standards.

Article 7.X.3.

The Three Rs

The internationally accepted tenet, the "Three Rs", comprises the following alternatives:

- replacement which refers to the use of methods utilizing cells, tissues or organs of vertebrate *animals* (relative replacement), as well as those that do not require the use of vertebrate *animals* to achieve the scientific aims (absolute replacement);
- reduction which 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*;
- refinement which refers to the use of methods that prevent, alleviate or minimise ~~known and potential~~ 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.X.34.

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.

A requirement for keeping records on animal use, as appropriate to the institution, project proposal and species, should be included. It may be appropriate to maintain such records on a regional or national basis and to provide some degree of public access without compromising personnel or animal safety, or releasing proprietary information.

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 national bodies. Typically An each 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. Where the local committee does not perform ethical review, this may be undertaken by regional or national ethical review bodies. It is important that the local committee reports to senior management within the institution to ensure it has ~~an~~ 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.

In providing this oversight and ensuring the implementation of the Three Rs, the following expertise should be included as a minimum:

- one scientist with experience in animal research, whose role is to ensure that protocols are designed and implemented in accordance with sound science;
- 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*.
- one public member to represent general community interests who is independent of the institution 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 representatives on.

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;

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- 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 local 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; and
- k) resources/infrastructure necessary to support the proposed work (e.g. facilities, equipment, qualified staff trained and found competent to perform the procedures described in the proposed project).

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 procedures and experimental procedures; observations made by the veterinary staff during their rounds; or by inspections by the local oversight body committee, 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. Animal care and use programme review

The animal care and use programme 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 oversight 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, and A requirement for the components of such a programme should be included in relevant regulations to empower the Competent Authority to take appropriate action to ensure compliance.

Article 7.X.45.

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 qualified 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 issues to the competence of staff.

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- 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, including the normal behaviour of the species, and they should understand research methodology. 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.X.56.

Provision of Veterinary Care

Adequate veterinary care includes responsibility for promoting an *animals* 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* must should have authority and responsibility for making judgements concerning *animal welfare*. Veterinary advice and care should be available at all times.

- 1) Clinical Responsibilities. Preventive medicine programmes that include vaccinations, ectoparasite and endoparasite treatments and other *disease* control measures should be initiated according to currently acceptable veterinary medical practices appropriate to the particular animal species and source. *Disease surveillance* is a major responsibility of the *veterinarian* and should include routine monitoring of colony *animals* for the presence of parasitic, bacterial and viral agents that may cause overt or sub clinical *diseases*. The *veterinarian* **must 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 **must should** be managed in accordance with applicable regulations.
- 2) Post mortem examinations. In the case of unexpected *disease* 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 m-M** 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 **complies 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* **have has** the authority to ensure euthanasia **or other measure are is** carried out as required to relieve pain and distress unless the Project Proposal approval specifically does not permit such intervention on the basis of the scientific purpose and the ethical evaluation.

Ideal humane endpoints are those that can be used to end a study before the onset of pain and/or distress, without jeopardising the study's objectives. In consultation with the veterinarian, humane endpoints should be described in the Project Proposal and, thus, established prior to commencement of the study. They should form part of the ethical review. Endpoint criteria should be easy to assess over the course of the study. Except in rare cases, death (other than euthanasia) as a planned endpoint is considered ethically unacceptable.

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* ~~must~~ should be acquired legally. It is preferable that *animals* are purchased from recognised sources producing or securing high quality *animals*.

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 scientifically justified 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. The use of wild caught nonhuman primates is generally discouraged.

- 2) Documentation. Relevant documentation related to the source of the *animals*, including 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 ~~must~~ should be validated by periodic genetic monitoring, typically using biochemical or immunological markers. Detailed and accurate documentation of the colony breeding records ~~must~~ should be maintained.
- 5) Genetically altered or cloned animals (also genetically modified animal and genetically engineered animal). A genetically altered or cloned *animals* is an *animal* that has had undergone genetic modification of its nuclear or mitochondrial genomes through a deliberate human intervention, or the progeny of such an *animal(s)*, where they have inherited the modification. If genetically altered or cloned *animals* are used, such use should be conducted in accordance with relevant regulatory guidance. With such *animals*, as well as harmful mutant lines arising from spontaneous mutations and induced mutagenesis, consideration should be given to addressing and monitoring special husbandry and *welfare* needs associated with abnormal phenotypes. Records should be kept of biocontainment requirements, genetic and phenotypic information, and individual identification, and be communicated by the animal provider to the recipient. Archiving and sharing of genetically altered lines is recommended to facilitate the sourcing of these customised *animals*.
- 6) Animals captured in the wild. If wild *animals* are to be used, the capture technique should be humane and give due regard to human and animal health, welfare and safety. Field studies have the potential to cause disturbance to the habitat thus adversely affecting both target and non-target species. The potential for such disturbance should be assessed and minimised. The effects of a series of stressors, such as trapping, handling, transportation, sedation, anaesthesia, marking and sampling, can be cumulative, and may produce severe, possibly fatal, consequences. An assessment of the potential sources of stress and management plans to eliminate or minimise distress should form part of the Project Proposal.

- 7) Endangered species. Endangered species should only be used in exceptional circumstances where there is strong scientific justification that the desired outcomes cannot be achieved using any other species.
- 8) Transport, importation and exportation. *Animals* should be transported under conditions that are appropriate to their physiological and behavioural needs and pathogen status, with care to ensure appropriate physical containment of the *animals* as well as exclusion of contaminants. The amount of time *animals* spend on a *journey* should be kept to a minimum. It is important to ensure that there is a well constructed journey plan, with key staff identified who have responsibility for the *animals* and that relevant documentation accompanies *animals* during transport to avoid unnecessary delays during the *journey* from the sender to the receiving institution.
- 9) Risks to biosecurity. To reduce risks to biosecurity related to *animals*, the pathogen status of *animals* should be confirmed and appropriate biocontainment and bioexclusion measures should be practised. Biosecurity risks to *animals* arising from exposure to humans should also be addressed. 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.X.7g.

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.

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- 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 kept to a minimum appropriately limited to avoid repeated large 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, but not nearly as narrowly as temperature.
- 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 ~~away from~~ 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.X. ~~89.~~

Husbandry

Good husbandry practices enhance the health and *welfare* of the *animals* used and contributes to the scientific validity of animal research. Animal care and accommodation should, as a minimum, demonstrably conform to relevant published animal care, accommodation and husbandry guidelines and regulations.

The housing environment and husbandry practices should take into consideration the normal behaviour of the species, including their social behaviour and age of the *animal*, and should minimise stress to the *animal*. During the conduct of husbandry procedures, personnel should be keenly aware of their potential impact on the *animals' welfare*.

- 1) Transportation. Transportation is a typically stressful experience, ~~for animals should be transported.~~ Therefore, every precaution should be taken to avoid unnecessary stress through inadequate ventilation, exposure to extreme temperatures, lack of feed and water, long delays, etc. Consignments of animals should be accepted into the facility without avoidable delay and, after inspection, should be transferred to clean cages or pens and be supplied with feed and water as appropriate. Social animals should be transported in established pairs or groups and maintained in these on arrival.
- 2) Acclimatisation. Newly received *animals* should be given a period for physiological and behavioural stabilisation before their use. The length of time for stabilisation will depend on the type and duration of transportation, the age and species involved, place of origin, and the intended use of the *animals*. Facilities should be available to isolate *animals* showing signs of ill health.

- 3) Cages and pens. Cages and pens should be made out of material that can be readily cleaned and decontaminated. Their design should be such that the *animals* are unlikely to injure themselves. Space allocations should be reviewed and modified as necessary to address individual housing situations and animal needs (for example, for prenatal and postnatal care, obese *animals*, and group or individual housing). Both the quantity and quality of space provided is important. Whenever it is appropriate, social *animals* should be housed in pairs or groups, rather than individually, provided that such housing is not contraindicated by the protocol in question and does not pose an undue risk to the *animals*.
- 4) Enrichment. *Animals* should be housed with a goal of maximising species specific appropriate behaviours and avoiding or minimising stress induced behaviours. One way to achieve this is to enrich the structural and social environment of the research *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 significantly 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, and storing and preparing feed to avoid chemical, physical and microbiological contamination, deterioration or destruction. Utensils used for feeding should be regularly cleaned and, if necessary, sterilised.
- 6) Water. Uncontaminated potable drinking water should normally be available at all times. Watering devices, such as drinking tubes and automatic watering systems, should be checked daily to ensure their proper maintenance, cleanliness, and operation.
- 7) Bedding. Animals should have appropriate bedding provided, with additional nesting material if appropriate to the species. Animal bedding is a controllable environmental factor that can influence experimental data and *animal welfare*. Bedding should be dry, absorbent, non-dusty, non-toxic and free from infectious agents, vermin or chemical contamination. Soiled bedding should be removed and replaced with fresh material as often as is necessary to keep the *animals* clean and dry.
- 8) Hygiene. The successful operation of a facility depends very much on good hygiene. Special care should be taken to avoid spreading *infection* between *animals* through fomites, including through personnel traffic between animal rooms. Adequate routines and facilities for the cleaning, washing, decontamination and, when necessary, sterilisation of cages, cage accessories and other equipment should be established. A very high standard of cleanliness and organisation should also be maintained throughout the facility.
- 9) Identification. Animal identification is an important component of record keeping. *Animals* may be identified individually or by group. Where it is desirable to individually identify *animals*, this should be done by a reliable and the least painful method.

Annex XIX (contd)

- 10) Handling. Staff dealing with *animals* should have a caring and respectful attitude towards the *animals* and be competent in handling and restraint. Familiarising *animals* to handling during routine husbandry and procedures reduces stress both to *animals* and personnel. For some species, for example dogs and non-human primates, a training programme to encourage cooperation during procedures can be beneficial to the *animals*, the animal care staff and the scientific programme. For certain species, social contact with humans should be a priority. However, in some cases handling should be avoided. This may be particularly the case with wild *animals*. Consideration should be given to setting up habituation and training programmes suitable for the *animals*, the procedures and length of projects.
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CHAPTER 8.1

ANTHRAX

Article 8.1.1.

General provisions

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

There is no evidence that anthrax is transmitted by animals before the onset of clinical and pathological signs. Early detection of *outbreaks*, quarantine of affected premises, destruction of diseased animals and fomites, and implementation of appropriate sanitary procedures at *abattoirs* and dairy factories will ensure the safety of products of animal origin intended for human consumption.

For the purposes of the *Terrestrial Code*, the *incubation period* for anthrax shall be 20 days.

Anthrax should be notifiable in the whole country.

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

When authorising import or transit of commodities covered in the chapter, with the exception of those listed in Article 8.1.1bis., Veterinary Authorities should require the conditions prescribed in this chapter.

Article 8.1.1.bis

Safe commodities

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

Article 8.1.2.

Recommendations for the importation of ruminants, equines and pigs

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

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

AND

2. were kept for the 20 days prior to shipment in an *establishment* where no *case* of anthrax was officially declared during that period; or
3. were vaccinated, not less than 20 days and not more than 6 months prior to shipment in accordance with the *Terrestrial Manual*.

Annex XX (contd)

Article 8.1.3.

Recommendations for the importation of products of animal origin (from ruminants, equines and pigs) intended for agricultural or industrial use

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

- ~~1. originate from animals not showing clinical signs of anthrax; or~~
- ~~2. have been processed to ensure the destruction of both bacillary and spore forms of *Bacillus anthracis*, in conformity with one of the procedures referred to in Chapter X.X. (under study).~~

Article 8.1.4.

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

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

1. have shown no sign of anthrax during ante-mortem and post-mortem inspections; and
2. were not immunised vaccinated against anthrax using live vaccine during the 21 days prior to slaughter or a longer period depending on the manufacturer's recommendations; and
23. come from *establishments* which are not placed under quarantine restriction on account of anthrax control and in which:
 - a) there has been no *case* of anthrax during the 20 days prior to *slaughter*;
 - b) ~~no vaccination against anthrax has been carried out during the 42 days prior to slaughter.~~

Article 8.1.5.

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

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

1. have shown no sign of anthrax during ante-mortem and post-mortem inspections; and
2. come from *establishments* which are not placed under quarantine restriction on account of anthrax control.

Article 8.1.6.

Recommendations for the importation of wool

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

1. ~~originate from animals showing no clinical signs of anthrax at the time of shearing; and~~
21. originate from *establishments* where no *case* of anthrax has been reported since the previous shearing of all animals;

OR

32. have been treated in accordance with the recommendations in Article 8.1.11.

Article 8.1.7.

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

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

1. **the milk** originates from animals showing no clinical signs of anthrax at the time of milking; ~~or~~
2. ~~were~~ **if the milk originates from herds or flocks that have had a case of anthrax within the previous 20 days, it has been chilled promptly and processed using a heat treatment of 120 °C for 106 seconds at least equivalent to pasteurisation (under study) at least equivalent to pasteurisation.**

Reference

SA XU, THEODORE P. LABUZA & FRANCISCO DIEZ GONZALEZ (2006). Thermal Inactivation of *Bacillus anthracis* in Cow's Milk. *Applied and Environmental Microbiology*, juin 2006, Vol 72, N°6, pp. 4479-4483.

Article 8.1.8.

Recommendations for the importation of bristles (from pigs)

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

1. have shown no sign of anthrax during ante-mortem and post-mortem inspections; and
2. come from establishments which are not placed under quarantine restriction on account of anthrax control;

OR

3. have been processed to ensure the destruction of *B. anthracis* by:
 - a) boiling for 60 minutes; and
 - b) drying in hot air.
 - c) immersion for 24 hours in a 2% solution of formaldehyde at >20 °C.

Annex XX (contd)

References

REINHARD BÖHM. Institut für Umwelt und Tierhygiene Sowie Tiermedizin mit Tierklinik, Universität Hohenheim. Communication personnelle au Dr Wolf Arno Valder, Commission des normes sanitaires pour les animaux terrestres de l'OIE.

E.A. SPOTTS WHITNEY, M.E. BEATTY, T.H. R.J. TAYLOR, R. WEYANT, J. SOBEL, M.J. ARDUINO & D.A. ASHFORD. (2003). Inactivation of *Bacillus anthracis* spores. *Emerging Infectious Diseases*, 9 (6), 623-627.

Article 8.1.9.

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

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that these products have been processed to ensure the destruction of *B. anthracis* by one of the following methods:

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

1. fumigation with ethylene oxide 500 mg/L. at relative humidity 20-40%, at 55 °C for 30 minutes; or
2. fumigation with formaldehyde 400 mg/m³. at relative humidity 30%. at >15 °C for 4 hours; or
3. fumigation with methylene bromide 3.4-3.9 g/L. in the presence of moisture, at room temperature for 24 hours; or
3. gamma irradiation with a dose of 40 kGy.

References

REINHARD BÖHM. Institut für Umwelt und Tierhygiene Sowie Tiermedizin mit Tierklinik, Universität Hohenheim. Communication personnelle au Dr Wolf Arno Valder, Commission des normes sanitaires pour les animaux terrestres de l'OIE.

P. TURNBULL P. & O. COSIVI. (2008). *Anthrax in humans and animals*, 4th Edition, WHO/FAO/OIE

E.A. SPOTTS WHITNEY, M.E. BEATTY, T.H. R.J. TAYLOR, R. WEYANT, J. SOBEL, M.J. ARDUINO & D.A. ASHFORD. (2003). Inactivation of *Bacillus anthracis* spores. *Emerging Infectious Diseases*, 9 (6), 623-627.

Article 8.1.10.

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

The following procedure should be used to inactivate any *B. anthracis* spores which may be present during the production of bone-meal or meat-and-bone meal from ruminants, equines and pigs:

1. the raw material should be reduced to a maximum particle size of 50 mm before heating; and
2. the raw material should be heated under saturated steam conditions to a temperature of not less than 133°C for a minimum of 20 minutes at an absolute pressure of 3 bar or be subjected to an industrial process demonstrated to be of equivalent efficacy.

References

REINHARD BÖHM. Institut für Umwelt und Tierhygiene Sowie Tiermedizin mit Tierklinik, Universität Hohenheim. Communication personnelle au Dr Wolf Arno Valder, Commission des normes sanitaires pour les animaux terrestres de l'OIE.

P. TURNBULL P. & O. COSIVI. (2008). Anthrax in humans and animals, 4th Edition, WHO/FAO/OIE

Article 8.1.11.**Procedures for the inactivation of *B. anthracis* spores in wool and hair**

In situations in which wool or hair may be contaminated with *B. anthracis* spores, the following five-step disinfection procedure is recommended:

1. immersion in 0.25-0.3% soda liquor for 10 minutes at 450.5 °C;
2. immersion in soap liquor for 10 minutes at 450.5 °C;
3. immersion in 2% formaldehyde solution for 10 minutes at 450.5 °C;
4. a second immersion in 2% formaldehyde solution for 10 minutes at 450.5 °C;
5. rinsing on cold water followed by drying in hot air.

References

REINHARD BÖHM. Institut für Umwelt und Tierhygiene Sowie Tiermedizin mit Tierklinik, Universität Hohenheim. Communication personnelle au Dr Wolf Arno Valder, Commission des normes sanitaires pour les animaux terrestres de l'OIE.

P. TURNBULL P. & O. COSIVI. (2008). Anthrax in humans and animals, 4th Edition, WHO/FAO/OIE

Article 8.1.12.**Procedures for the inactivation of *B. anthracis* spores in manure, dung and bedding**

In situations in which manure, dung or bedding may be contaminated with *B. anthracis* spores, the following are recommended:

1. small volumes by incineration; or
2. chemothermal treatment by composting with quicklime as follows:
 - a) mix the manure with granulated quicklime at a rate of 100 kg quicklime per m³ and spray with water mix with one of the following at a rate of 1-1.5L/m³:
 - i) 10% formaldehyde (approximately 30% formalin), or
 - ii) 4% gluteraldehyde (pH 8.0-8.5);
 - b) turn the material after 5 weeks;
 - c) leave for a further 5 weeks.

Annex XX (contd)

Note: spontaneous combustion of the composting pile is possible.

References

~~REINHARD BÖHM. Institut für Umwelt und Tierhygiene Sowie Tiermedizin mit Tierklinik, Universität Hohenheim. Communication personnelle au Dr Wolf Arno Valder, Commission des normes sanitaires pour les animaux terrestres de l'OIE.~~

Article 8.1.13.

Procedures for the inactivation of *B. anthracis* spores in liquid manure (slurry)

In situations in which liquid manure (slurry) may be contaminated with *B. anthracis* spores, the following is recommended:

1. disinfection with formalin (35% aqueous solution of formaldehyde) with stirring for one hour stirring daily:

 - a) for slurry up to 5% dry matter. 50 kg formalin per m³ for 4 days;
 - b) for slurry >5% and <10% dry matter. 100 kg formalin per m³ for 4 days.

References

~~REINHARD BÖHM. Institut für Umwelt und Tierhygiene Sowie Tiermedizin mit Tierklinik, Universität Hohenheim. Communication personnelle au Dr Wolf Arno Valder, Commission des normes sanitaires pour les animaux terrestres de l'OIE.~~

~~P. TURNBULL P. & O. COSIVI. (2008). Anthrax in humans and animals, 4th Edition, WHO/FAO/OIE.~~

Article 8.1.14.

Procedures for the disinfection of surfaces in animal houses, buildings contaminated with *B. anthracis*

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:

1. a preliminary disinfection should be carried out using one of the following disinfectants at a rate of 1-1.5 L/m³ for 2 hours:
 - a) 10% formaldehyde (approximately 30% formalin); or
 - b) 4% glutaraldehyde (pH 8.0-8.5);
2. all surfaces should be washed and scrubbed using ample hot water and, when cleaned and waste water is free from dirt particles, dried;

3. a final disinfection step should be carried out using one of the following disinfectants applied at a rate of 0.4 L/m³ for 2 hours:
- a) 10% formaldehyde (approximately 30% formalin), repeated after one hour; or
 - b) 4% glutaraldehyde (pH 8.0-8.5), repeated after one hour; or
 - c) 3% hydrogen peroxide; or
 - d) 1% peracetic acid, repeated after one hour.

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.

References

P. TURNBULL P. & O. COSIVI. (2008). Anthrax in humans and animals, 4th Edition, WHO/FAO/OIE.

E.A. SPOTTS WHITNEY, M.E. BEATTY, T.H. R.J. TAYLOR, R. WEYANT, J. SOBEL, M.J. ARDUINO & D.A. ASHFORD. (2003). Inactivation of *Bacillus anthracis* spores. *Emerging Infectious Diseases*, 9 (6), 623–627.

Article 8.1.15.

Procedures for the fumigation of rooms contaminated with *B. anthracis*

Contaminated rooms which cannot be cleared before cleaning and disinfection can be fumigated to eliminate *B. anthracis* spores. The following procedure is recommended:

1. all windows, doors and vents to the outside should be sealed with heavy adhesive tape; and
2. for rooms up to 30 m³, 4 L 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.

References

P. TURNBULL P. & O. COSIVI. (2008). Anthrax in humans and animals, 4th Edition, WHO/FAO/OIE

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CHAPTER 8.2.

AUJESZKY'S DISEASE

Article 8.2.1.

General provisions

The Aujeszky's disease (AD) free or provisionally free status of a country or *zone* can only be determined if the following conditions are fulfilled:

1. a *risk assessment* has been conducted identifying all potential factors for AD occurrence and their historic perspective;
2. AD is notifiable in the whole country, and all clinical cases suggestive of AD are subjected to field and laboratory investigations;
3. an on-going awareness programme is in place to encourage reporting of all cases suggestive of AD in susceptible species;
4. the *Veterinary Authority* has current knowledge of, and authority over, all *establishments* containing pigs in the whole country;
5. domestic pigs are properly identified when leaving their *establishment* of origin with an indelible mark giving the identification number of their *herd* of origin; a reliable tracing back procedure is in place for all pigs leaving their *establishment* of origin.

An AD infected *establishment* means an *establishment* in which the virus has been isolated or identified, or a positive serological result (total or gE antibodies) has been confirmed in a *laboratory*.

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

When authorising import or transit of ~~either the commodities listed covered in this~~ chapter, with the exception of those listed in Article 8.2.1 bis, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the AD status of the *exporting country or zone*.

Article 8.2.1 bis

Safe commodities

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

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

Annex XXI (contd)

Article 8.2.2.

AD free country or zone1. Qualification

A country or *zone* may be considered free from the *disease* without formally applying a specific *surveillance* programme (historical freedom) if the *disease* has not been reported for at least 25 years, and if for at least the past 10 years:

- a) it has been a *notifiable disease*;
- b) an early detection system has been in place;
- c) measures to prevent the introduction of the AD virus into the country or *zone* have been in place;
- d) no vaccination against the *disease* has been carried out;
- e) *infection* is not known to be established in wild swine, or measures have been implemented to prevent any transmission of the AD virus from wild swine to domestic pigs.

A country or *zone* which does not meet the conditions of the above paragraph may be considered free from AD when:

- f) animal health regulations to control the movement of *commodities* listed in Article 8.2.6. with the exception of those listed in Article 8.2.1.bis in order to prevent the introduction of *infection* into the *establishments* of the country or *zone* have been in place for at least 2 years;
- g) vaccination against AD has been banned for all domestic pigs in the country or *zone* for at least 2 years;
- h) if AD has never been reported in the country or *zone*, serological surveys, with negative results, have been conducted on a representative sample of all pig *establishments* in conformity with the recommendations in Chapter X.X. (under study) no more than 3 years prior to qualification; the serological surveys should be directed at the detection of antibodies to the whole virus, and based on the breeding pig population or, for *establishments* that contain no breeding pigs, on a comparable number of fattening pigs; or
- i) if AD has been reported in the country or *zone*, a *surveillance* and control programme has been in place to detect every infected *establishment* and eradicate AD from it; the *surveillance* programme should be carried out in conformity with the recommendations in Chapter X.X. (under study) and demonstrate that no *establishments* within the country or *zone* have had any clinical, virological or serological evidence of AD for at least 2 years.

In order for a country to reach free status, all of its *zones* must should have reached AD free status.

In countries or *zones* with wild swine, measures should be implemented to prevent any transmission of the AD virus from wild swine to domestic pigs.

2. Maintenance of free status

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

- a) periodic serological surveys directed at the detection of antibodies to the whole AD virus should be carried out on a statistically significant number of breeding pigs, in conformity with the recommendations in Chapter X.X. (under study);
- b) the importation of the *commodities* ~~listed in Article 8.2.6.~~ with the exception of those listed in Article 8.2.1 bis into the country or *zone* is carried out in conformity with the import conditions contained in the relevant Articles of the present chapter;
- c) the ban on AD vaccination remains in force;
- d) measures aimed at preventing the transmission of the AD virus from wild swine to domestic pigs remain in force.

3. Recovery of free status

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

- a) all the pigs in the *outbreak* have been slaughtered; and, during and after the application of this measure, an epidemiological investigation including clinical examination, and serological and/or virological testing has been carried out in all pig *establishments* which have been directly or indirectly in contact with the infected *establishment* and in all pig *establishments* located within a 5-kilometre radius of the *outbreak*, demonstrating that these *establishments* are not infected; or
- b) vaccination with gE- deleted vaccines has been applied and:
 - i) a serological testing procedure (differential ELISA) has been implemented in the *establishments* where vaccination has been applied to demonstrate the absence of *infection*;
 - ii) the movement of pigs from these *establishments* has been banned, except for immediate *slaughter*, until the above procedure has demonstrated the absence of *infection*;
 - iii) all vaccinated animals have been slaughtered;
 - iv) during and after the application of the measures described in points i) to iii) above, a thorough epidemiological investigation including clinical examination and serological and/or virological testing has been carried out in all pig *establishments* which have been directly or indirectly in contact with the infected *establishment* and in all pig *establishments* located within a 5-kilometre radius of the *outbreak*, demonstrating that these *establishments* are not infected.

Article 8.2.3.

AD provisionally free country or zone

1. Qualification

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

Annex XXI (contd)

- a) animal health regulations to control the movement of *commodities* listed in Article 8.2.6, with the exception of those listed in Article 8.2.1.bis in order to prevent the introduction of *infection* into the *establishments* of the country or *zone* have been in place for at least 2 years;
- b) if AD has never been reported in the country or *zone*, a serological survey, with negative results, has been conducted on a representative sample of all pig *establishments* in conformity with the recommendations in Chapter X.X. (under study) (at a level of confidence not sufficient to meet requirements for freedom); the serological survey should be directed at the detection of antibodies to the whole virus, and based on the breeding pig population or, for *establishments* that contain no breeding pigs, on a comparable number of fattening pigs; or
- c) if AD has been reported in the country or *zone*, a *surveillance* and control programme has been in place to detect infected *establishments* and eradicate AD from these *establishments*, the *herd* prevalence rate in the country or *zone* has not exceeded 1% for at least 3 years (the sampling procedure described in point 1e) of the definition of 'AD free establishment' should be applied within the *establishments* of the country or *zone*), and at least 90% of the *establishments* in the country or *zone* are qualified free;
- d) in countries or *zones* with wild swine, measures should be taken to prevent any transmission of the AD virus between wild swine and domestic pigs.

2. Maintenance of provisionally free status

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

- a) the measures described in points 1b) and 1d) above should be continued;
- b) the percentage of infected *establishments* remains $\leq 1\%$;
- c) the importation of the *commodities* listed in Article 8.2.6, with the exception of those listed in Article 8.2.1.bis into the country or *zone* is carried out in conformity with the import conditions contained in the relevant Articles of the present chapter.

3. Recovery of provisionally free status

Should the percentage of infected *establishments* exceed 1% in a provisionally free country or *zone*, the status of the country or *zone* is cancelled and may be restored only once the percentage of infected *establishments* has remained $\leq 1\%$ for at least 6 months, and this result is confirmed by a serological survey conducted in conformity with point 1c) above.

Article 8.2.4.

AD infected country or zone

Countries and *zones* which do not fulfil the conditions to be considered free or provisionally free of AD should be considered as infected.

Article 8.2.5.

AD free establishment1. Qualification

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

- a) it is under the control of the *Veterinary Authority*;
- b) no clinical, virological or serological evidence of AD has been found for at least one year;
- c) the introduction of pigs, semen and embryos/ova into the *establishment* is carried out in conformity with the import conditions for these *commodities* contained in the relevant articles of the present chapter;
- d) vaccination against AD has not been carried out in the *establishment* for at least 12 months, and any previously vaccinated pigs are free from gE antibodies;
- e) a number of breeding pigs from the *establishment* has been subjected, with negative results, to serological tests to the whole AD virus, applying a sampling procedure set out in conformity with the recommendations in Chapter X.X. (under study); these tests **must should** have been carried out on two occasions, at an interval of 2 months; for *establishments* that contain no breeding pigs, the tests should be carried out only once on a comparable number of fattening or weaning pigs;
- f) a *surveillance* and control programme has been in place to detect infected *establishments* located within a 5-kilometre radius of the *establishment* and no *establishment* is known to be infected within this *zone*.

2. Maintenance of free status

For *establishments* located in an infected country or *infected zone*, the testing procedure described in point 1e) above should be carried out every 4 months.

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

3. Recovery of free status

Should a free *establishment* become infected, or should an *outbreak* occur within a 5-kilometre radius of a free *establishment*, the free status of the *establishment* should be suspended until the following conditions are met:

- a) in the infected *establishment*:
 - i) all the pigs in the *establishment* have been slaughtered, or
 - ii) at least 30 days after removal of all infected animals, all breeding animals have been subjected to a serological test to the whole AD virus, with negative results, on two occasions, at an interval of 2 months;

Annex XXI (contd)

- b) in other *establishments* located in the 5kilometre radius *zone*: a number of breeding pigs from each *establishment* has been subjected, with negative results, to serological tests to the whole AD virus (non vaccinated *establishments*) or to gE antibodies (vaccinated *establishments*), applying the sampling procedure described in point 1e above.

~~Article 8.2.6.~~**Trade in commodities**

~~Commodities other than those listed below are not considered to have the potential to spread AD when they are the subject of international trade.~~

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

- ~~1. domestic and wild swine;~~
- ~~2. semen of domestic and wild swine;~~
- ~~3. embryos/ova of domestic and wild swine;~~
- ~~4. offal (head, and thoracic and abdominal viscera) of swine and products containing swine offal;~~
- ~~5. pathological material and biological products (see Chapter 5.8.).~~

Article 8.2.7.

Recommendations for importation from AD free countries or zonesfor domestic pigs

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

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

Article 8.2.8.

Recommendations for importation from AD provisionally free countries or zonesfor domestic pigs for breeding or rearing

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

1. showed no clinical sign of AD on the day of shipment;
2. have been kept exclusively in AD free *establishments* since birth;

3. have not been vaccinated against AD;
4. were subjected to a serological test to the whole AD virus, with negative results, within 15 days prior to shipment.

Article 8.2.9.

Recommendations for importation from AD infected countries or zones

for domestic pigs for breeding or rearing

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

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

Article 8.2.10.

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

for domestic pigs for slaughter

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

1. a *surveillance* and control programme is in place in the country or *zone* to detect infected *establishments* and eradicate AD;
2. the animals:
 - a) are not being eliminated as part of an eradication programme;
 - b) showed no clinical sign of AD on the day of shipment;
 - c) have been kept exclusively in AD free *establishments* since birth; or
 - d) have been vaccinated against AD at least 15 days prior to shipment.

[*Note: Appropriate precautions should be taken both by the exporting country and the importing country to ensure that the pigs are transported directly from the place of shipment to the abattoir for immediate slaughter.*]

Annex XXI (contd)

Article 8.2.11.

Recommendations for importation from AD free countries or zonesfor wild swine

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

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

Article 8.2.12.

Recommendations for importation from AD free countries or zonesfor semen of pigs

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

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

Article 8.2.13.

Recommendations for importation from AD provisionally free countries or zonesfor semen of pigs

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

1. the donor animals:
 - a) have been kept for at least 4 months prior to semen collection in an *artificial insemination centre* which has the status of AD free *establishment*, and where all boars are subjected to a serological test to the whole AD virus, with negative results, every 4 months;
 - b) showed no clinical sign of AD on the day of collection;
2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.2.14.

Recommendations for importation from AD infected countries or zonesfor semen of pigs

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

1. the donor animals:
 - a) were kept in an AD free *establishment* for at least 6 months prior to entering the *artificial insemination centre*;
 - b) have been kept for at least 4 months prior to semen collection in the *artificial insemination centre* which has the status of AD free *establishment*, and where all boars are subjected to a serological test to the whole AD virus, with negative results, every 4 months;
 - c) were subjected to a serological test to the whole AD virus, with negative results, within 10 days prior to or 21 days after semen collection;
 - d) showed no clinical sign of AD on the day of collection;
2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.2.15.

Recommendations for importation from AD free countries or zonesfor *in vivo* derived embryos of pigs

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

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

Article 8.2.16.

Recommendations for importation from AD provisionally free countries or zonesfor *in vivo* derived embryos of pigs

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

Annex XXI (contd)

1. the donor females:
 - a) showed no clinical sign of AD on the day of collection of the embryos;
 - b) were kept in an AD free *establishment* for at least 3 months prior to collection;
2. the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 8.2.17.

Recommendations for importation from AD infected countries or zonesfor *in vivo* derived embryos of pigs

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

1. the donor females:
 - a) showed no clinical sign of AD on the day of collection of the embryos;
 - b) were kept in an AD free *establishment* for at least 3 months prior to collection;
 - c) were subjected to a serological test to the whole AD virus, with negative results, within 10 days prior to collection;
2. the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 8.2.18.

Recommendations for importation from AD free countries or zonesfor offal (head, and thoracic and abdominal viscera) of pigs or products containing pig offal

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

Article 8.2.19.

Recommendations for importation from AD provisionally free countries or zones or from AD infected countries or zonesfor offal (head, and thoracic and abdominal viscera) of pigs

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

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

Article 8.2.20.

Recommendations for importation from AD provisionally free countries or zones or from AD infected countries or zonesfor products containing pig offal (head, and thoracic and abdominal viscera)

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

1. either the entire consignment of offal used to prepare the products complied with the conditions referred to in Article 8.2.19.; or
2. the products have been processed to ensure the destruction of the AD virus; and
3. the necessary precautions were taken after processing to avoid contact of the products with any source of AD virus.

— text deleted

CHAPTER 8.3.

BLUETONGUE

Article 8.3.1.

General provisions

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

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

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

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

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

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

Article 8.3.2.

Trade in Safe commodities

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

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

Annex XXII (contd)

~~When authorising import or transit of other commodities listed in this chapter, Veterinary Authorities should require the conditions prescribed in this chapter relevant to the BTV status of the ruminant population of the exporting country or zone.~~

Article 8.3.3.

BTV free country or zone

1. A country or a *zone* may be considered free from BTV when bluetongue is notifiable in the whole country and either:
 - a) ~~the country or zone lies wholly north of 53°N or south of 34°S, and is not adjacent to a country or zone not having a free status; or~~
 - ba) a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21. has demonstrated no evidence of BTV in the country or *zone* during the past 2 years; or
 - eb) a *surveillance* programme has demonstrated no evidence of *Culicoides* ~~likely to be competent BTV vectors~~ in the country or *zone*.
2. A BTV free country or *zone* in which ongoing vector surveillance performed according to point 5 of Article 8.3.19. has found no evidence ~~that of~~ *Culicoides* ~~likely to be competent BTV vectors are present~~ will not lose its free status through the importation of vaccinated, seropositive or infective animals, or semen or embryos/ova from infected countries or *infected zones*.
3. A BTV free country or *zone* in which *surveillance* has found evidence that *Culicoides* ~~likely to be competent BTV vectors~~ are present will not lose its free status through the importation of vaccinated or seropositive animals from infected countries or *infected zones*, provided:
 - a) the animals have been vaccinated, at least 60 days prior to dispatch, in accordance with the *Terrestrial Manual* with a vaccine which covers all serotypes whose presence has been demonstrated in the source population through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21., and the animals are identified in the accompanying certification as having been vaccinated; or
 - b) the animals are not vaccinated and ~~a surveillance programme in accordance with Articles 8.3.16. to 8.3.21. has been in place in the source population for a period of, at least 60 days immediately prior to dispatch, and no evidence of BTV transmission has been detected~~ are demonstrated to have specific antibodies against the bluetongue virus serotypes whose presence has been demonstrated in the exporting country or zone.
4. A BTV free country or *zone* adjacent to an infected country or *infected zone* should include a *zone* as described in Article 8.3.1. in which *surveillance* is conducted in accordance with Articles 8.3.16. to 8.3.21. Animals within this *zone* ~~must~~ should be subjected to continuing *surveillance*. The boundaries of this *zone* ~~must~~ should be clearly defined, and ~~must~~ should take account of geographical and epidemiological factors that are relevant to BTV transmission.

Article 8.3.4.

BTV seasonally free zone

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

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

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

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

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

Article 8.3.5.

BTV infected country or zone

A BTV infected country or *infected zone* is a clearly defined area where evidence of BTV has been reported during the past 2 years.

Article 8.3.6.

Recommendations for importation from BTV free countries or zones

for ruminants and other BTV susceptible herbivores

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

1. the animals were kept in a BTV free country or *zone* since birth or for at least 60 days prior to shipment; or
2. the animals were kept in a BTV free country or *zone* for at least 28 days, then were subjected, with negative results, to a serological test to detect antibody to the BTV group according to the *Terrestrial Manual* and remained in the BTV free country or *zone* until shipment; or
3. the animals were kept in a BTV free country or *zone* for at least 7 days, then were subjected, with negative results, to an agent identification test according to the *Terrestrial Manual*, and remained in the BTV free country or *zone* until shipment; or
4. the animals:
 - a) were kept in a BTV free country or *zone* for at least 7 days;
 - b) were vaccinated, at least 60 days before the introduction into the free country or *zone*, in accordance with the *Terrestrial Manual* against all serotypes whose presence has been demonstrated in the source population through a *surveillance* programme as described in Articles 8.3.16. to 8.3.21.;
 - c) were identified as having been vaccinated; and
 - d) remained in the BTV free country or *zone* until shipment;

Annex XXII (contd)

AND

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

Article 8.3.7.

Recommendations for importation from BTV seasonally free zonesfor ruminants and other BTV susceptible herbivores

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

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

AND

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

Article 8.3.8.

Recommendations for importation from BTV infected countries or zonesfor ruminants and other BTV susceptible herbivores

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

1. were protected from attack from *Culicoides* ~~likely to be competent BTV vectors~~ in an insect proof *establishment* for at least 60 days prior to shipment and during transportation to the *place of shipment*; or
2. were protected from attack from *Culicoides* ~~likely to be competent BTV vectors~~ in an insect proof *establishment* for at least 28 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, with negative results, carried out at least 28 days after introduction into the ~~quarantine station~~ *insect proof establishment*; or
3. were protected from attack from *Culicoides* ~~likely to be competent BTV vectors~~ in an insect proof *establishment* for at least 14 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to an agent identification test according to the *Terrestrial Manual*, with negative results, carried out at least 14 days after introduction into the ~~quarantine station~~ *insect proof establishment*; or
4. were vaccinated, at least 60 days before shipment, in accordance with the *Terrestrial Manual* against all serotypes whose presence has been demonstrated in the source population through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21., and were identified in the accompanying certification as having been vaccinated or,
5. ~~if animals demonstrated to have antibodies for at least 60 days prior to dispatch against all serotypes whose presence has been demonstrated in the source population through a surveillance programme in accordance with Articles 8.3.16. to 8.3.21., have been protected from vectors for at least 60 days prior to shipment; or~~
5. ~~are not vaccinated, a surveillance programme in accordance with Articles 8.3.16. to 8.3.21. has been in place in the source population for a period of at least 60 days immediately prior to shipment, and no evidence of BTV transmission has been detected and were protected from attack from *Culicoides* likely to be competent BTV vectors during transportation to the *place of shipment*.~~

Article 8.3.9.

Recommendations for importation from BTV free countries or zonesfor semen of ruminants and other BTV susceptible herbivores

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

1. the donor animals:
 - a) were kept in a BTV free country or *zone* for at least 60 days before commencement of, and during, collection of the semen; or

Annex XXII (contd)

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

Article 8.3.10.

Recommendations for importation from BTV seasonally free zones

for semen of ruminants and other BTV susceptible herbivores

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

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

Article 8.3.11.

Recommendations for importation from BTV infected countries or zones

for semen of ruminants and other BTV susceptible herbivores

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

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

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

Article 8.3.12.

Recommendations for importation from BTV free countries or zones

for *in vivo* derived embryos of ruminants (other than bovines) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos

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

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

Article 8.3.13.

Recommendations for importation from BTV seasonally free zones

for *in vivo* derived embryos/oocytes of ruminants (other than bovines) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos

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

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

Article 8.3.14.

Recommendations for importation from BTV infected countries or zones

for *in vivo* derived embryos/oocytes of ruminants (other than bovines) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos

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

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

Article 8.3.15.

Protecting animals from *Culicoides* attack

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

Potential *risk management* strategies include:

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

Article 8.3.16.

Surveillance: introduction

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

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

~~Susceptible wild ruminant populations should be included in surveillance when these animals are intended for trade.~~

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

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

Article 8.3.17.

Surveillance: case definition

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

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

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

The following defines the occurrence of BTV infection:

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

Annex XXII (contd)

Article 8.3.18.

Surveillance: general conditions and methods

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

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

Article 8.3.19.

Surveillance strategies

The target population for *surveillance* aimed at identification of *disease* and/or *infection* should cover susceptible domestic ruminants within the country or *zone*. Active and passive *surveillance* for BTV infection should be ongoing. *Surveillance* should be composed of random or targeted approaches using virological, serological and clinical methods appropriate for the infection status of the country or *zone*.

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

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

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

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

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

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

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

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

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

1. Clinical surveillance

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

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

Annex XXII (contd)2. Serological surveillance

An active programme of *surveillance* of host populations to detect evidence of BTV transmission is essential to establish BTV status in a country or *zone*. Serological testing of ruminants is one of the most effective methods of detecting the presence of BTV. The species tested depends on the epidemiology of BTV infection, and the species available, in the local area. Cattle are usually the most sensitive indicator species. Management variables that may influence likelihood of *infection*, such as the use of insecticides and animal housing, should be considered.

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

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

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

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

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

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

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

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

3. Virological surveillance

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

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

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

4. Sentinel animals

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

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

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

Care is necessary in choosing the sites for the sentinel groups. The aim is to maximise the chance of detecting BTV activity at the geographical location for which the sentinel site acts as a sampling point. The effect of secondary factors that may influence events at each location, such as climate, may also be analysed. To avoid bias, sentinel groups should comprise animals selected to be of similar age and susceptibility to BTV infection. Cattle are the most appropriate sentinels but other domestic ruminant species may be used. The only feature distinguishing groups of sentinels should be their geographical location.

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

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

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

Annex XXII (contd)5. Vector surveillance

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

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

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

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

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

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

Article 8.3.20.

Documentation of BTV infection free status1. Members declaring freedom from BTV infection for the country or zone: additional surveillance procedures

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

2. Additional requirements for countries or zones that practise vaccination

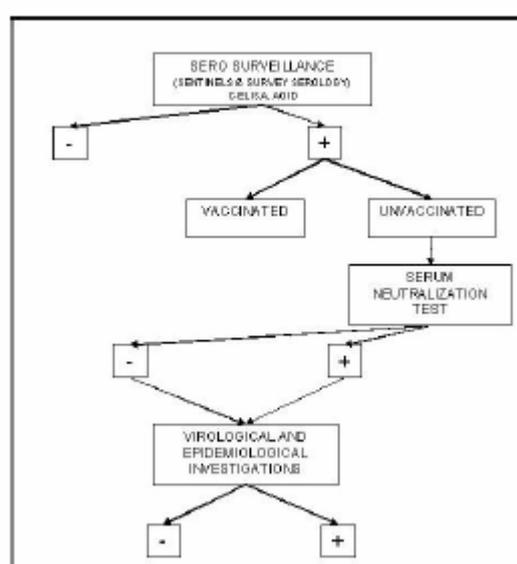
Vaccination to prevent the transmission of BTV may be part of a disease control programme. The level of *flock* or *herd* immunity required to prevent transmission will depend on the *flock* or *herd* size, composition (e.g. species) and density of the susceptible population. It is therefore impossible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

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

Article 8.3.21.

The use and interpretation of serological and virus detection tests

Fig. 1. Application of laboratory tests in serological surveillance



1. Serological testing

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

2. Virus detection

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

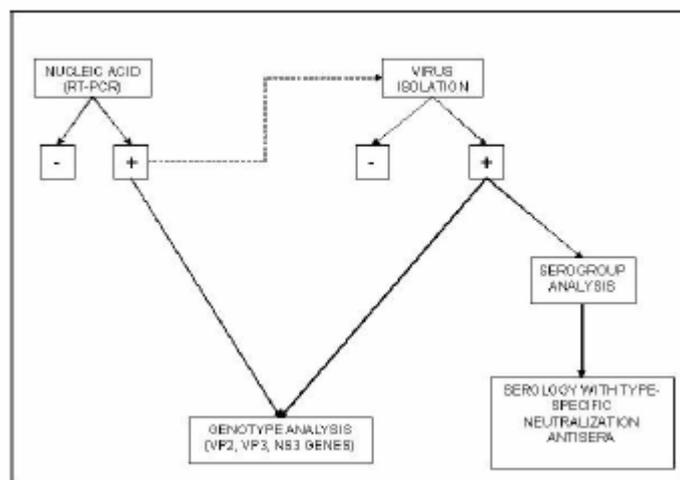
Interpretation of positive and negative results (both true and false) differs markedly between these tests because they detect different aspects of BTV *infection*, specifically (1) infectious BTV (virus isolation) and (2) nucleic acid (PCR). The following are especially relevant to interpretation of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

Annex XXII (contd)

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

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

Fig. 2. Application of laboratory tests in virological surveillance



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CHAPTER 8.5.
FOOT AND MOUTH DISEASE

Article 8.5.1.

Introduction

For the purposes of the *Terrestrial Code*, the *incubation period* for foot and mouth disease (FMD) shall be 14 days.

For the purposes of this Chapter, ruminants include animals of the family of Camelidae (except *Camelus dromedarius*).

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

For the purposes of *international trade*, this Chapter deals not only with the occurrence of clinical signs caused by FMDV, but also with the presence of infection with FMDV in the absence of clinical signs.

The following defines the occurrence of FMDV infection:

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

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

Article 8.5.2.

FMD free country where vaccination is not practised

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

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

1. have a record of regular and prompt animal disease reporting;

Annex XXIII (contd)

2. send a declaration to the OIE stating that:
 - a) there has been no *outbreak* of FMD during the past 12 months;
 - b) no evidence of FMDV infection has been found during the past 12 months;
 - c) no vaccination against FMD has been carried out during the past 12 months;
 - d) no vaccinated animal has been introduced since the cessation of vaccination;
3. supply documented evidence that:
 - a) *surveillance* for ~~both~~ FMD and FMDV infection in accordance with Articles 8.5.40. to 8.5.46. is in operation;
 - b) regulatory measures for the early detection, prevention and control of FMD have been implemented.
4. describe in detail the boundaries and measures of a *protection zone*, if applicable.

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

Article 8.5.3.

FMD free country where vaccination is practised

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

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

1. have a record of regular and prompt animal disease reporting;
2. send a declaration to the OIE stating that there has been no *outbreak* of FMD for the past 2 years and no evidence of FMDV circulation for the past 12 months, with documented evidence that:
 - a) there has been no *outbreak* of FMD during the past 2 years;
 - b) no evidence of FMDV circulation has been found during the past 12 months;
3. supply documented evidence that:
 - a) *surveillance* for FMD and FMDV circulation in accordance with Articles 8.5.40. to 8.5.46. is in operation, ~~and that regulatory measures for the prevention and control of FMD have been implemented;~~
 - b) regulatory measures for the early detection, prevention and control of FMD have been implemented;

- b) routine vaccination is carried out for the purpose of the prevention of FMD;
- c) the vaccine used complies with the standards described in the *Terrestrial Manual* and is appropriate for the strains of virus currently circulating;

4. describe in detail the boundaries and measures of a protection zone, if applicable.

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

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

Article 8.5.4.

FMD free zone where vaccination is not practised

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

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

1. have a record of regular and prompt animal disease reporting;
2. send a declaration to the OIE stating that ~~it wishes to establish a FMD free zone where vaccination is not practised, and that~~ within the proposed FMD free zone:
 - a) there has been no *outbreak* of FMD during the past 12 months;
 - b) no evidence of FMDV infection has been found during the past 12 months;
 - c) no vaccination against FMD has been carried out during the past 12 months;
 - d) no vaccinated animal has been introduced into the zone since the cessation of vaccination, except in accordance with Article 8.5.9.;
 - e) ~~documented evidence shows that surveillance in accordance with Articles 8.5.40. to 8.5.46. is in operation for both FMD and FMDV infection;~~

Annex XXIII (contd)

3. supply documented evidence that:

- a) surveillance for FMD and FMDV infection in accordance with Articles 8.5.40. to 8.5.46. is in operation;
- b) regulatory measures for the early detection, prevention and control of FMD have been implemented;

34. describe in detail and supply documented evidence that these are properly implemented and supervised:

- a) ~~regulatory measures for the prevention and control of both FMD and FMDV infection;~~
- b~~a~~) the boundaries of the proposed FMD free zone and, if applicable, the ~~protection zone or physical or geographical barriers,~~
- b) the boundaries and measures of a protection zone, if applicable.
- c) the system for preventing the entry of the virus (including the control of the movement of susceptible animals) into the proposed FMDV free zone (in particular if the procedure described in Article 8.5.9. is implemented).

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

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

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

Article 8.5.5.

FMD free zone where vaccination is practised

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

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

1. have a record of regular and prompt animal disease reporting;
2. send a declaration to the OIE stating that ~~it wishes to establish a FMD free zone where vaccination is practised and that~~ within the proposed FMD free zone;
 - a) there has been no *outbreak* of FMD for the past 2 years;
 - b) no evidence of FMDV circulation ~~for~~ has been found during the past 12 months;

- e) ~~documented evidence shows that surveillance in accordance with Articles 8.5.40. to 8.5.46. is in operation for FMD and FMDV circulation;~~
3. supply documented evidence that:
- a) surveillance for FMD and FMDV infection in accordance with Articles 8.5.40. to 8.5.46. is in operation;
 - b) regulatory measures for the early detection, prevention and control of FMD have been implemented;
 - c) routine vaccination is carried out for the purpose of the prevention of FMD;
 - d) the vaccine used complies with the standards described in the *Terrestrial Manual* and is appropriate for the strains of virus currently circulating;
3. ~~supply documented evidence that the vaccine used complies with the standards described in the *Terrestrial Manual*;~~
4. describe in detail and supply documented evidence that these are properly implemented and supervised:
- a) ~~regulatory measures for the prevention and control of both FMD and FMDV circulation;~~
 - b) ~~the boundaries of the proposed FMD free zone where vaccination is practised and, if applicable, the protection zone or physical or geographical barriers,~~
 - b) the boundaries and measures of a protection zone, if applicable.
 - c) the system for preventing the entry of the virus (including the control of the movement of susceptible animals) into the proposed FMD free zone (in particular if the procedure described in Article 8.5.9. is implemented).

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

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

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

Article 8.5.5.bis

FMD free compartment

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

Annex XXIII (contd)

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

1. have a record of regular and prompt animal disease reporting and if not FMD free, have **an official control programme** and a *surveillance* system for FMD in place according to Articles 8.5.40. to 8.5.42. that allows an accurate knowledge of the prevalence of FMD in the country or *zone*.
2. declare for the FMD free *compartment* that:
 - a) there has been no *outbreak* of FMD during the past 12 months;
 - b) no evidence of FMDV infection has been found during the past 12 months;
 - c) vaccination against FMD is prohibited;
 - d) no animal vaccinated against FMD within the past 12 months is in the *compartment*;
 - e) animals, semen and embryos should only enter the *compartment* in accordance with relevant Articles in this chapter;
 - ef) documented evidence shows that *surveillance* in accordance with Articles 8.5.40. to 8.5.46. is in operation for ~~both~~ FMD and FMDV infection;
 - fg) an *animal identification* and *traceability* system in accordance with Chapters 4.1 and 4.2. is in place;
3. describe in detail the animal subpopulation in the *compartment* ~~in detail~~ and the *biosecurity plan management system* for prevention and control of both FMD and FMDV infection, including the system for preventing the entry of the virus and its implementation and supervision.
4. **The *compartment* should be approved by the *Veterinary Authority*. The first approval should only be granted when no *outbreak* of FMD has occurred within the *zone* in which the *compartment* is situated, during the last 3 months.**

Article 8.5.6.

FMD infected country or zone

A FMD infected country is a country that does not fulfil the requirements to qualify as either a FMD free country where vaccination is not practised or a FMD free country where vaccination is practised.

A FMD infected zone is a *zone* that does not fulfil the requirements to qualify as either a FMD free zone where vaccination is not practised or a FMD free zone where vaccination is practised.

Article 8.5.7.

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

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

For this to be achieved, the *Veterinary Authority* should provide documented evidence that:

1. the *outbreaks* are limited based on the following factors:
 - a) immediately on suspicion, a rapid response including notification has been made;
 - b) standstill of animal movements has been imposed, and effective controls on the movement of other *commodities* mentioned in this Chapter are in place;
 - c) epidemiological investigation (trace-back, trace-forward) has been completed;
 - d) the *infection* has been confirmed;
 - e) the primary *outbreak* and likely source of the *outbreak* has been identified;
 - f) all *cases* have been shown to be epidemiologically linked;
 - g) no new *cases* have been found in the *containment zone* within a minimum of two *incubation periods* as defined in Article 8.5.1. after the stamping-out of the last detected *case* is completed;
2. a *stamping-out policy* has been applied;
3. the susceptible animal population within the *containment zones* should be clearly identifiable as belonging to the *containment zone*;
4. increased passive and targeted *surveillance* in accordance with Articles 8.5.40. to 8.5.46. in the rest of the country or *zone* has been carried out and has not detected any evidence of *infection*;
5. animal health measures that effectively prevent the spread of the FMDV to the rest of the country or *zone*, taking into consideration physical and geographical barriers, are in place;
6. ongoing *surveillance* in the *containment zone* is in place;

The free status of the areas outside the *containment zone* would be suspended pending the establishment of the *containment zone*. The free status of these areas could be reinstated irrespective of the provisions of Article 8.5.8., once the *containment zone* is clearly established, by complying with points 1 to 6 above. The *containment zone* should be managed in such a way that it can be demonstrated that *commodities* for international trade can be shown to have originated outside the *containment zone*.

The recovery of the FMD free status of the *containment zone* should follow the provisions of Article 8.5.8.

Article 8.5.8.

Recovery of free status

1. When a FMD *outbreak* or FMDV *infection* occurs in a FMD free country or zone where vaccination is not practised, one of the following waiting periods is required to regain the status of FMD free country or zone where vaccination is not practised:
 - a) 3 months after the last *case* where a *stamping-out policy* and serological *surveillance* are applied in accordance with Articles 8.5.40. to 8.5.46.; or
 - b) 3 months after the *slaughter* of all vaccinated animals where a *stamping-out policy*, emergency vaccination and serological *surveillance* are applied in accordance with Articles 8.5.40. to 8.5.46.; or

Annex XXIII (contd)

- c) 6 months after the last *case* or the last vaccination (according to the event that occurs the latest), where a *stamping-out policy*, emergency vaccination not followed by the slaughtering of all vaccinated animals, and serological *surveillance* are applied in accordance with Articles 8.5.40. to 8.5.46., provided that a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of *infection* in the remaining vaccinated population.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.5.2. or 8.5.4. applies.

2. When a FMD *outbreak* or FMDV *infection* occurs in a FMD free country or zone where vaccination is practised, one of the following waiting periods is required to regain the status of FMD free country or zone where vaccination is practised:
- a) 6 months after the last *case* where a *stamping-out policy*, emergency vaccination and serological *surveillance* in accordance with Articles 8.5.40. to 8.5.46. are applied, provided that the serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation; or
- b) 18 months after the last *case* where a *stamping-out policy* is not applied, but emergency vaccination and serological *surveillance* in accordance with Articles 8.5.40. to 8.5.46. are applied, provided that the serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation.

3. When a FMD outbreak or FMDV infection occurs in a FMD free compartment, Article 8.5.5.bis. applies.

Article 8.5.9.

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

In order not to jeopardise the status of a free zone, FMD susceptible animals should only leave the *infected zone* if moved by mechanised transport directly to slaughter in the nearest designated *abattoir* **located in a protection zone directly to slaughter.**

~~In the absence of an abattoir in a protection zone, live FMD susceptible animals can be transported to the nearest abattoir in a free zone directly to slaughter only~~ under the following conditions:

1. no FMD susceptible animal has been introduced into the *establishment* of origin and no animal in the *establishment* of origin has shown clinical signs of FMD for at least 30 days prior to movement;
2. the animals were kept in the *establishment* of origin for at least 3 months prior to movement;
3. FMD has not occurred within a 10-kilometre radius of the *establishment* of origin for at least 3 months prior to movement;
4. the animals **must should** be transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *abattoir* without coming into contact with other susceptible animals;
5. such an *abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of animals from the *infected zone*;
6. *vehicles* and the *abattoir* **must should** be subjected to thorough cleansing and *disinfection* immediately after use.

The meat should be treated according to Article 8.5.23. or 8.5.24. Other All products obtained from the animals and any products coming into contact with them must should be considered infected, and treated in such a way as to destroy any residual virus in accordance with Articles 8.5.32. to 8.5.39.

Animals moved into a free zone for other purposes must should be moved under the supervision of the *Veterinary Authority* and comply with the conditions in Article 8.5.12.

Article 8.5.9.bis

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

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

1. the containment zone has been officially established according to the requirements in Article 8.5.7.:
2. the animals should be transported under the supervision of the Veterinary Authority in a vehicle, which was cleansed and disinfected before loading, directly from the establishment of origin to the abattoir without coming into contact with other susceptible animals;
3. such an abattoir is not approved for the export of fresh meat during the time it is handling the meat of animals from the containment zone;
4. vehicles and the abattoir should be subjected to thorough cleansing and disinfection immediately after use.

The meat should be treated according to point 2 of Article 8.5.23. or 8.5.24. Other products obtained from the animals and any products coming into contact with them should be treated in such a way as to destroy any residual virus in accordance with Articles 8.5.32. to 8.5.39.

Article 8.5.10.

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

for FMD susceptible animals

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

1. showed no clinical sign of FMD on the day of shipment;
2. were kept since birth or for at least the past 3 months in a FMD free country or zone where vaccination is not practised or a FMD free compartment;
3. have not been vaccinated;
4. if transiting an infected zone were not exposed to any source of FMD infection during transportation to the place of shipment.

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Article 8.5.11.

Recommendations for importation from FMD free countries or zones where vaccination is practisedfor domestic ruminants and pigs

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

1. showed no clinical sign of FMD on the day of shipment;
2. were kept in a FMD free country or zone since birth or for at least the past 3 months; and
3. have not been vaccinated and were subjected, with negative results, to tests for antibodies against FMD virus, when destined to a FMD free country or zone where vaccination is not practised;
4. if transiting an *infected zone*, were not exposed to any source of FMD *infection* during transportation to the *place of shipment*.

Article 8.5.12.

Recommendations for importation from FMD infected countries or zonesfor domestic ruminants and pigs

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

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

Article 8.5.13.

Recommendations for importation from FMD free countries or zones where vaccination is not practised or FMD free compartmentsfor fresh semen of domestic ruminants and pigs

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

1. the donor animals:
 - a) showed no clinical sign of FMD on the day of collection of the semen;
 - b) were kept for at least 3 months prior to collection in a FMD free country or zone where vaccination is not practised or a FMD free compartment;
2. the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5. and 4.6.

Article 8.5.14.

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

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

1. the donor animals:
 - a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
 - b) were kept for at least 3 months prior to collection in a FMD free country or zone where vaccination is not practised or a FMD free compartment ~~for at least 3 months prior to collection~~;
2. the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5. and 4.6.

Article 8.5.15.

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

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

1. the donor animals:
 - a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
 - b) were kept for at least 3 months prior to collection in a FMD free country or ~~zone free from FMD~~;

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- c) if destined to a FMD free country or zone where vaccination is not practised:
 - i) have not been vaccinated and were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMD virus, with negative results; or
 - ii) had been vaccinated at least twice, with the last vaccination not more than 12 and not less than one month prior to collection;
- 2. no other animal present in the *artificial insemination centre* has been vaccinated within the month prior to collection;
- 3. the semen:
 - a) was collected, processed and stored in conformity with the provisions of Chapter 4.5. and 4.6.;
 - b) was stored in the country of origin for a period of at least one month following collection, and during this period no animal on the *establishment* where the donor animals were kept showed any sign of FMD.

Article 8.5.16.

Recommendations for importation from FMD infected countries or zones

for semen of domestic ruminants and pigs

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

- 1. the donor animals:
 - a) showed no clinical sign of FMD on the day of collection of the semen;
 - b) were kept in an *establishment* where no animal had been added in the 30 days before collection, and that FMD has not occurred within 10 kilometres for the 30 days before and after collection;
 - c) have not been vaccinated and were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMD virus, with negative results; or
 - d) had been vaccinated at least twice, with the last vaccination not more than 12 and not less than one month prior to collection;
- 2. no other animal present in the *artificial insemination centre* has been vaccinated within the month prior to collection;
- 3. the semen:
 - a) was collected, processed and stored in conformity with the provisions of Chapter 4.5. and 4.6.;
 - b) was subjected, with negative results, to a test for FMDV *infection* if the donor animal has been vaccinated within the 12 months prior to collection;
 - c) was stored in the country of origin for a period of at least one month following collection, and during this period no animal on the *establishment* where the donor animals were kept showed any sign of FMD.

Article 8.5.17.

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

Irrespective of the FMD status of the *exporting country or zone or compartment*, *Veterinary Authorities* should authorise without restriction on account of FMD the import or transit through their territory of *in vivo* derived embryos of cattle subject to the presentation of an *international veterinary certificate* attesting that the embryos were collected, processed and stored in conformity with the provisions of Chapter 4.7. or Chapter 4.9.

Article 8.5.18.

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

for *in vitro* produced embryos of cattle

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

1. the donor females:
 - a) showed no clinical sign of FMD at the time of collection of the oocytes;
 - b) were kept at the time of collection in a FMD free country or zone where vaccination is not practised or a FMD free compartment;
2. fertilisation was achieved with semen meeting the conditions referred to in Articles 8.5.13., 8.5.14., 8.5.15. or 8.5.16., as relevant;
3. the oocytes were collected, and the embryos were processed and stored in conformity with the provisions of Chapter 4.8. or Chapter 4.9., as relevant.

Article 8.5.19.

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

for *in vitro* produced embryos of cattle

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

1. the donor females:
 - a) showed no clinical sign of FMD at the time of collection of the oocytes;
 - b) were kept for at least 3 months prior to collection in a FMD free country or zone where vaccination is practised;
 - c) if destined for a FMD free country or zone where vaccination is not practised or a FMD free compartment:
 - i) have not been vaccinated and were subjected, with negative results, to tests for antibodies against FMD virus; or

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- ii) had been vaccinated at least twice, with the last vaccination not less than one month and not more than 12 months prior to collection;
- 2. no other animal present in the *establishment* has been vaccinated within the month prior to collection;
- 3. fertilization was achieved with semen meeting the conditions referred to in Articles 8.5.13., 8.5.14., 8.5.15. or 8.5.16., as relevant;
- 4. the oocytes were collected, and the embryos were processed and stored in conformity with the provisions of Chapter 4.8. or Chapter 4.9., as relevant.

Article 8.5.20.

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

for fresh meat of FMD susceptible animals

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

- 1. have been kept in the FMD free country or zone where vaccination is not practised or in a FMD free compartment since birth, or which have been imported in accordance with Article 8.5.10., Article 8.5.11. or Article 8.5.12.;
- 2. have been slaughtered in an approved *abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results.

Article 8.5.21.

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

for fresh meat of cattle and buffaloes (*Bubalus bubalis*) (excluding feet, head and viscera)

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

- 1. have been kept in the FMD free country or zone where vaccination is practised ~~since birth~~, or which have been imported in accordance with Article 8.5.10., Article 8.5.11. or Article 8.5.12.;
- 2. have been slaughtered in an approved *abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results.

Article 8.5.22.

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

for fresh meat or meat products of pigs and ruminants other than cattle and buffaloes

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

1. have been kept in the FMD free country or zone where vaccination is practised ~~since birth~~, or which have been imported in accordance with Article 8.5.10., Article 8.5.11. or Article 8.5.12.;
2. have been slaughtered in an approved *abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results.

Article 8.5.23.

Recommendations for importation from FMD infected countries or zones, where an official control programme exists, involving compulsory systematic vaccination of cattle

for fresh meat of cattle and buffaloes (*Bubalus bubalis*) (excluding feet, head and viscera)

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

1. comes from animals which:
 - a) have remained in the *exporting country* for at least 3 months prior to *slaughter*;
 - b) have remained, during this period, in a part of the country where cattle are regularly vaccinated against FMD and where official controls are in operation;
 - c) have been vaccinated at least twice with the last vaccination not more than 12 months and not less than one month prior to *slaughter*;
 - d) were kept for the past 30 days in an *establishment*, and that FMD has not occurred within a ten-kilometre radius of the *establishment* during that period;
 - e) have been transported, in a *vehicle* which was cleansed and disinfected before the cattle were loaded, directly from the *establishment* of origin to the approved *abattoir* without coming into contact with other animals which do not fulfil the required conditions for export;
 - f) have been slaughtered in an approved *abattoir*:
 - i) which is officially designated for export;
 - ii) in which no FMD has been detected during the period between the last *disinfection* carried out before *slaughter* and the shipment for export has been dispatched;
 - g) have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results within 24 hours before and after *slaughter*;
2. comes from deboned carcasses:
 - a) from which the major lymphatic nodes have been removed;
 - b) which, prior to deboning, have been submitted to maturation at a temperature above + 2°C for a minimum period of 24 hours following *slaughter* and in which the pH value was below 6.0 when tested in the middle of both the longissimus dorsi.

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Article 8.5.24.

Recommendations for importation from FMD infected countries or zonesfor meat products of domestic ruminants and pigs

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

1. the entire consignment of *meat* comes from animals which have been slaughtered in an approved *abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results;
2. the *meat* has been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Article 8.5.32.;
3. the necessary precautions were taken after processing to avoid contact of the *meat products* with any potential source of FMD virus.

Article 8.5.25.

Recommendations for importation from FMD free countries or zones (where vaccination either is or is not practised) or FMD free compartmentsfor milk and milk products intended for human consumption and for products of animal origin (from FMD susceptible animals) intended for use in animal feeding or for agricultural or industrial use

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products come from animals which have been kept in a FMD free country ~~or~~ zone or compartment ~~since birth~~, or which have been imported in accordance with Article 8.5.10., Article 8.5.11. or Article 8.5.12.

Article 8.5.26.

Recommendations for importation from FMD infected countries or zones where an official control programme existsfor milk, cream, milk powder and milk products

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

1. these products:
 - a) originate from *herds* or *flocks* which were not infected or suspected of being infected with FMD at the time of *milk* collection;
 - b) have been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Article 8.5.36. and in Article 8.5.37.;
2. the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMD virus.

Article 8.5.27.

Recommendations for importation from FMD infected countries

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

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

Article 8.5.28.

Recommendations for importation from FMD infected countries

for wool, hair, bristles, raw hides and skins (from domestic or wild ruminants and pigs)

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

1. these products have been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Articles 8.5.33., 8.5.34. and 8.5.35.;
2. the necessary precautions were taken after collection or processing to avoid contact of the products with any potential source of FMD virus.

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

Article 8.5.29.

Recommendations for importation from FMD infected countries or zones

for straw and forage

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

1. are free of grossly identifiable contamination with material of animal origin;
2. have been subjected to one of the following treatments, which, in the case of material sent in bales, has been shown to penetrate to the centre of the bale:
 - a) either to the action of steam in a closed chamber such that the centre of the bales has reached a minimum temperature of 80°C for at least 10 minutes,
 - b) or to the action of formalin fumes (formaldehyde gas) produced by its commercial solution at 35-40% in a chamber kept closed for at least 8 hours and at a minimum temperature of 19°C;

OR

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

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Article 8.5.30.

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

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

Article 8.5.31.

Recommendations for importation from FMD infected countries or zonesfor skins and trophies derived from FMD susceptible wild animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of the FMD virus in conformity with the procedures referred to in Article 8.5.38.

Article 8.5.32.

Procedures for the inactivation of the FMD virus in meat

For the inactivation of viruses present in meat, one of the following procedures should be used:

1. Canning

Meat is subjected to heat treatment in a hermetically sealed container to reach an internal core temperature of at least 70°C for a minimum of 30 minutes or to any equivalent treatment which has been demonstrated to inactivate the FMD virus.

2. Thorough cooking

Meat, previously deboned and defatted, shall be subjected to heating so that an internal temperature of 70°C or greater is maintained for a minimum of 30 minutes.

After cooking, it shall be packed and handled in such a way that it cannot be exposed to a source of virus.

3. Drying after salting

When *rigor mortis* is complete, the meat **must should** be deboned, salted with cooking salt (NaCl) and completely dried. It **must should** not deteriorate at ambient temperature.

'Drying' is defined in terms of the ratio between water and protein which **must should** not be greater than 2.25:1.

Article 8.5.33.

Procedures for the inactivation of the FMD virus in wool and hair

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

1. industrial washing, which consists of the immersion of the wool in a series of baths of water, soap and sodium hydroxide (soda) or potassium hydroxide (potash);
2. chemical depilation by means of slaked lime or sodium sulphide;
3. fumigation in formaldehyde in a hermetically sealed chamber for at least 24 hours. The most practical method is to place potassium permanganate in containers (which **must** **should** NOT be made of plastic or polyethylene) and add commercial formalin; the amounts of formalin and potassium permanganate are respectively 53 ml and 35 g per cubic metre of the chamber;
4. industrial scouring which consists of the immersion of wool in a water-soluble detergent held at 60-70°C;
5. storage of wool at 18°C for 4 weeks, or 4°C for 4 months, or 37°C for 8 days.

Article 8.5.34.

Procedures for the inactivation of the FMD virus in bristles

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

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

Article 8.5.35.

Procedures for the inactivation of the FMD virus in raw hides and skins

For the inactivation of viruses present in raw hides and skins for industrial use, the following procedure should be used: salting for at least 28 days in sea salt containing 2% sodium carbonate.

Article 8.5.36.

Procedures for the inactivation of the FMD virus in milk and cream for human consumption

For the inactivation of viruses present in *milk* and cream for human consumption, one of the following procedures should be used:

1. a sterilisation process applying a minimum temperature of 132°C for at least one second (ultra-high temperature [UHT]), or
2. if the milk has a pH less than 7.0, a sterilisation process applying a minimum temperature of 72°C for at least 15 seconds (high temperature - short time pasteurisation [HTST]), or
3. if the milk has a pH of 7.0 or over, the HTST process applied twice.

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Article 8.5.37.

Procedures for the inactivation of the FMD virus in milk for animal consumption

For the inactivation of viruses present in *milk* for animal consumption, one of the following procedures should be used:

1. the HTST process applied twice;
2. HTST combined with another physical treatment, e.g. maintaining a pH 6 for at least one hour or additional heating to at least 72°C combined with desiccation;
3. UHT combined with another physical treatment referred to in point 2 above.

Article 8.5.38.

Procedures for the inactivation of the FMD virus in skins and trophies from wild animals susceptible to the disease

For the inactivation of viruses present in skins and trophies from wild animals susceptible to FMD, one of the following procedures should be used prior to complete taxidermal treatment:

1. boiling in water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers or teeth is removed;
2. gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher);
3. soaking, with agitation, in a 4% (w/v) solution of washing soda (sodium carbonate - Na₂CO₃) maintained at pH 11.5 or above for at least 48 hours;
4. soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained at below pH 3.0 for at least 48 hours; wetting and dressing agents may be added;
5. in the case of raw hides, salting for at least 28 days with sea salt containing 2% washing soda (sodium carbonate - Na₂CO₃).

Article 8.5.39.

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

For the inactivation of viruses present in casings of **small** ruminants and pigs, the following procedures should be used: salting for at least 30 days either with dry salt (NaCl) or with saturated brine (*A_w* < 0.80), or with phosphate salts/sodium chloride mixture, and kept at room temperature **at of** about 20° during this entire period.

Article 8.5.40.

Surveillance: introduction

Articles 8.5.40. to 8.5.46. define the principles and provide a guide for the *surveillance* of FMD in accordance with Chapter 1.4. applicable to Members seeking establishment of freedom from FMD, either with or without the use of vaccination. Guidance is provided for Members seeking reestablishment of freedom from FMD for the entire country or for a *zone*, either with or without vaccination or a *compartment*, following an *outbreak*, and for the maintenance of FMD status.

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

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

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

Article 8.5.41.

Surveillance: general conditions and methods

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

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

Surveillance strategies

1. Introduction

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

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

The strategy employed may be based on randomised sampling requiring *surveillance* consistent with demonstrating the absence of FMDV *infection*/circulation at an acceptable level of statistical confidence. The frequency of sampling should be dependent on the epidemiological situation.

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

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

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

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

2. Clinical surveillance

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

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

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

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

3. Virological surveillance

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

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

4. Serological surveillance

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

- a) natural *infection* with FMDV;
- b) vaccination against FMD;
- c) maternal antibodies derived from an immune dam (maternal antibodies in cattle are usually found only up to 6 months of age but in some individuals and in some species, maternal antibodies can be detected for considerably longer periods);
- d) heterophile (cross) reactions.

Annex XXIII (contd)

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

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

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

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

Article 8.5.43.

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

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

Article 8.5.44.

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

In addition to the general conditions described in the above-mentioned articles, a Member applying for recognition of country or *zone* freedom from FMD with vaccination should show evidence of an effective *surveillance* programme planned and implemented according to general conditions and methods in this Chapter. Absence of clinical *disease* in the country or *zone* for the past 2 years should be demonstrated. Furthermore, *surveillance* should demonstrate that FMDV has not been circulating in any susceptible population during the past 12 months. This will require serological *surveillance* incorporating tests able to detect antibodies to NSPs as described in the *Terrestrial Manual*. Vaccination to prevent the transmission of FMDV may be part of a disease control programme. The level of *herd* immunity required to prevent transmission will depend on the size, composition (e.g. species) and density of the susceptible population. It is therefore impossible to be prescriptive. However, the aim should, in general, be to vaccinate at least 80% of the susceptible population. The vaccine **must should** comply with the *Terrestrial Manual*. Based on the epidemiology of FMD in the country or *zone*, it may be that a decision is reached to vaccinate only certain species or other subsets of the total susceptible population. In that case, the rationale should be contained within the dossier accompanying the application to the OIE for recognition of status.

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

Article 8.5.45.

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

In addition to the general conditions described in the above-mentioned articles, a country re-applying for country or *zone* freedom from FMD where vaccination is practised or not practised should show evidence of an active *surveillance* programme for FMD as well as absence of FMDV *infection*/circulation.

This will require serological *surveillance* incorporating, in the case of a country or a *zone* practising vaccination, tests able to detect antibodies to NSPs as described in the *Terrestrial Manual*.

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

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

The time periods before which an application can be made for re-instatement of freedom from FMD depends on which of these alternatives is followed. The time periods are prescribed in Article 8.5.8.

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

Article 8.5.46.

The use and interpretation of serological tests (see Figure 1)

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

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

Annex XXIII (contd)

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

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

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

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

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

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

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

The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation.

All the epidemiological information should be substantiated, and the results should be collated in the final report.

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

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

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

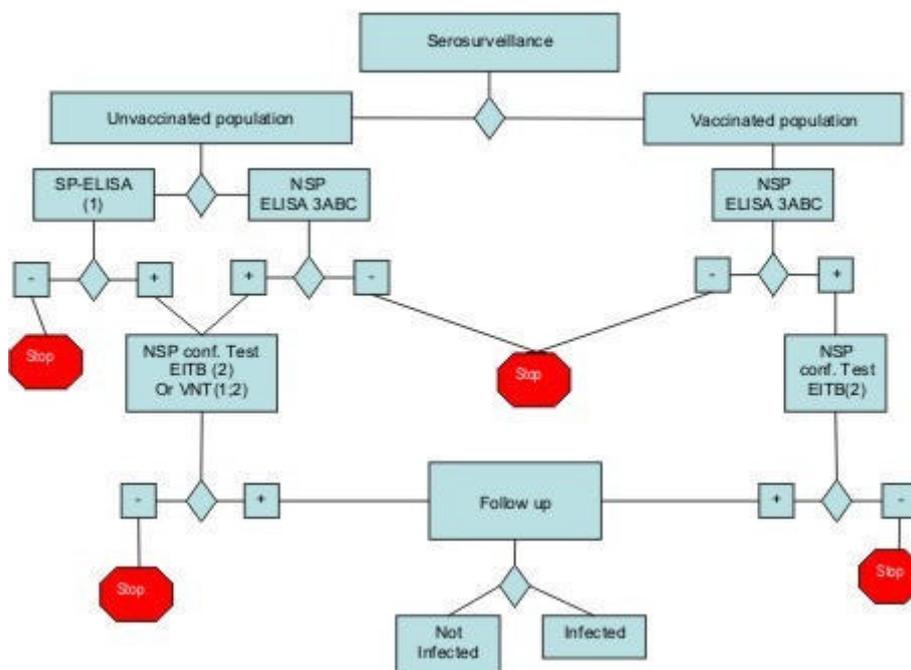
- b) Following clinical examination, serum samples should be collected from representative numbers of cattle susceptible animals that were in physical contact with the primary sampling unit. The magnitude and prevalence of antibody reactivity observed should not differ in a statistically significant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

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

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

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

Fig. 1. Schematic representation of laboratory tests for determining evidence of FMDV infection through or following serological surveys



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

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CHAPTER 8.11.

RIFT VALLEY FEVER

Article 8.11.1.

General provisions

For the purposes of the *Terrestrial Code*, the *infective period* for Rift Valley fever (RVF) shall be 30 days.

For the purposes of this chapter, ruminants include camels.

The historic distribution of RVF is the sub-Saharan African continent, Madagascar and the Arabian Peninsula.

Countries or *zones* within the historic distribution of RVF or adjacent to those that are historically infected should be subjected to *surveillance*.

Epidemics of RVF may occur in infected areas after flooding. They are separated by inter-epidemic periods that may last for several decades in arid areas and, during these periods, the prevalence of *infection* in humans, animals and mosquitoes can be difficult to detect.

In the absence of clinical *disease*, the RVF status of a country or *zone* within the historically infected regions of the world should be determined by a *surveillance* programme (carried out in accordance with Chapter 1.4.) focusing on mosquitoes and serology of susceptible mammals. The programme should concentrate on parts of the country or *zone* at high risk because of historical, geographic and climatic factors, ruminant and mosquito population distribution, and proximity to areas where epidemics have recently occurred.

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

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 8.11.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the RVF status of the ruminant population of the *exporting country* or *zone*.

Article 8.11.2.

Trade in Safe commodities

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

1. hides and skins;
2. wool and fiber.

~~When authorising import or transit of other *commodities* listed in this chapter, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the RVF status of the ruminant population of the *exporting country* or *zone*.~~

Annex XXIV (contd)

Article 8.11.3.

RVF infection free country or zone

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

1. the country or *zone* lies outside the historically infected regions, and not adjacent to historically infected regions; or
2. a *surveillance* programme as described in Article 8.11.1. has demonstrated no evidence of RVF infection in humans, animals or mosquitoes in the country or *zone* during the past 4 years following a RVF epidemic.

The provisions of the last paragraph of Article 8.11.1. may need to be complied with on a continuous basis in order to maintain freedom from *infection*, depending on the geographical location of the country or *zone*.

A RVF infection free country or *zone* in which *surveillance* and monitoring has found no evidence that RVF infection is present will not lose its free status through the importation of permanently marked seropositive animals or those destined for direct *slaughter*.

Article 8.11.4.

RVF infected country or zone without disease

A RVF *disease* free country or *zone* is a country or *zone* that is not *infection* free (see Article 8.11.3.) but in which *disease* has not occurred in humans or animals in the past 6 months provided that climatic changes predisposing to *outbreaks* of RVF have not occurred during this time.

Article 8.11.5.

RVF infected country or zone with disease

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

Article 8.11.6.

Recommendations for importation from RVF infection free countries or zonesfor ruminants

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

1. were kept in a RVF free country or *zone* since birth or for at least 30 days prior to shipment; and
2. if the animals were exported from a free *zone*, either:
 - a) did not transit through an *infected zone* during transportation to the *place of shipment*; or
 - b) were protected from mosquito attack at all times when transiting through an *infected zone*.

Article 8.11.7.

Recommendations for importation from RVF infection free countries or zones

for meat and meat products of domestic and wild ruminants

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

Article 8.11.8.

Recommendations for importation from RVF infected countries/zones without disease

for ruminants

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

1. showed no evidence of RVF on the day of shipment;
2. met one of the following conditions:
 - a) were kept in a RVF infected country/zone free of *disease* since birth or for the last 6 months providing that climatic changes predisposing to *outbreaks* of RVF have not occurred during this time; or
 - b) were vaccinated against RVF at least 21 days prior to shipment with a modified live virus vaccine; or
 - c) were held in a mosquito-proof *quarantine station* for at least 30 days prior to shipment during which the animals showed no clinical signs of RVF and were protected from mosquitoes between quarantine and the *place of shipment* as well as at the *place of shipment*;

AND

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

Article 8.11.9.

Recommendations for importation from RVF infected countries or zones without disease

for meat and meat products of domestic and wild ruminants

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

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

Annex XXIV (contd)

Article 8.11.10.

Recommendations for importation from RVF infected countries or zones with diseasefor ruminants

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

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

OR

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

Article 8.11.11.

Recommendations for importation from RVF infected countries or zones with diseasefor meat and meat products of domestic and wild ruminants

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

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

Article 8.11.12.

Recommendations for importation from RVF infected countries or zones with diseasefor *in vivo* derived embryos of ruminants

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

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

OR

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

Article 8.11.13.

(Under study) Recommendations for importation from RVF infected countries or zones with disease or from RVF infected countries or zones without diseasefor milk and milk products

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

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

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CHAPTER 8.16 .

WEST NILE FEVER

Article 8.16.1.

General provisions

West Nile fever (WNF) is a zoonotic disease caused by certain strains of the mosquito transmitted West Nile virus (WNV).

For the purpose of this chapter, the susceptible species are equidae, geese, ducks (under study) ~~and chicken and turkey chicks less than 12 days old (under study)~~ and birds other than *poultry*.

WNV is maintained in a mosquito–bird–mosquito transmission cycle, whereas humans and equidae are considered dead-end hosts. Most human *infections* occur by natural transmission from mosquitoes.

In relation to domestic animal trade, geese and ducks pose a *risk* for the spread of the WNV as some species have been documented to develop a viraemia sufficient to infect mosquitoes.

Surveillance for WNF should be carried out according to Chapter X.X.

The following criteria define the occurrence of WNF:

1. WNV has been isolated from an animal that shows signs consistent with WNF; or
2. viral antigen or viral ribonucleic acid (RNA) specific to WNV has been identified in samples from one or more animals that show clinical signs consistent with WNF, or that is epidemiologically linked to a confirmed or suspected *outbreak* of WNF; or
3. antibodies to WNV ~~that are not a consequence of vaccination,~~ **unvaccinated** animal, that shows clinical signs consistent with WNF; or ~~that~~ is epidemiologically linked to a confirmed or suspected *outbreak* of WNF.

For the purposes of the *Terrestrial Code*, the *incubation period* for WNF shall be 15 days.

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

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 8.16.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the WNF status of the *exporting country or zone*.

Article 8.16.2.

Trade in Safe commodities

Members should not impose trade restrictions on dead-end hosts such as horses.

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

Annex XXV (contd)

1. *hatching eggs* ;
2. eggs for human consumption;
3. egg products;
4. *poultry* semen;
5. *fresh meat* and *meat products* of *poultry*,
6. products of *poultry* origin intended for use in animal feeding, or for agricultural or industrial use;
7. feathers and down from *poultry*;
8. semen of horses;
9. *meat* and *meat products* of horses.

~~When authorising import or transit of other commodities listed in this chapter, Veterinary Authorities should require the conditions prescribed in this chapter relevant to the WNF status of the exporting country or zone.~~

Article 8.16.3.

WNF free country or zone

1. A country or *zone* may be considered free from WNF when WNF is notifiable in the whole country and either:
 - a) no occurrence of WNF *cases*, where *infection* occurred within the territory of the Member, have been recorded for the past 2 years; or
 - b) a *surveillance* programme in accordance with Chapter X.X. has demonstrated no evidence of WNV in the country or *zone* during the past 2 years.
2. A WNF free country or *zone* will not lose its free status through the importation from WNF infected countries or *infected zones* of:
 - a) seropositive animals;
 - b) semen, embryo or ova;
 - c) animals vaccinated in accordance with the *Terrestrial Manual* at least 30 days prior to dispatch, and are identified in the accompanying certification as having been vaccinated; or
 - d) animals not vaccinated if a *surveillance* programme in accordance with Chapter X.X. has been in place in the source population for a period of 30 days immediately prior to dispatch, and no evidence of WNV transmission has been detected.

Article 8.16.4.

WNF seasonally free country or zone

1. A WNF seasonally free country or *zone* is one in which for part of a year, *surveillance* demonstrates no evidence either of WNV transmission or presence of mosquitoes likely to be competent WNV vectors.
2. For the application of Article 8.16.6., the seasonally free period is taken to commence 21 days following the last evidence of WNV transmission (as demonstrated by the *surveillance* programme), or the cessation of activity of mosquitoes likely to be competent WNV vectors.
3. For the application of Article 8.16.6., the seasonally free period is taken to conclude either:
 - a) at least 21 days before the earliest date that historical data show WNV transmission cycle has recommenced; or
 - b) immediately if current climatic data or data from a *surveillance* programme indicate an earlier resurgence of activity of mosquitoes likely to be competent WNV vectors.
4. A WNF seasonally free country or *zone* will not lose its free status through the importation from WNF infected countries or *infected zones* of:
 - a) seropositive animals;
 - b) semen, embryo or ova;
 - c) animals vaccinated in accordance with the *Terrestrial Manual* at least 30 days prior to dispatch, and are identified in the accompanying certification as having been vaccinated; or
 - d) animals not vaccinated if a *surveillance* programme in accordance with Chapter X.X. has been in place in the source population for a period of 30 days immediately prior to dispatch, and no evidence of WNV transmission has been detected.

Article 8.16.5.

Recommendations for importation from WNF free countries or zones

for susceptible species (other than horses) ducks (under study), geese and birds other than poultry

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

1. the animals were kept in a WNF free country or *zone* since birth or for at least 30 days prior to shipment; or
2. the animals were kept in a WNF free country or *zone* for at least 15 days, were subjected, with negative results, to an agent identification test according to the *Terrestrial Manual* carried out on a sample collected at least 3 days after the commencement of the residence period and remained in the WNF free country or *zone* until shipment; or
3. the animals:
 - a) were vaccinated in accordance with the *Terrestrial Manual* 30 days before introduction into the free country or *zone*; and

Annex XXV (contd)

- b) were identified as having been vaccinated; and
- c) were kept in a WNF free country or *zone* for at least 15 days; and
- d) remained in the WNF free country or *zone* until shipment;

AND

- 4. if the animals were exported from a WNF free *zone*, either:
 - a) did not transit through an infected country or *infected zone* during transportation to the *place of shipment*; or
 - b) were protected from mosquito attacks at all times when transiting through an infected country or *infected zone*; or
 - c) had been vaccinated in accordance with point 3 above.

Article 8.16.6.

Recommendations for importation from WNF seasonally free countries or zones

for susceptible species (other than horses) ducks (under study), geese and birds other than poultry

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

- 1. were kept during the seasonally free period in a WNF seasonally free country or *zone* since birth or for at least 30 days prior to shipment; or
- 2. were kept during the WNF seasonally free period in a WNF seasonally free country or *zone* for at least 15 days prior to shipment, and were subjected during the residence period in the country or *zone* to an agent identification test according to the *Terrestrial Manual*, with negative results, carried out on a sample collected at least 3 days after the commencement of the residence period and remained in the WNF seasonally free country or *zone* until shipment; or
- 3. were kept during the seasonally free period in a WNF seasonally free country or *zone* for at least 15 days prior to shipment, and were vaccinated in accordance with the *Terrestrial Manual* 30 days before introduction into the free country or *zone* against WNF, were identified as having been vaccinated and remained in the WNF seasonally free country or *zone* until shipment;

AND

- 4. if the animals were exported from a WNF seasonally free country or *zone*, either:
 - a) did not transit through an infected country or *infected zone* during transportation to the *place of shipment*; or
 - b) were protected from mosquito attacks at all times when transiting through an infected country or *infected zone*; or
 - c) were vaccinated in accordance with point 3 above.

Article 8.16.7.

Recommendations for importation from WNF infected countries or infected zones

for susceptible species (other than horses) ducks (under study) and geese

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

1. were protected from mosquito attacks for at least 30 days prior to shipment; or
2. were subjected to a serological test according to the *Terrestrial Manual* to detect WNV neutralizing antibodies with positive results; or
3. were protected from mosquito attacks for at least 15 days prior to shipment, and were subjected during that period to an agent identification test according to the *Terrestrial Manual*, with negative results, carried out on a sample collected at least 3 days after being introduced in the mosquito-free zone, or
4. were vaccinated at least 30 days before shipment in accordance with the *Terrestrial Manual* against WNV and were identified in the accompanying certification as having been vaccinated; or
5. are not vaccinated and a *surveillance* programme in accordance with Chapter X.X. has been in place in the source population for a period of 30 days immediately prior to shipment, and no evidence of WNV transmission has been detected;

AND

6. were protected from mosquito attacks during transportation to the *place of shipment*.

Article 8.16.8.

Recommendations for the importation from WNF infected countries or zones of birds

for birds other than poultry

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

1. the birds showed no clinical sign of WNF on the day of shipment; and
2. the birds were kept in a *quarantine station* in a mosquito-free environment for 30 days prior to shipment and a statistically valid sample was subjected, with negative results, to an agent identification test according to the *Terrestrial Manual* at least 3 days after the commencement of the residence period.

Article 8.16.9.

Protecting animals from mosquito attacks

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

Annex XXV (contd)

Potential *risk management* strategies include:

1. treating animals with insect repellents prior to and during transportation;
2. ensuring *vehicles* do not stop en route unless the animals are held behind insect proof netting;
3. *surveillance* for vectors at common stopping and offloading points to gain information on seasonal variations;
4. integrated pest management practices at holding, common stopping and offloading points;
5. using historical, ongoing and/or WNF modelling information to identify low risk ports and transport routes.

— text deleted

CHAPTER 10.4 .

AVIAN INFLUENZA

Article 10.4.1.

General provisions

1. For the purposes of *international trade*, avian influenza in its notifiable form (NAI) is defined as an *infection of poultry* caused by any influenza A virus of the H5 or H7 subtypes or by any AI virus with an intravenous pathogenicity index (IVPI) greater than 1.2 (or as an alternative at least 75% mortality) as described below. NAI viruses can be divided into highly pathogenic notifiable avian influenza (HPNAI) and low pathogenicity notifiable avian influenza (LPNAI):
 - a) HPNAI viruses have an IVPI in 6-week-old chickens greater than 1.2 or, as an alternative, cause at least 75% mortality in 4-to 8-week-old chickens infected intravenously. H5 and H7 viruses which do not have an IVPI of greater than 1.2 or cause less than 75% mortality in an intravenous lethality test should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0); if the amino acid motif is similar to that observed for other HPNAI isolates, the isolate being tested should be considered as HPNAI;
 - b) LPNAI are all influenza A viruses of H5 and H7 subtype that are not HPNAI viruses.
2. *Poultry* is defined as 'all domesticated birds, including backyard *poultry*, used for the production of meat or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds, as well as fighting cocks used for any purpose'.

Birds that are kept in captivity for any reason other than those reasons referred to in the preceding paragraph, including those that are kept for shows, races, exhibitions, competitions or for breeding or selling these categories of birds as well as pet birds, are not considered to be *poultry*.
3. For the purposes of *international trade*, this chapter deals not only with the occurrence of clinical signs caused by NAI virus, but also with the presence of *infection* with NAI virus in the absence of clinical signs.
4. For the purposes of *international trade*, a Member should not impose immediate bans on the trade in *poultry commodities* in response to a notification, according to Article 1.2.3. of the *Terrestrial Code*, of *infection* with HPAI and LPAI virus in birds other than *poultry*, including wild birds.
5. Antibodies to H5 or H7 subtype of NAI virus, which have been detected in *poultry* and are not a consequence of vaccination, have to be immediately investigated. In the case of isolated serological positive results, NAI infection may be ruled out on the basis of a thorough epidemiological and laboratory investigation that does not demonstrate further evidence of NAI infection.
6. The following defines the occurrence of *infection* with NAI virus:
 - a) HPNAI virus has been isolated and identified as such or viral RNA specific for HPNAI has been detected in *poultry* or a product derived from *poultry*, or
 - b) LPNAI virus has been isolated and identified as such or viral RNA specific for LPNAI has been detected in *poultry* or a product derived from *poultry*.

Annex XXVI (contd)

For the purposes of the *Terrestrial Code*, 'NAI free establishment' means an *establishment* in which the *poultry* have shown no evidence of NAI infection, based on *surveillance* in accordance with Articles 10.4.28. to 10.4.34.

For the purposes of the *Terrestrial Code*, the *incubation period* for NAI shall be 21 days.

Standards for diagnostic tests, including pathogenicity testing, are described in the *Terrestrial Manual*. Any vaccine used should comply with the standards described in the *Terrestrial Manual*.

Article 10.4.2.

Determination of the NAI status of a country, zone or compartment

The NAI status of a country, a *zone* or a *compartment* can be determined on the basis of the following criteria:

1. NAI is notifiable in the whole country, an on-going NAI awareness programme is in place, and all notified suspect occurrences of NAI are subjected to field and, where applicable, *laboratory* investigations;
2. appropriate *surveillance* is in place to demonstrate the presence of *infection* in the absence of clinical signs in *poultry*, and the risk posed by birds other than *poultry*; this may be achieved through a NAI *surveillance* programme in accordance with Articles 10.4.28. to 10.4.34.;
3. consideration of all epidemiological factors for NAI occurrence and their historical perspective.

Article 10.4.3.

NAI free country, zone or compartment

A country, *zone* or *compartment* may be considered free from NAI when it has been shown that neither HPNAI nor LPNAI infection in *poultry* has been present in the country, *zone* or *compartment* for the past 12 months, based on *surveillance* in accordance with Articles 10.4.28. to 10.4.34.

If *infection* has occurred in *poultry* in a previously free country, *zone* or *compartment*, NAI free status can be regained:

1. In the case of HPNAI *infections*, 3 months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that *surveillance* in accordance with Articles 10.4.28. to 10.4.34. has been carried out during that three-month period.
2. In the case of LPNAI *infections*, *poultry* may be kept for *slaughter* for human consumption subject to conditions specified in Articles 10.4.20. or 10.4.21. or a *stamping-out policy* may be applied; in either case, 3 months after the *disinfection* of all affected *establishments*, providing that *surveillance* in accordance with Articles 10.4.28. to 10.4.34. has been carried out during that three-month period.

Article 10.4.4.

HPNAI free country, zone or compartment

A country, *zone* or *compartment* may be considered free from HPNAI when:

1. it has been shown that HPNAI infection in *poultry* has not been present in the country, *zone* or *compartment* for the past 12 months, although its LPNAI status may be unknown; or

2. when, based on *surveillance* in accordance with Articles 10.4.28. to 10.4.34., it does not meet the criteria for freedom from NAI but any NAI virus detected has not been identified as HPNAI virus.

The *surveillance* may need to be adapted to parts of the country or existing *zones* or *compartments* depending on historical or geographical factors, industry structure, population data, or proximity to recent *outbreaks*

If *infection* has occurred in *poultry* in a previously free country, *zone* or *compartment*, HPNAI free status can be regained 3 months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that *surveillance* in accordance with Articles 10.4.28. to 10.4.34. has been carried out during that three-month period.

Article 10.4.5.

Recommendations for importation from a NAI free country, zone or compartment

for live poultry (other than day-old poultry)

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

1. the *poultry* showed no clinical sign of NAI on the day of shipment;
2. the *poultry* were kept in a NAI free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;
3. the *poultry* are transported in new or appropriately sanitized *containers*;
4. if the *poultry* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.6.

Recommendations for the importation of live birds other than poultry

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. on the day of shipment, the birds showed no clinical sign of *infection* with a virus which would be considered NAI in *poultry* ~~on the day of shipment~~;
2. the birds were kept in isolation approved by the *Veterinary Services* since they were hatched or for at least the 21 days prior to shipment and showed no clinical sign of *infection* with a virus which would be considered NAI in *poultry* during the isolation period;
3. a statistically valid sample of the birds, selected in accordance with the provisions of Article 10.4.30. at a design prevalence acceptable to the importing country was subjected to a diagnostic test within 14 days prior to shipment to demonstrate freedom from *infection* with a virus which would be considered NAI in *poultry*;
4. the birds are transported in new or appropriately sanitized *containers*;
5. if the birds have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Annex XXVI (contd)

Article 10.4.7.

Recommendations for importation from a NAI free country, zone or compartmentfor day-old live poultry

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

1. the *poultry* were kept in a NAI free country, *zone* or *compartment* since they were hatched;
2. the *poultry* were derived from parent *flocks* which had been kept in a NAI free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;
3. the *poultry* are transported in new or appropriately sanitized *containers*;
4. if the *poultry* or the parent *flocks* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*

Article 10.4.8.

Recommendations for importation from a HPNAI free country, zone or compartmentfor day-old live poultry

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

1. the *poultry* were kept in a HPNAI free country, *zone* or *compartment* since they were hatched;
2. the *poultry* were derived from parent *flocks* which had been kept in a NAI free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;
3. the *poultry* are transported in new or appropriately sanitized *containers*;
4. if the *poultry* or the parent *flocks* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*

Article 10.4.9.

Recommendations for the importation of day-old live birds other than poultry

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. on the day of shipment, the birds showed no clinical signs of infection with a virus which would be considered suggestive of NAI in poultry on the day of shipment;
2. the birds were hatched and kept in isolation approved by the *Veterinary Services*;
3. the parent *flock* birds were subjected to a diagnostic test at the time of the collection of the eggs to demonstrate freedom from *infection* with NAIV;
4. the birds are transported in new or appropriately sanitized *containers*;

5. if the birds or parent *flocks* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.10.

Recommendations for importation from a NAI free country, zone or compartment

for hatching eggs of poultry

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

1. the eggs came from a NAI free country, *zone* or *compartment*;
2. the eggs were derived from parent *flocks* which had been kept in a NAI free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;
3. the eggs are transported in new or appropriately sanitized ~~containers~~ packaging materials;
4. if the parent *flocks* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.11.

Recommendations for importation from a HPNAI free country, zone or compartment

for hatching eggs of poultry

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

1. the eggs came from a HPNAI free country, *zone* or *compartment*;
2. the eggs were derived from parent *flocks* which had been kept in a NAI free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;
3. the eggs have had their surfaces sanitised (in accordance with Chapter 6.4.);
4. the eggs are transported in new or appropriately sanitized ~~containers~~ packaging materials;
5. if the parent *flocks* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.12.

Recommendations for the importation of hatching eggs from birds other than poultry

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. the parent *flock* birds were subjected to a diagnostic test 7 days prior to and at the time of the collection of the eggs to demonstrate freedom from *infection* with NAIV;

Annex XXVI (contd)

2. the eggs have had their surfaces sanitized (in accordance with Chapter 6.4.);
3. the eggs are transported in new or appropriately sanitized ~~containers~~ packaging materials;
4. if the parent *flocks* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*

Article 10.4.13.

Recommendations for importation from a NAI free country, zone or compartment
for eggs for human consumption

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

1. the eggs were produced and packed in a NAI free country, *zone* or *compartment*;
2. the eggs are transported in new or appropriately sanitized ~~containers~~ packaging materials.

Article 10.4.14.

Recommendations for importation from a HPNAI free country, zone or compartment
for eggs for human consumption

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

1. the eggs were produced and packed in a HPNAI free country, *zone* or *compartment*;
2. the eggs have had their surfaces sanitized (in accordance with Chapter 6.4.);
3. the eggs are transported in new or appropriately sanitized ~~containers~~ packaging materials.

Article 10.4.15.

Recommendations for importation of egg products of poultry

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. the *commodity* is derived from eggs which meet the requirements of Articles 10.4.11. or 10.4.14.; or
2. the *commodity* has been processed to ensure the destruction of NAI virus in accordance with Article 10.4.26.;

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 10.4.16.

Recommendations for importation from a NAI free country, zone or compartmentfor poultry semen

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

1. showed no clinical sign of NAI on the day of semen collection;
2. were kept in a NAI free country, *zone* or *compartment* for at least the 21 days prior to and at the time of semen collection.

Article 10.4.17.

Recommendations for the importation from a HPNAI free country, zone or compartmentfor poultry semen

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

1. showed no clinical sign of HPNAI on the day of semen collection;
2. were kept in a HPNAI free country, *zone* or *compartment* for at least the 21 days prior to and at the time of semen collection.

Article 10.4.18.

Recommendations for the importation of semen of birds other than poultry

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the donor birds:

1. were kept in isolation approved by the *Veterinary Services* for at least the 21 days prior to semen collection;
2. showed no clinical sign of *infection* with a virus which would be considered NAI in *poultry* during the isolation period;
3. were tested within 14 days prior to semen collection and shown to be free of NAI infection.

~~Article 10.4.19.~~~~**Recommendations for importation from a NAI free country, zone or compartment**~~~~for fresh meat of poultry~~

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

- ~~1. which have been kept in a NAI free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;~~

Annex XXVI (contd)

- ~~2. which have been slaughtered in an approved *abattoir* in a NAI free country, *zone* or *compartment* and have been subjected to ante-mortem and post-mortem inspections in accordance with Chapter 6.2. and have been found free of any signs suggestive of NAI.~~

Article 10.4.20.

Recommendations for importation from either a NAI or HPNAI free country, zone or compartment

for fresh meat of poultry

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

1. which have been kept in a ~~HPNAI free~~ country, *zone* or *compartment* free from NAI or HPNAI since they were hatched or for at least the past 21 days;
2. which have been slaughtered in an approved *abattoir* in a ~~HPNAI free~~ country, *zone* or *compartment* free from NAI or HPNAI and have been subjected to ante-mortem and post-mortem inspections in accordance with Chapter 6.2. and have been found free of any signs suggestive of NAI.

Article 10.4.21.

Recommendations for the importation of meat products of poultry

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. the *commodity* is derived from *fresh meat* which meet the requirements of Articles ~~10.4.19. or~~ 10.4.20.; or
2. the *commodity* has been processed to ensure the destruction of NAI virus in accordance with Article 10.4.27.;

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 10.4.22.

Recommendations for the importation of products of poultry origin, other than feather meal and poultry meat meal, intended for use in animal feeding, or for agricultural or industrial use ~~other than feather meal~~

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* were processed in a NAI free country, *zone* or *compartment* from *poultry* which were kept in a NAI free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*; or
2. these *commodities* have been processed to ensure the destruction of NAI virus (under study);

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 10.4.23.

Recommendations for the importation of feathers and down of poultry

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* originated from *poultry* as described in Articles ~~10.4.19.~~ or 10.4.20. and were processed in a NAI free country, *zone* or *compartment*; or
2. these *commodities* have been processed to ensure the destruction of NAI virus (under study);

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 10.4.24.

Recommendations for the importation of feathers and down of birds other than poultry

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* have been processed to ensure the destruction of NAI virus (under study); and
2. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 10.4.25.

Recommendations for the importation of feather meal and poultry meat meal

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* were processed in a NAI free country, *zone* or *compartment* from *poultry* which were kept in a NAI free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*; or
2. these *commodities* have been processed either;
 - a) with moist heat at a minimum temperature of 118°C for minimum of 40 minutes; or
 - b) with a continuous hydrolysing process under at least 3.79 bar of pressure with steam at a minimum temperature of 122 °C for a minimum of 15 minutes; or
 - c) with an alternative rendering process that ensures that the internal temperature throughout the product reaches at least 74 °C.

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Annex XXVI (contd)

Article 10.4.26.

Procedures for the inactivation of the AI virus in eggs and egg products

The following times for industry standard temperatures are suitable for the inactivation of AI virus present in eggs and egg products:

	Core Temperature (°C)	Time
Whole egg	60	188 seconds
Whole egg blends	60	188 seconds
Whole egg blends	61.1	94 seconds
Liquid egg white	55.6	870 seconds
Liquid egg white	56.7	232 seconds
10% salted yolk	62.2	138 seconds
Dried egg white	67	20 hours
Dried egg white	54.4	513 hours

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

Article 10.4.27.

Procedures for the inactivation of the AI virus in meat

A procedure which produces a core temperature of 70°C for 3.5 seconds is suitable for the inactivation of AI virus present in meat.

	Core Temperature (°C)	Time
Poultry meat	60.0	507 seconds
	65.0	42 seconds
	70.0	3.5 seconds
	73.9	0.51 seconds

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

Article 10.4.28.

Surveillance: introduction

Articles 10.4.28. to 10.4.34. define the principles and provide a guide on the *surveillance of for* NAI complementary to Chapter 1.4., applicable to Members seeking to determine their NAI status. This may be for the entire country, *zone* or *compartment*. Guidance for Members seeking free status following an *outbreak* and for the maintenance of NAI status is also provided.

The presence of avian influenza viruses in wild birds creates a particular problem. In essence, no Member can declare itself free from avian influenza (AI) in wild birds. However, the definition of NAI in this Chapter refers to the *infection in poultry* only, and Articles 10.4.28. to 10.4.34. were developed under this definition.

The impact and epidemiology of NAI differ widely in different regions of the world and therefore it is impossible to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from NAI at an acceptable level of confidence will need to be adapted to the local situation. Variables such as the frequency of contacts of *poultry* with wild birds, different biosecurity levels and production systems and the commingling of different susceptible species including domestic waterfowl require specific *surveillance* strategies to address each specific situation. It is incumbent upon the Member to provide scientific data that explains the epidemiology of NAI in the region concerned and also demonstrates how all the risk factors are managed. There is therefore considerable latitude available to Members to provide a well-reasoned argument to prove that absence of NAI virus (NAIV) infection is assured at an acceptable level of confidence.

Surveillance for NAI should be in the form of a continuing programme designed to establish that the country, *zone* or *compartment*, for which application is made, is free from NAIV infection.

Article 10.4.29.

Surveillance: general conditions and methods

1. A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. In particular:
 - a) a formal and ongoing system for detecting and investigating *outbreaks of disease* or NAI infection should be in place;
 - b) a procedure should be in place for the rapid collection and transport of samples from suspect cases of NAI to a *laboratory* for NAI diagnosis as described in the *Terrestrial Manual*;
 - c) a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.
2. The NAI *surveillance* programme should:
 - a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious *cases*. Farmers and workers, who have day-to-day contact with *poultry*, as well as diagnosticians, should report promptly any suspicion of NAI to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All suspected cases of NAI should be investigated immediately. As suspicion cannot always be resolved by epidemiological and clinical investigation alone, samples should be taken and submitted to a *laboratory* for appropriate tests. This requires that sampling kits and other equipment are available for those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in NAI diagnosis and control. In cases where potential public health implications are suspected, notification to the appropriate public health authorities is essential;

Annex XXVI (contd)

- b) implement, when relevant, regular and frequent clinical inspection, serological and virological testing of high-risk groups of *animals*, such as those adjacent to a NAI infected country, *zone* or *compartment*, places where birds and *poultry* of different origins are mixed, such as live bird markets, *poultry* in close proximity to waterfowl or other potential sources of NAIIV.

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

Article 10.4.30.

Surveillance strategies

1. Introduction

The target population for *surveillance* aimed at identification of *disease* and *infection* should cover all the susceptible *poultry* species within the country, *zone* or *compartment*. Active and passive *surveillance* for NAI should be ongoing. The frequency of active *surveillance* should be at least every 6 months. *Surveillance* should be composed of random and targeted approaches using molecular, virological, serological and clinical methods.

The strategy employed may be based on randomised sampling requiring *surveillance* consistent with demonstrating the absence of NAIIV infection at an acceptable level of confidence. Random *surveillance* is conducted using serological tests described in the *Terrestrial Manual*. Positive serological results should be followed up with molecular and or virological methods.

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

A Member should justify the *surveillance* strategy chosen as adequate to detect the presence of NAIIV infection in accordance with Chapter 1.4. and the prevailing epidemiological situation, including *cases* of HPAI detected in any birds. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clear clinical signs (e.g. chickens). Similarly, virological and serological testing could be targeted to species that may not show clinical signs (e.g. ducks).

If a Member wishes to declare freedom from NAIIV infection in a specific *zone* or *compartment*, the design of the survey and the basis for the sampling process would need to be aimed at the population within the *zone* or *compartment*.

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

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

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

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

2. Clinical surveillance

Clinical *surveillance* aims at the detection of clinical signs of NAI at the *flock* level. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection should not be underrated. Monitoring of production parameters, such as increased mortality, reduced feed and water consumption, presence of clinical signs of a respiratory *disease* or a drop in egg production, is important for the early detection of NAIIV infection. In some cases, the only indication of LPNAIV infection may be a drop in feed consumption or egg production.

Clinical *surveillance* and *laboratory* testing should always be applied in series to clarify the status of NAI suspects detected by either of these complementary diagnostic approaches. *Laboratory* testing may confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive serology. Any sampling unit within which suspicious animals are detected should have restrictions imposed upon it until NAI infection is ruled out.

Identification of suspect *flocks* is vital to the identification of sources of NAIIV and to enable the molecular, antigenic and other biological characteristics of the virus to be determined. It is essential that NAIIV isolates are sent regularly to the regional Reference Laboratory for genetic and antigenic characterization.

3. Virological surveillance

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

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

Annex XXVI (contd)4. Serological surveillance

Serological *surveillance* aims at the detection of antibodies against NAIV. Positive NAIV antibody test results can have four possible causes:

- a) natural *infection* with NAIV;
- b) vaccination against NAI;
- c) maternal antibodies derived from a vaccinated or infected parent *flock* are usually found in the yolk and can persist in progeny for up to 4 weeks;
- d) false positive results due to the lack of specificity of the test.

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

The discovery of clusters of seropositive *flocks* may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or *infection*. As clustering may signal *infection*, the investigation of all instances **must should** be incorporated in the survey design. Clustering of positive *flocks* is always epidemiologically significant and therefore should be investigated.

If vaccination cannot be excluded as the cause of positive serological reactions, diagnostic methods to differentiate antibodies due to *infection* or vaccination should be employed.

The results of random or targeted serological surveys are important in providing reliable evidence that no NAIV infection is present in a country, *zone* or *compartment*. It is therefore essential that the survey be thoroughly documented.

5. Virological and serological surveillance in vaccinated populations

The *surveillance* strategy is dependent on the type of vaccine used. The protection against AI is haemagglutinin subtype specific. Therefore, two broad vaccination strategies exist: 1) inactivated whole AI viruses, and 2) haemagglutinin expression-based vaccines.

In the case of vaccinated populations, the *surveillance* strategy should be based on virological and/or serological methods and clinical *surveillance*. It may be appropriate to use sentinel birds for this purpose. These birds should be unvaccinated, AI virus antibody free birds and clearly and permanently identified. Sentinel birds should be used only if no appropriate *laboratory* procedures are available. The interpretation of serological results in the presence of vaccination is described in Article 10.4.34.

Article 10.4.31.

Documentation of NAI or HPNAI free status1. Members declaring freedom from NAI or HPNAI for the country, zone or compartment: additional surveillance procedures

In addition to the general conditions described in above mentioned articles, a Member declaring freedom from NAI or HPNAI for the entire country, or a *zone* or a *compartment* should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and should be planned and implemented according to general conditions and methods described in this Chapter, to demonstrate absence of NAIV or HPNAIV infection, during the preceding 12 months in susceptible *poultry* populations (vaccinated and non-vaccinated). This requires the support of a *laboratory* able to undertake identification of NAIV or HPNAIV infection through virus detection and antibody tests described in the *Terrestrial Manual*. This *surveillance* may be targeted to *poultry* population at specific risks linked to the types of production, possible direct or indirect contact with wild birds, multi-age *flocks*, local trade patterns including live bird markets, use of possibly contaminated surface water, and the presence of more than one species on the holding and poor biosecurity measures in place.

2. Additional requirements for countries, zones or compartments that practise vaccination

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

In all vaccinated *flocks* there is a need to perform virological and serological tests to ensure the absence of virus circulation. The use of sentinel *poultry* may provide further confidence of the absence of virus circulation. The tests have to be repeated at least every 6 months or at shorter intervals according to the risk in the country, *zone* or *compartment*.

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

Article 10.4.32.

Countries, zones or compartments declaring that they have regained freedom from NAI or HPNAI following an outbreak: additional surveillance procedures

In addition to the general conditions described in the above-mentioned articles, a Member declaring that it has regained country, *zone* or *compartment* freedom from NAI or HPNAI virus infection should show evidence of an active *surveillance* programme depending on the epidemiological circumstances of the *outbreak* to demonstrate the absence of the *infection*. This will require *surveillance* incorporating virus detection and antibody tests described in the *Terrestrial Manual*. The use of sentinel birds may facilitate the interpretation of *surveillance* results.

A Member declaring freedom of country, *zone* or *compartment* after an *outbreak* of NAI or HPNAI (with or without vaccination) should report the results of an active *surveillance* programme in which the NAI or HPNAI susceptible *poultry* population undergoes regular clinical examination and active *surveillance* planned and implemented according to the general conditions and methods described in these recommendations. The *surveillance* should at least give the confidence that can be given by a randomized representative sample of the populations at risk.

Article 10.4.33.

NAI free establishments within HPNAI free compartments: additional surveillance procedures

The declaration of NAI free *establishments* requires the demonstration of absence of NAIIV infection. Birds in these *establishments* should be randomly tested using virus detection or isolation tests, and serological methods, following the general conditions of these recommendations. The frequency of testing should be based on the risk of *infection* and at a maximum interval of 21 days.

The use and interpretation of serological and virus detection tests

Poultry infected with NAI virus produce antibodies to haemagglutinin (HA), neuraminidase (NA), nonstructural proteins (NSPs), nucleoprotein/matrix (NP/M) and the polymerase complex proteins. Detection of antibodies against the polymerase complex proteins will not be covered in this Chapter. Tests for NP/M antibodies include direct and blocking ELISA, and agar gel immunodiffusion (AGID) tests. Tests for antibodies against NA include the neuraminidase inhibition (NI), indirect fluorescent antibody and direct and blocking ELISA tests. For the HA, antibodies are detected in haemagglutination inhibition (HI), ELISA and neutralization (SN) tests. The HI test is reliable in avian species but not in mammals. The SN test can be used to detect subtype specific antibodies to the haemagglutinin and is the preferred test for mammals and some avian species. The AGID test is reliable for detection of NP/M antibodies in chickens and turkeys, but not in other avian species. As an alternative, blocking ELISA tests have been developed to detect NP/M antibodies in all avian species.

The HI and NI tests can be used to subtype AI viruses into 16 haemagglutinin and 9 neuraminidase subtypes. Such information is helpful for epidemiological investigations and in categorization of AI viruses.

Poultry can be vaccinated with a variety of AI vaccines including inactivated whole AI virus vaccines, and haemagglutinin expression-based vaccines. Antibodies to the haemagglutinin confer subtype specific protection. Various strategies can be used to differentiate vaccinated from infected birds including serosurveillance in unvaccinated sentinel birds or specific serological tests in the vaccinated birds.

AI virus *infection* of unvaccinated birds including sentinels is detected by antibodies to the NP/M, subtype specific HA or NA proteins, or NSP. *Poultry* vaccinated with inactivated whole AI vaccines containing an influenza virus of the same H sub-type but with a different neuraminidase may be tested for field exposure by applying serological tests directed to the detection of antibodies to the NA of the field virus. For example, birds vaccinated with H7N3 in the face of a H7N1 epidemic may be differentiated from infected birds (DIVA) by detection of subtype specific NA antibodies of the N1 protein of the field virus. Alternatively, in the absence of DIVA, inactivated vaccines may induce low titres of antibodies to NSP and the titre in infected birds would be markedly higher. Encouraging results have been obtained experimentally with this system, but it has not yet been validated in the field. In *poultry* vaccinated with haemagglutinin expression-based vaccines, antibodies are detected to the specific HA, but not any of the other AI viral proteins. *Infection* is evident by antibodies to the NP/M or NSP, or the specific NA protein of the field virus. Vaccines used should comply with the standards of the *Terrestrial Manual*.

All *flocks* with seropositive results should be investigated. Epidemiological and supplementary *laboratory* investigation results should document the status of NAI infection/circulation for each positive *flock*.

A confirmatory test should have a higher specificity than the screening test and sensitivity at least equivalent than that of the screening test.

Information should be provided on the performance characteristics and validation of tests used.

1. The follow-up procedure in case of positive test results if vaccination is used

In case of vaccinated populations, one has to exclude the likelihood that positive test results are indicative of virus circulation. To this end, the following procedure should be followed in the investigation of positive serological test results derived from *surveillance* conducted on NAI-vaccinated *poultry*. The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated, and the results should be collated in the final report.

Knowledge of the type of vaccine used is crucial in developing a serological based strategy to differentiate infected from vaccinated animals.

- a) Inactivated whole AI virus vaccines can use either homologous or heterologous neuraminidase subtypes between the vaccine and field strains. If *poultry* in the population have antibodies to NP/M and were vaccinated with inactivated whole AI virus vaccine, the following strategies should be applied:
 - i) sentinel birds should remain NP/M antibody negative. If positive for NP/M antibodies, indicating AI virus infection, specific HI tests should be performed to identify H5 or H7 AI virus infection;
 - ii) if vaccinated with inactivated whole AI virus vaccine containing homologous NA to field virus, the presence of antibodies to NSP could be indicative of *infection*. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins;
 - iii) if vaccinated with inactivated whole AI virus vaccine containing heterologous NA to field virus, presence of antibodies to the field virus NA or NSP would be indicative of *infection*. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins.
- b) Haemagglutinin expression-based vaccines contain the HA protein or gene homologous to the HA of the field virus. Sentinel birds as described above can be used to detect AI infection. In vaccinated or sentinel birds, the presence of antibodies against NP/M, NSP or field virus NA is indicative of *infection*. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins.

2. The follow-up procedure in case of positive test results indicative of infection for determination of infection due to HPNAI or LPNAI virus

The detection of antibodies indicative of a NAI virus infection as indicated in point a)i) above will result in the initiation of epidemiological and virological investigations to determine if the infections are due to HPNAI or LPNAI viruses.

Annex XXVI (contd)

Virological testing should be initiated in all antibody-positive and at risk populations. The samples should be evaluated for the presence of AI virus, by virus isolation and identification, and/or detection of influenza A specific proteins or nucleic acids (Figure 2). Virus isolation is the gold standard for detecting *infection* by AI virus and the method is described in the *Terrestrial Manual*. All AI virus isolates should be tested to determine HA and NA subtypes, and *in vivo* tested in chickens and/or sequencing of HA proteolytic cleavage site of H5 and H7 subtypes for determination of classification as HPNAI, LPNAI or LPAI (not notifiable) viruses. As an alternative, nucleic acid detection tests have been developed and validated; these tests have the sensitivity of virus isolation, but with the advantage of providing results within a few hours. Samples with detection of H5 and H7 HA subtypes by nucleic acid detection methods should either be submitted for virus isolation, identification, and *in vivo* testing in chickens, or sequencing of nucleic acids for determination of proteolytic cleavage site as HPNAI or LPNAI viruses. The antigen detection systems, because of low sensitivity, are best suited for screening clinical field cases for *infection* by Type A influenza virus looking for NP/M proteins. NP/M positive samples should be submitted for virus isolation, identification and pathogenicity determination.

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

- a) characterization of the existing production systems;
- b) results of clinical *surveillance* of the suspects and their cohorts;
- c) quantification of vaccinations performed on the affected sites;
- d) sanitary protocol and history of the affected *establishments*;
- e) control of *animal identification* and movements;
- f) other parameters of regional significance in historic NAIIV transmission.

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

Fig. 1. Schematic representation of laboratory tests for determining evidence of NAI infection through or following serological surveys

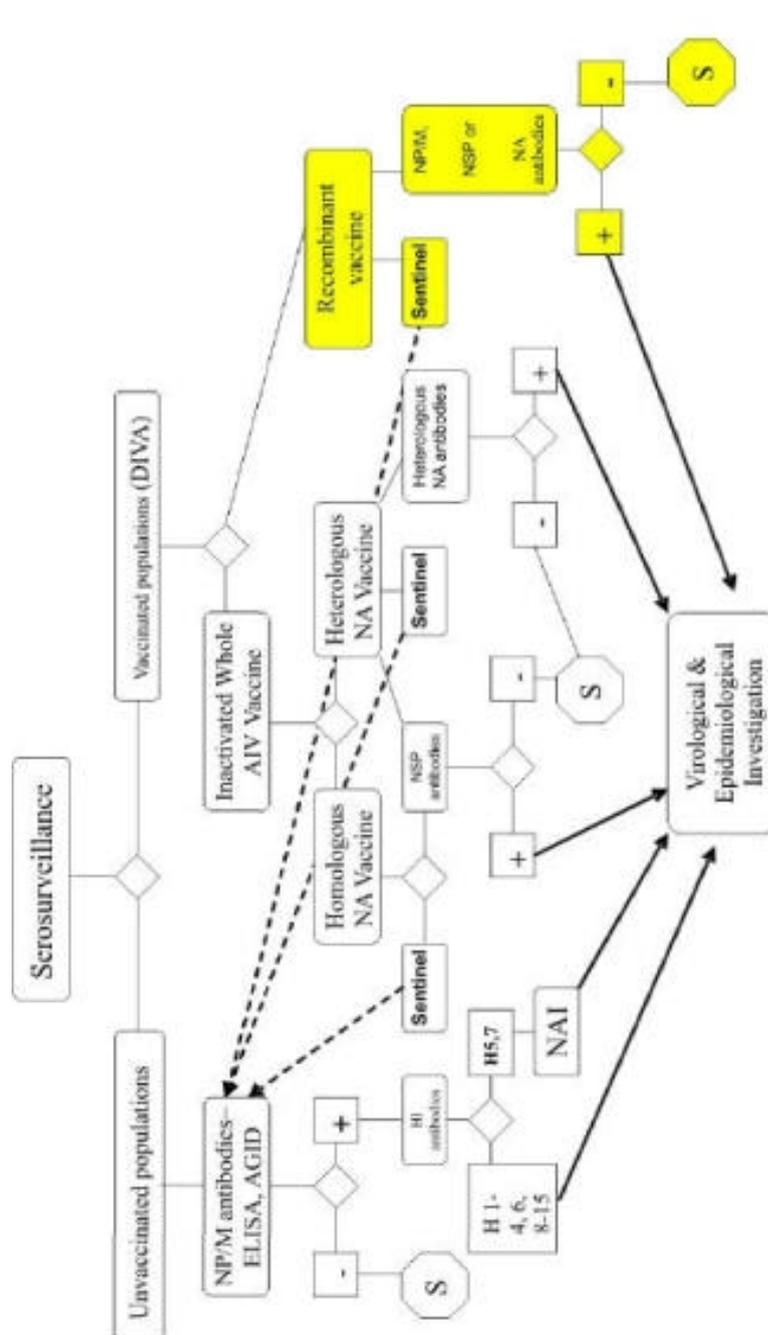
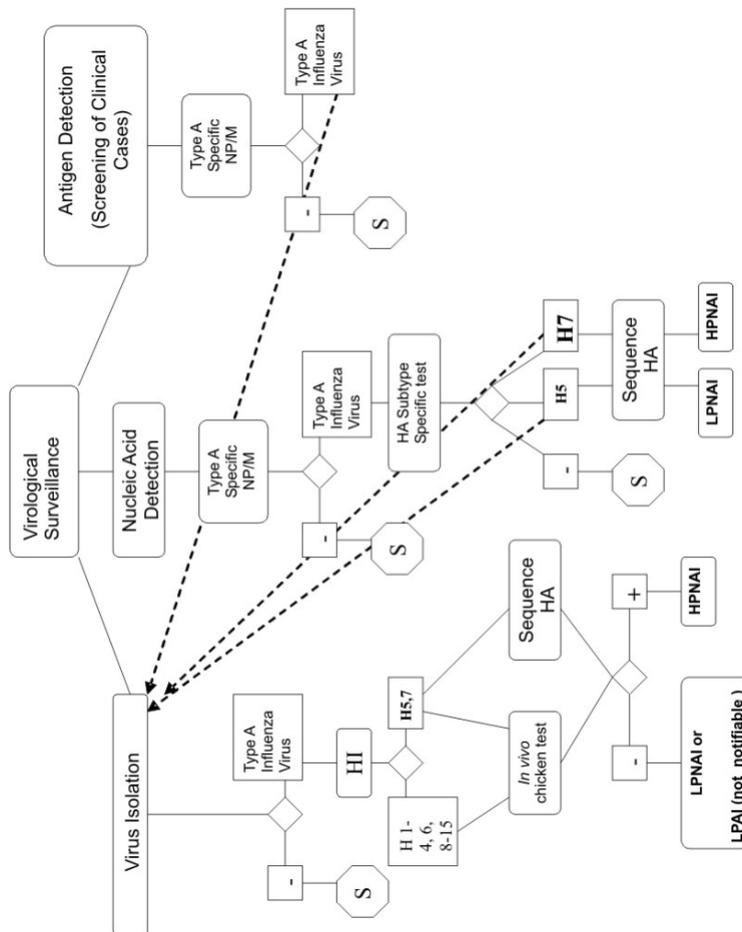


Fig. 2. Schematic representation of laboratory tests for determining evidence of NAI infection using virological methods



The above diagram indicates the tests which are recommended for use in the investigation of *poultry flocks*.

— text deleted

CHAPTER 10.13.
NEWCASTLE DISEASE

Article 10.13.1.

General provisions

1. For the purposes of *international trade*, Newcastle disease (ND) is defined as an *infection of poultry* caused by a virus (NDV) of avian paramyxovirus serotype 1 (APMV-1) that meets one of the following criteria for virulence:
 - a) the virus has an intracerebral pathogenicity index (ICPI) in day-old chicks (*Gallus gallus*) of 0.7 or greater; or
 - b) multiple basic amino acids have been demonstrated in the virus (either directly or by deduction) at the C-terminus of the F2 protein and phenylalanine at residue 117, which is the N-terminus of the F1 protein. The term 'multiple basic amino acids' refers to at least three arginine or lysine residues between residues 113 and 116. Failure to demonstrate the characteristic pattern of amino acid residues as described above would require characterisation of the isolated virus by an ICPI test.

In this definition, amino acid residues are numbered from the N-terminus of the amino acid sequence deduced from the nucleotide sequence of the F0 gene, 113–116 corresponds to residues –4 to –1 from the cleavage site.'

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

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

3. This Chapter deals with NDV *infection of poultry* as defined in point 2 above, in the presence or absence of clinical signs. For the purposes of *international trade*, a Member should not impose immediate bans on the trade in *poultry commodities* in response to a notification, according to Article 1.2.3. of the *Terrestrial Code*, of infection with NDV in birds other than *poultry*, including wild birds.
4. The occurrence of *infection* with NDV is defined as the isolation and identification of NDV as such or the detection of viral RNA specific for NDV.
5. For the purposes of the *Terrestrial Code*, the *incubation period* for ND shall be 21 days.
6. Standards for diagnostic tests, including pathogenicity testing, are described in the *Terrestrial Manual*. When the use of ND vaccines is appropriate, those vaccines should comply with the standards described in the *Terrestrial Manual*.

Annex XXVII (contd)

Article 10.13.2.

Determination of the ND status of a country, zone or compartment

The ND status of a country, a *zone* or a *compartment* can be determined on the basis of the following criteria:

1. ND is notifiable in the whole country, an on-going ND awareness programme is in place, and all notified suspect occurrences of ND are subjected to field and, where applicable, *laboratory* investigations;
2. appropriate *surveillance* is in place to demonstrate the presence of NDV *infection* in the absence of clinical signs in *poultry*, this may be achieved through an ND *surveillance* programme in accordance with Articles 10.13.22. to 10.13.26.;
3. consideration of all epidemiological factors for ND occurrence and their historical perspective.

Article 10.13.3.

ND free country, zone or compartment

A country, *zone* or *compartment* may be considered free from ND when it has been shown that NDV *infection* in *poultry* has not been present in the country, *zone* or *compartment* for the past 12 months, based on *surveillance* in accordance with Articles 10.13.22. to 10.13.26.

If *infection* has occurred in *poultry* in a previously free country, *zone* or *compartment*, ND free status can be regained three months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that *surveillance* in accordance with Articles 10.13.22. to 10.13.26. has been carried out during that three-month period.

Article 10.13.4.

Recommendations for importation from an ND free country, zone or compartment as defined in Article 10.13.3.for live poultry (other than day-old poultry)

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

1. the *poultry* showed no clinical sign suggestive of ND on the day of shipment;
2. the *poultry* were kept in an ND free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;
3. the *poultry* are transported in new or appropriately sanitized *containers*;
4. if the *poultry* have been vaccinated against ND, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.13.5.

Recommendations for the importation of live birds other than poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. the birds showed no clinical sign suggestive of infection by NDV on the day of shipment;
2. the birds were kept in isolation approved by the *Veterinary Services* since they were hatched or for at least the 21 days prior to shipment and showed no clinical sign of *infection* during the isolation period;
3. a statistically valid sample of the birds, selected in accordance with the provisions of Article 10.413.3024, at a design prevalence acceptable to the importing country was subjected to a diagnostic test within 14 days prior to shipment to demonstrate freedom from *infection* with NDV;
4. the birds are transported in new or appropriately sanitized *containers*;
5. if the birds have been vaccinated against ND, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.13.6.

Recommendations for importation from an ND free country, zone or compartmentfor day-old live poultry

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

1. the *poultry* were hatched and kept in an ND free country, *zone* or *compartment* since they were hatched;
2. the *poultry* were derived from parent *flocks* which had been kept in an ND free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;
3. the *poultry* are transported in new or appropriately sanitized *containers*;
4. if the *poultry* or parent *flocks* have been vaccinated against ND, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.13.7.

Recommendations for the importation of day-old live birds other than poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. the birds showed no clinical sign suggestive of infection by NDV on the day of shipment;
2. the birds were hatched and kept in isolation approved by the *Veterinary Services*;
3. the parent *flock* birds were subjected to a diagnostic test at the time of the collection of the eggs to demonstrate freedom from *infection* with NDV;

Annex XXVII (contd)

4. the birds are transported in new or appropriately sanitized *containers*;
5. if the birds or parent *flocks* have been vaccinated against ND, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*

Article 10.13.8.

Recommendations for importation from an ND free country, zone or compartment

for hatching eggs of poultry

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

1. the eggs came from an ND free country, *zone* or *compartment*;
2. the eggs were derived from parent *flocks* which had been kept in an ND free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;
3. the eggs are transported in new or appropriately sanitized ~~*containers*~~ packaging materials;
4. if the parent *flocks* have been vaccinated against ND, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*

Article 10.13.9.

Recommendations for the importation of hatching eggs from birds other than poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. the parent *flock* birds were subjected to a diagnostic test 7 days prior to and at the time of the collection of the eggs to demonstrate freedom from *infection* with NDV;
2. the eggs have had their surfaces sanitized (in accordance with Chapter 6.4.);
3. the eggs are transported in new or appropriately sanitized ~~*containers*~~ packaging materials;
4. if the parent *flocks* have been vaccinated against ND, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*

Article 10.13.10.

Recommendations for importation from an ND free country, zone or compartment

for eggs for human consumption

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

1. the eggs were produced and packed in an ND free country, *zone* or *compartment*;
2. the eggs are transported in new or appropriately sanitized ~~containers~~ packaging materials.

Article 10.13.11.

Recommendations for importation of egg products of poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. the *commodity* is derived from eggs which meet the requirements of Article 10.13.10.; or
2. the *commodity* has been processed to ensure the destruction of NDV in accordance with Article 10.13.20. (under study);

AND

3. the necessary precautions were taken to avoid contact of the egg products with any source of NDV.

Article 10.13.12.

Recommendations for importation from an ND free country, zone or compartment

for poultry semen

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

1. showed no clinical sign suggestive of ND on the day of semen collection;
2. were kept in an ND free country, *zone* or *compartment* for at least the 21 days prior to and at the time of semen collection.

Article 10.13.13.

Recommendations for the importation of semen of birds other than poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the donor birds:

1. were kept in isolation approved by the *Veterinary Services* for at least the 21 days prior to and on the day of semen collection;
2. showed no clinical sign suggestive of *infection* with NDV during the isolation period and on the day of semen collection;
3. were subjected to a diagnostic test within 14 days prior to semen collection to demonstrate freedom from *infection* with NDV.

Annex XXVII (contd)

Article 10.13.14.

Recommendations for importation from an ND free country, zone or compartmentfor fresh meat of poultry

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

1. which have been kept in an ND free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;
2. which have been slaughtered in an approved *abattoir* in an ND free country, *zone* or *compartment* and have been subjected to ante-mortem and post-mortem inspections in accordance with Chapter 6.2. and have been found free of any sign suggestive of ND.

Article 10.13.15.

Recommendations for importation of meat products of poultry

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

1. the *commodity* is derived from *fresh meat* which meet the requirements of Article 10.13.14.; or
2. the *commodity* has been processed to ensure the destruction of NDV in accordance with Article 10.13.21. (under study);

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NDV.

Article 10.13.16.

Recommendations for the importation of products of poultry origin, other than feather meal and poultry meat meal, intended for use in animal feeding, or for agricultural or industrial use other than feather meal

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* were processed in a ND free country, *zone* or *compartment* from *poultry* which were kept in a ND free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*; or
2. these *commodities* have been processed to ensure the destruction of NDV (under study);

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NDV.

Article 10.13.17.

Recommendations for the importation of feathers and down of poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* originated from *poultry* as described in Article 10.13.14. and were processed in a ND free country, *zone* or *compartment*; or
2. these *commodities* have been processed to ensure the destruction of NDV (under study);

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NDV.

Article 10.13.18.

Recommendations for the importation of feathers and down of birds other than poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* have been processed to ensure the destruction of NDV (under study); and
2. the necessary precautions were taken to avoid contact of the *commodity* with any source of NDV

Article 10.13.19.

Recommendations for the importation of feather meal and poultry meat meal

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* were processed in a ND free country, *zone* or *compartment* from *poultry* which were kept in a ND free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*; or
2. these *commodities* have been processed either:
 - a) with moist heat at a minimum temperature of 118°C for minimum of 40 minutes; or
 - b) with a continuous hydrolysing process under at least 3.79 bar of pressure with steam at a minimum temperature of 122 °C for a minimum of 15 minutes; or
 - c) with an alternative rendering process that ensures that the internal temperature throughout the product reaches at least 74 °C for a minimum of 280 seconds;

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of ND virus.

Annex XXVII (contd)Article 10.13.20 (~~under study~~)**Procedures for the inactivation of the ND virus in eggs and egg products**

The following times and temperatures are suitable for the inactivation of ND virus present in eggs and egg products:

	Core t Temperature (°C)	Time
Whole egg	55	2,521 seconds
Whole egg	57	1,596 seconds
Whole egg	59	674 seconds
Liquid egg white	55	2,278 seconds
Liquid egg white	57	986 seconds
Liquid egg white	59	301 seconds
10% salted yolk	55	176 seconds
Dried egg white	57	50.4 hours

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

Article 10.13.21 (~~under study~~)**Procedures for the inactivation of the ND virus in meat**

A procedure which produces a core temperature of 70°C for 574 seconds is The following times for industry standard temperatures are suitable for the inactivation of ND virus present in *meat*.

	Core t Temperature (°C)	Time
Poultry meat	65.0	840 seconds
	70.0	574 seconds
	74.0	280 seconds
	80.0	203 seconds

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

Article 10.13.22.

Surveillance: introduction

Articles 10.13.22. to 10.13.26. define the principles and provide a guide on the *surveillance* for ND as defined in Article 10.13.1. and is complementary to Chapter 1.4. It is applicable to Members seeking to determine their ND status. This may be for the entire country, *zone* or *compartment*. Guidance for Members seeking free status following an *outbreak* and for the maintenance of ND status is also provided.

Surveillance for ND is complicated by the known occurrence of avian paramyxovirus serotype 1 (APMV-1) infections in many bird species, both domestic and wild, and the widespread utilization of ND vaccines in domestic *poultry*.

The impact and epidemiology of ND differ widely in different regions of the world and therefore it is not possible to provide specific recommendations for all situations. Therefore, *surveillance* strategies employed for demonstrating freedom from ND at an acceptable level of confidence will need to be adapted to the local situation. Variables such as the frequency of contacts of *poultry* with wild birds, different biosecurity levels, production systems and the commingling of different susceptible species require specific *surveillance* strategies to address each specific situation. It is incumbent upon the Member to provide scientific data that explains the epidemiology of ND in the region concerned and also demonstrates how all the risk factors are managed. There is, therefore, considerable latitude available to Members to provide a well-reasoned argument to prove freedom from NDV *infection*.

Surveillance for ND should be in the form of a continuing programme designed to establish that the country, *zone* or *compartment*, for which application is made, is free from NDV *infection*.

Article 10.13.23.

Surveillance: general conditions and methods

1. A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. In particular there should be in place:
 - a) a formal and ongoing system for detecting and investigating outbreaks of *disease* or NDV *infection*;
 - b) a procedure for the rapid collection and transport of samples from suspect cases of ND to a *laboratory* for ND diagnosis as described in the *Terrestrial Manual*;
 - c) a system for recording, managing and analysing diagnostic and *surveillance* data.
2. The ND *surveillance* programme should:
 - a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers, who have day-to-day contact with *poultry*, as well as diagnosticians, should report promptly any suspicion of ND to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All suspected cases of ND should be investigated immediately. As suspicion cannot be resolved by epidemiological and clinical investigation alone, samples should be taken and submitted to a *laboratory* for appropriate tests. This requires that sampling kits and other equipment are available to those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in ND diagnosis and control;

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- b) implement, when relevant, regular and frequent clinical, virological and serological *surveillance* of high risk groups of *poultry* within the target population (e.g. those adjacent to an ND infected country, *zone*, *compartment*, places where birds and *poultry* of different origins are mixed, or other sources of NDV).

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

Article 10.13.24.

Surveillance strategies

1. Introduction

Any *surveillance* programme requires inputs from professionals competent and experienced in this field and should be thoroughly documented. The design of *surveillance* programmes to prove the absence of NDV *infection* / circulation needs to be carefully followed to avoid producing results that are either unreliable, or excessively costly and logistically complicated.

If a Member wishes to declare freedom from NDV infection in a country, *zone* or *compartment*, the subpopulation used for *surveillance* ~~of~~ for the *disease* / *infection* should be representative of all *poultry* within the country, *zone* or *compartment*. Multiple *surveillance* methods should be used concurrently to accurately define the true ND status of *poultry* populations. Active and passive *surveillance* for ND should be ongoing with the frequency of active *surveillance* being appropriate to the disease situation in the country. *Surveillance* should be composed of random and/or targeted approaches, dependent on the local epidemiological situation and using clinical, virological and serological methods as described in the *Terrestrial Manual*. If alternative tests are used they ~~must~~ should have been validated as fit-for-purpose in accordance with OIE standards. A Member should justify the *surveillance* strategy chosen as adequate to detect the presence of NDV infection in accordance with Chapter 1.4. and the prevailing epidemiological situation.

In surveys, the sample size selected for testing should be statistically justified to detect *infection* at a predetermined target prevalence. The sample size and expected prevalence determine the level of confidence in the results of the survey. The survey design and frequency of sampling should be dependent on the historical and current local epidemiological situation. The Member should justify the choice of survey design and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4.

Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in a population) may be an appropriate strategy.

It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clear clinical signs (e.g. unvaccinated chickens). Similarly, virological and serological testing could target species that may not show clinical signs (Article 10.13.2.) of ND and are not routinely vaccinated (e.g. ducks). *Surveillance* may also target *poultry* populations at specific risk, for example direct or indirect contact with wild birds, multi-age *flocks*, local trade patterns including live *poultry* markets, the presence of more than one species on the holding and poor biosecurity measures in place. In situations where wild birds have been shown to play a role in the local epidemiology of ND, *surveillance* of wild birds may be of value in alerting *Veterinary Services* to the possible exposure of *poultry*, and in particular, of free ranging *poultry*.

The sensitivity and specificity of the diagnostic tests are key factors in the choice of survey design, which should anticipate the occurrence of false positive and false negative reactions. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination / *infection* history and for the different species in the target population. If the characteristics of the testing system are known, the rate at which these false reactions are likely to occur can be calculated in advance. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as *flocks* which may be epidemiologically linked to it.

The results of active and passive *surveillance* are important in providing reliable evidence that no NDV infection is present in a country, *zone* or *compartment*.

2. Clinical surveillance

Clinical *surveillance* aims to detect clinical signs suggestive of ND at the *flock* level and should not be underestimated as an early indication of *infection*. Monitoring of production parameters (e.g. a drop in feed or water consumption or egg production) is important for the early detection of NDV infection in some populations, as there may be no, or mild clinical signs, particularly if they are vaccinated. Any sampling unit within which suspicious animals are detected should be considered as infected until evidence to the contrary is produced. Identification of infected *flocks* is vital to the identification of sources of NDV.

A presumptive diagnosis of clinical ND in suspect infected populations should always be confirmed by virological testing in a *laboratory*. This will enable the molecular, antigenic and other biological characteristics of the virus to be determined.

It is desirable that NDV isolates are sent promptly to an OIE Reference Laboratory for archiving and further characterization if required.

3. Virological surveillance

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

- a) monitor at risk populations;
- b) confirm suspect clinical cases;
- c) follow up positive serological results in unvaccinated populations or sentinel birds;
- d) test 'normal' daily mortalities (if warranted by an increased risk e.g. *infection* in the face of vaccination or in establishments epidemiologically linked to an *outbreak*).

4. Serological surveillance

Where vaccination is carried out, serological *surveillance* is of limited value. Serological *surveillance* cannot be used to discriminate between NDV and other APMV-1. Test procedures and interpretations of results are as described in the *Terrestrial Manual*. Positive NDV antibody test results can have five possible causes:

- a) natural *infection* with APMV-1;
- b) vaccination against ND;

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- c) exposure to vaccine virus;
- d) maternal antibodies derived from a vaccinated or infected parent *flock* are usually found in the yolk and can persist in progeny for up to 4 weeks;
- e) non-specific test reactions.

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

Discovery of seropositive, unvaccinated *flocks* **must should** be investigated further by conducting a thorough epidemiological investigation. Since seropositive results are not necessarily indicative of *infection*, virological methods should be used to confirm the presence of NDV in such populations. Until validated strategies and tools to differentiate vaccinated animals from those infected with field APMV-1 are available, serological tools should not be used to identify NDV *infection* in vaccinated populations.

5. Use of sentinel poultry

There are various applications of the use of sentinel *poultry* as a *surveillance* tool to detect virus circulation. They may be used to monitor vaccinated populations or species which are less susceptible to the development of clinical *disease* for the circulation of virus. Sentinel *poultry* should be immunologically naïve and may be used in vaccinated *flocks*. In case of the use of sentinel *poultry*, the structure and organisation of the *poultry* sector, the type of vaccine used and local epidemiological factors will determine the type of production systems where sentinels should be placed, the frequency of placement and monitoring of the sentinels.

Sentinel *poultry* **must should** be in close contact with, but should be identified to be clearly differentiated from, the target population. Sentinel *poultry* **must should** be observed regularly for evidence of clinical *disease* and any disease incidents investigated by prompt *laboratory* testing. The species to be used as sentinels should be proven to be highly susceptible to *infection* and ideally develop clear signs of clinical *disease*. Where the sentinel *poultry* do not necessarily develop overt clinical *disease* a programme of regular active testing by virological and serological tests should be used (the development of clinical *disease* may be dependent on the sentinel species used or use of live vaccine in the target population that may infect the sentinel *poultry*). The testing regime and the interpretation of the results will depend on the type of vaccine used in the target population. Sentinel birds should be used only if no appropriate *laboratory* procedures are available.

Article 10.13.25.

Documentation of ND free status: additional surveillance procedures

The requirements for a country, *zone* or *compartment* to declare freedom from ND are given in Article 10.13.3.

A Member declaring freedom of a country, *zone* or *compartment* (with or without vaccination) should report the results of a *surveillance* programme in which the ND susceptible *poultry* population undergoes regular *surveillance* planned and implemented according to the general conditions and methods described in these recommendations.

1. Members declaring freedom from ND for the country, zone or compartment

In addition to the general conditions described in the *Terrestrial Code*, a Member declaring freedom from ND for the entire country, or a *zone* or a *compartment* should provide evidence for the existence of an effective *surveillance* programme. The *surveillance* programme should be planned and implemented according to general conditions and methods described in this Chapter to demonstrate absence of NDV *infection* in *poultry* during the preceding 12 months.

2. Additional requirements for countries, zones or compartments that practice vaccination

Vaccination against ND may be used as a component of a disease prevention and control programme. The vaccine used ~~must~~ should comply with the provisions of the *Terrestrial Manual*.

In vaccinated populations there is a need to perform *surveillance* to ensure the absence of NDV circulation. The use of sentinel *poultry* may provide further confidence of the absence of virus circulation. The *surveillance* should be repeated at least every 6 months or at shorter intervals according to the risk in the country, *zone* or *compartment*, or evidence to show the effectiveness of the vaccination programme is regularly provided.

Article 10.13.26.

Countries, zones or compartments regaining freedom from ND following an outbreak: additional surveillance procedures

A Member regaining country, *zone* or *compartment* freedom from ND should show evidence of an active *surveillance* programme depending on the epidemiological circumstances of the *outbreak* to demonstrate the absence of the *infection*.

A Member declaring freedom of a country, *zone* or *compartment* after an *outbreak* of ND (with or without vaccination) should report the results of a *surveillance* programme in which the ND susceptible *poultry* population undergoes regular *surveillance* planned and implemented according to the general conditions and methods described in these recommendations.

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CHAPTER 11.6.

BOVINE SPONGIFORM ENCEPHALOPATHY

Article 11.6.1.

General provisions and safe commodities

The recommendations in this chapter are intended to manage the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agent in cattle (*Bos taurus* and *B. indicus*) only.

1. When authorising import or transit of the following *commodities* and any products made from these *commodities* and containing no other tissues from cattle, *Veterinary Authorities* should not require any BSE related conditions, regardless of the BSE risk status of the cattle population of the *exporting country, zone or compartment*:
 - a) *milk* and *milk products*;
 - b) semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;
 - c) hides and skins;
 - d) gelatine and collagen prepared exclusively from hides and skins;
 - e) tallow with maximum level of insoluble impurities of 0.15% in weight and derivatives made from this tallow;
 - f) dicalcium phosphate (with no trace of protein or fat);
 - g) deboned skeletal muscle meat (excluding mechanically separated meat) from cattle which were not subjected to a stunning process prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity or to a pithing process, and which passed ante-mortem and post-mortem inspections and which has been prepared in a manner to avoid contamination with tissues listed in Article 11.6.14.;
 - h) blood and blood by-products, from cattle which were not subjected to a stunning process, prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process.
2. When authorising import or transit of other *commodities* listed in this chapter, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the BSE risk status of the cattle population of the *exporting country, zone or compartment*.
3. When authorising import of *commodities* according to the conditions prescribed in this chapter, the risk status of an *importing country* is not affected by the BSE risk status of the *exporting country, zone or compartment*.

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

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Article 11.6.2.

The BSE risk status of the cattle population of a country, zone or compartment

The BSE risk status of the cattle population of a country, *zone* or *compartment* should be determined on the basis of the following criteria:

1. the outcome of a *risk assessment*, based on the provisions of the *Terrestrial Code*, identifying all potential factors for BSE occurrence and their historic perspective. Members should review the *risk assessment* annually to determine whether the situation has changed.

- a) Release assessment

Release assessment consists of assessing, through consideration of the following, the likelihood that the BSE agent has either been introduced into the country, *zone* or *compartment* via *commodities* potentially contaminated with it, or is already present in the country, *zone* or *compartment*:

- i) the presence or absence of the BSE agent in the indigenous ruminant population of the country, *zone* or *compartment* and, if present, evidence regarding its prevalence;
- ii) production of *meat-and-bone meal* or *greaves* from the indigenous ruminant population;
- iii) imported *meat-and-bone meal* or *greaves*;
- iv) imported cattle, sheep and goats;
- v) imported animal feed and feed ingredients;
- vi) imported products of ruminant origin for human consumption, which may have contained tissues listed in Article 11.6.14. and may have been fed to cattle;
- vii) imported products of ruminant origin intended for *in vivo* use in cattle.

The results of *surveillance* and other epidemiological investigations into the disposition of the *commodities* identified above should be taken into account in carrying out the assessment.

- b) Exposure assessment

If the release assessment identifies a *risk* factor, an exposure assessment should be conducted, consisting of assessing the likelihood of cattle being exposed to the BSE agent, through a consideration of the following:

- i) recycling and amplification of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;
- ii) the use of ruminant carcasses (including from fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;
- iii) the feeding or not of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants, including measures to prevent cross-contamination of animal feed;
- iv) the level of *surveillance* for BSE conducted on the cattle population up to that time and the results of that *surveillance*;

2. on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and *slaughter* of cattle to encourage reporting of all *cases* showing clinical signs consistent with BSE in target sub-populations as defined in Articles 11.6.20. to 11.6.22.;
3. the compulsory notification and investigation of all cattle showing clinical signs consistent with BSE;
4. the examination carried out in accordance with the *Terrestrial Manual* in a *laboratory* of brain or other tissues collected within the framework of the aforementioned *surveillance* and monitoring system.

When the *risk assessment* demonstrates negligible risk, the Member should conduct Type B *surveillance* in accordance with Articles 11.6.20. to 11.6.22.

When the *risk assessment* fails to demonstrate negligible risk, the Member should conduct Type A *surveillance* in accordance with Articles 11.6.20. to 11.6.22.

Article 11.6.3.

Negligible BSE risk

Commodities from the cattle population of a country, *zone* or *compartment* pose a negligible risk of transmitting the BSE agent if the following conditions are met:

1. a *risk assessment*, as described in point 1 of Article 11.6.2., has been conducted in order to identify the historical and existing risk factors, and the Member has demonstrated that appropriate specific measures have been taken for the relevant period of time defined below to manage each identified risk;
2. the Member has demonstrated that Type B *surveillance* in accordance with Articles 11.6.20. to 11.6.22. is in place and the relevant points target, in accordance with Table 1, has been met;
3. EITHER:
 - a) there has been no *case* of BSE or, if there has been a *case*, every *case* of BSE has been demonstrated to have been imported and has been completely destroyed, and
 - i) the criteria in points 2 to 4 of Article 11.6.2. have been complied with for at least 7 years; and
 - ii) it has been demonstrated through an appropriate level of control and audit, including that of cross contamination through feed of other mammalian origin, that for at least 8 years neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants;

OR

- b. if there has been an indigenous *case*, every indigenous *case* was born more than 11 years ago; and
 - i) the criteria in points 2 to 4 of Article 11.6.2. have been complied with for at least 7 years; and
 - ii) it has been demonstrated through an appropriate level of control and audit, including that of cross contamination through feed of other mammalian origin, that for at least 8 years neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants; and

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iii) all BSE *cases*, as well as:

- all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or
- if the results of the investigation are inconclusive, all cattle born in the same *herdas*, and within 12 months of the birth of, the BSE *cases*,

if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at *death*, are completely destroyed.

The Member or *zone* will be included in the list of negligible risk only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information for the previous 12 months on *surveillance* results and feed controls be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1. To maintain negligible risk status, all imports of cattle should comply with requirements in Articles 11.6.7., 11.6.8. or 11.6.9., as relevant.

Article 11.6.4.

Controlled BSE risk

Commodities from the cattle population of a country, *zone* or *compartment* pose a controlled risk of transmitting the BSE agent if the following conditions are met:

1. a *risk assessment*, as described in point 1 of Article 11.6.2., has been conducted in order to identify the historical and existing risk factors, and the Member has demonstrated that appropriate measures are being taken to manage all identified risks, but these measures have not been taken for the relevant period of time;
2. the Member has demonstrated that Type A *surveillance* in accordance with Articles 11.6.20. to 11.6.22. has been carried out and the relevant points target, in accordance with Table 1, has been met; Type B *surveillance* may replace Type A *surveillance* once the relevant points target is met;
3. EITHER:
 - a) there has been no *case* of BSE or, if there has been a *case*, every *case* of BSE has been demonstrated to have been imported and has been completely destroyed, the criteria in points 2 to 4 of Article 11.6.2. are complied with, and it can be demonstrated through an appropriate level of control and audit, including that of cross contamination through feed of other mammalian origin. that neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants, but at least one of the following two conditions applies:
 - i) the criteria in points 2 to 4 of Article 11.6.2. have not been complied with for 7 years;
 - ii) it cannot be demonstrated that controls over the feeding of *meat-and-bone meal* or *greaves* derived from ruminants to ruminants have been in place for 8 years;

OR

- b) there has been an indigenous *case* of BSE, the criteria in points 2 to 4 of Article 11.6.2. are complied with, and it can be demonstrated through an appropriate level of control and audit, including that of cross contamination through feed of other mammalian origin, that neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants;

and all BSE *cases*, as well as:

- all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or
- if the results of the investigation are inconclusive, all cattle born in the same *herd* as, and within 12 months of the birth of, the BSE *cases*,

if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at *death*, are completely destroyed.

The Member or *zone* will be included in the list of controlled risk only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information for the previous 12 months on *surveillance* results and feed controls be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1. To maintain controlled risk status, all imports of cattle should comply with requirements in Articles 11.6.7., 11.6.8. or 11.6.9., as relevant.

Article 11.6.5.

Undetermined BSE risk

The cattle population of a country, *zone* or *compartment* poses an undetermined BSE risk if it cannot be demonstrated that it meets the requirements of another category.

Article 11.6.6.

Recommendations for the importation of bovine commodities from a country, zone or compartment posing a negligible BSE risk

for all *commodities* from cattle not listed in point 1 of Article 11.6.1.

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the country, *zone* or *compartment* complies with the conditions in Article 11.6.3.

Article 11.6.7.

Recommendations for the importation of cattle from a country, zone or compartment posing a negligible BSE risk but where there has been an indigenous case

for cattle selected for export

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

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1. are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as described in point 3b)iii) of Article 11.6.3.;
2. were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants had been effectively enforced.

Article 11.6.8.

Recommendations for the importation of cattle from a country, zone or compartment posing a controlled BSE risk

for cattle

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

1. the country, *zone* or *compartment* complies with the conditions referred to in Article 11.6.4.;
2. cattle selected for export are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as described in point 3b) of Article 11.6.4.;
3. cattle selected for export were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants was effectively enforced.

Article 11.6.9.

Recommendations for the importation of cattle from a country, zone or compartment posing an undetermined BSE risk

for cattle

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

1. the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;
2. all BSE *cases*, as well as:
 - a) all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, or
 - b) if the results of the investigation are inconclusive, all cattle born in the same *herd* as, and within 12 months of the birth of, the BSE *cases*,
if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at *death*, are completely destroyed;
3. cattle selected for export:
 - a) are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as demonstrated in point 2 above;
 - b) were born at least 2 years after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants was effectively enforced.

Article 11.6.10.

Recommendations for the importation of meat and meat products from a country, zone or compartment posing a negligible BSE risk

for fresh meat and meat products from cattle (other than those listed in point 1 of Article 11.6.1.)

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

1. the country, zone or compartment complies with the conditions in Article 11.6.3.;
2. the cattle from which the *fresh meat* and *meat products* were derived, passed ante-mortem and post-mortem inspections;
3. in countries with negligible BSE risk where there have been indigenous cases, the cattle from which the *fresh meat* and *meat products* were derived were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants had been effectively enforced.

Article 11.6.11.

Recommendations for the importation of meat and meat products from a country, zone or compartment posing a controlled BSE risk

for fresh meat and meat products from cattle (other than those listed in point 1 of Article 11.6.1.)

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

1. the country, zone or compartment complies with the conditions referred to in Article 11.6.4.;
2. the cattle from which the *fresh meat* and *meat products* were derived passed ante-mortem and post-mortem inspections;
3. cattle from which the *fresh meat* and *meat products* destined for export were derived were not subjected to a stunning process, prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;
4. the *fresh meat* and *meat products* were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:
 - a) the tissues listed in points 1 and 2 of Article 11.6.14.,
 - b) mechanically separated meat from the skull and vertebral column from cattle over 30 months of age.

Article 11.6.12.

Recommendations for the importation of meat and meat products from a country, zone or compartment posing an undetermined BSE risk

for fresh meat and meat products from cattle (other than those listed in point 1 of Article 11.6.1.)

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

Annex XXVIII (contd)

1. the cattle from which the *fresh meat* and *meat products* originate:
 - a) have not been fed *meat-and-bone meal* or *greaves* derived from ruminants;
 - b) passed ante-mortem and post-mortem inspections;
 - c) were not subjected to a stunning process, prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;
2. the *fresh meat* and *meat products* were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:
 - a) the tissues listed in points 1 and 3 of Article 11.6.14.,
 - b) nervous and lymphatic tissues exposed during the deboning process,
 - c) mechanically separated meat from the skull and vertebral column from cattle over 12 months of age.

Article 11.6.13.

Recommendations on ruminant-derived meat-and-bone meal or greaves

1. Ruminant-derived *meat-and-bone meal* or *greaves*, or any commodities containing such products, which originate from a country, *zone* or *compartment* defined in Article 11.6.3., but where there has been an indigenous *case* of BSE, should not be traded if such products were derived from cattle born before the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants had been effectively enforced.
2. Ruminant-derived *meat-and-bone meal* or *greaves*, or any commodities containing such products, which originate from a country, *zone* or *compartment* defined in Articles 11.6.4. and 11.6.5. should not be traded between countries.

Article 11.6.14.

Recommendations on commodities that should not be traded

1. From cattle of any age originating from a country, *zone* or *compartment* defined in Articles 11.6.4. and 11.6.5., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: tonsils and distal ileum. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this chapter) should also not be traded.
2. From cattle that were at the time of *slaughter* over 30 12 months of age originating from a country, *zone* or *compartment* defined in Articles 11.6.4. and 11.6.5., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, and skull and vertebral column. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this chapter) should also not be traded.

3. From cattle that were at the time of *slaughter* over ~~12~~ 30 months of age originating from a country, *zone* or *compartment* defined in Articles 11.6.4. and 11.6.5., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: ~~brains, eyes, spinal cord, skull and~~ vertebral column. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this chapter) should also not be traded.

Article 11.6.15.

Recommendations for the importation of gelatine and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices

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

1. the *commodities* came from a country, *zone* or *compartment* posing a negligible BSE risk;

OR

2. they originate from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk and are derived from cattle which have passed ante-mortem and post-mortem inspections; and that

- a) vertebral columns from cattle over 30 months of age at the time of *slaughter* and skulls have been excluded;
- b) the bones have been subjected to a process which includes all of the following steps:
- i) degreasing,
 - ii) acid demineralisation,
 - iii) acid or alkaline treatment,
 - iv) filtration,
 - v) sterilisation at >138°C for a minimum of 4 seconds,
- or to an equivalent or better process in terms of infectivity reduction (such as high pressure heating).

Article 11.6.16.

Recommendations for the importation of tallow (other than as defined in Article 11.6.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

1. the tallow came from a country, *zone* or *compartment* posing a negligible BSE risk; or
2. it originates from a country, *zone* or *compartment* posing a controlled BSE risk, is derived from cattle which have passed ante-mortem and post-mortem inspections, and has not been prepared using the tissues listed in points 1 and 2 of Article 11.6.14.

Annex XXVIII (contd)

Article 11.6.17.

Recommendations for the importation of dicalcium phosphate (other than as defined in Article 11.6.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

1. the dicalcium phosphate came from a country, *zone* or *compartment* posing a negligible BSE risk; or
2. it originates from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk and is a by-product of bone gelatine produced according to Article 11.6.15.

Article 11.6.18.

Recommendations for the importation of tallow derivatives (other than those made from tallow as defined in Article 11.6.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

1. the tallow derivatives originate from a country, *zone* or *compartment* posing a negligible BSE risk; or
2. they are derived from tallow meeting the conditions referred to in Article 11.6.16.; or
3. they have been produced by hydrolysis, saponification or transesterification using high temperature and pressure.

Article 11.6.19.

Procedures for the reduction of BSE infectivity in meat-and-bone meal

The following procedure should be used to reduce the infectivity of any transmissible spongiform encephalopathy agents which may be present during the production of *meat-and-bone meal* containing ruminant proteins.

1. The raw material should be reduced to a maximum particle size of 50 mm before heating.
2. The raw material should be heated under saturated steam conditions to a temperature of not less than 133°C for a minimum of 20 minutes at an absolute pressure of 3 bar.

Article 11.6.20.

Surveillance: introduction

1. Depending on the risk category of a country, *zone* or *compartment* with regard to bovine spongiform encephalopathy (BSE), *surveillance* for BSE may have one or more goals:
 - a) detecting BSE, to a pre-determined design prevalence, in a country, *zone* or *compartment*;
 - b) monitoring the evolution of BSE in a country, *zone* or *compartment*;

- c) monitoring the effectiveness of a feed ban and/or other risk mitigation measures, in conjunction with auditing;
 - d) supporting a claimed BSE status;
 - e) gaining or regaining a higher BSE status.
2. When the BSE agent is present in a country or *zone*, the cattle population will comprise the following sectors, in order of decreasing size:
- a) cattle not exposed to the infective agent;
 - b) cattle exposed but not infected;
 - c) infected cattle, which may lie within one of three stages in the progress of BSE:
 - i) the majority will die or be killed before reaching a stage at which BSE is detectable by current methods;
 - ii) some will progress to a stage at which BSE is detectable by testing before clinical signs appear;
 - iii) the smallest number will show clinical signs.
3. The BSE status of a country, *zone* or *compartment* cannot be determined only on the basis of a *surveillance* programme but should be determined in accordance with all the factors listed in Article 11.6.2. The *surveillance* programme should take into account the diagnostic limitations associated with the above sectors and the relative distributions of infected cattle among them.
4. With respect to the distribution and expression of the BSE agent within the sectors described above, the following four subpopulations of cattle have been identified for *surveillance* purposes:
- a) cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects);
 - b) cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency *slaughter* or condemned at ante-mortem inspection (casualty or emergency *slaughter* or downer cattle);
 - c) cattle over 30 months of age which are found dead or killed, on farm, during transport or at an *abattoir* (fallen stock);
 - d) cattle over 36 months of age at routine *slaughter*.
5. A gradient is used to describe the relative value of *surveillance* applied to each subpopulation. *Surveillance* should focus on the first subpopulation, but investigation of other subpopulations will help to provide an accurate assessment of the BSE situation in the country, *zone* or *compartment*. This approach is consistent with Articles 11.6.20. to 11.6.22.
6. When establishing a *surveillance* strategy, authorities need to take into account the inherent difficulties of obtaining samples on farm, and overcome them. These difficulties include higher cost, the necessity to educate and motivate owners, and counteracting potentially negative socio-economic implications.

Surveillance: description of cattle subpopulations1. Cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects)

Cattle affected by illnesses that are refractory to treatment, and displaying progressive behavioural changes such as excitability, persistent kicking when milked, changes in *herd* hierarchical status, hesitation at doors, gates and barriers, as well as those displaying progressive neurological signs without signs of infectious illness are candidates for examination. These behavioural changes, being very subtle, are best identified by those who handle animals on a daily basis. Since BSE causes no pathognomonic clinical signs, all Members with cattle populations will observe individual animals displaying clinical signs consistent with BSE. It should be recognised that cases may display only some of these signs, which may also vary in severity, and such animals should still be investigated as potential BSE affected animals. The rate at which such suspicious cases are likely to occur will differ among epidemiological situations and cannot therefore be predicted reliably.

This subpopulation is the one exhibiting the highest prevalence. The accurate recognition, reporting and classification of such animals will depend on the ongoing owner/veterinarian awareness programme. This and the quality of the investigation and *laboratory* examination systems (Article 11.6.2.), implemented by the *Veterinary Services*, are essential for the credibility of the *surveillance* system.

2. Cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency slaughter or condemned at ante-mortem inspection (casualty or emergency slaughter, or downer cattle)

These cattle may have exhibited some of the clinical signs listed above which were not recognised as being consistent with BSE. Experience in Members where BSE has been identified indicates that this subpopulation is the one demonstrating the second highest prevalence. For that reason, it is the second most appropriate population to target in order to detect BSE.

3. Cattle over 30 months of age which are found dead or killed on farm, during transport or at an abattoir (fallen stock)

These cattle may have exhibited some of the clinical signs listed above prior to *death*, but were not recognised as being consistent with BSE. Experience in Members where BSE has been identified indicates that this subpopulation is the one demonstrating the third highest prevalence.

4. Cattle over 36 months of age at routine slaughter

Experience in Members where BSE has been identified indicates that this subpopulation is the one demonstrating the lowest prevalence. For that reason, it is the least appropriate population to target in order to detect BSE. However, sampling in this subpopulation may be an aide in monitoring the progress of the epizootic and the efficacy of control measures applied, because it offers continuous access to a cattle population of known class, age structure and geographical origin. Testing of routine slaughter cattle 36 months of age or less is of relatively very little value (Table 2).

Article 11.6.22.

Surveillance activities

In order to implement efficiently a *surveillance* strategy for BSE, a Member **must** should use documented records or reliable estimates of the age distribution of the adult cattle population and the number of cattle tested for BSE stratified by age and by subpopulation within the country, *zone* or *compartment*.

The approach assigns 'point values' to each sample, based on the subpopulation from which it was collected and the likelihood of detecting infected cattle in that subpopulation. The number of points a sample is assigned is determined by the subpopulation from which the sample is collected and the age of the animal sampled. The total points accumulation is then periodically compared to the target number of points for a country, *zone* or *compartment*.

A *surveillance* strategy should be designed to ensure that samples are representative of the *herd* of the country, *zone* or *compartment*, and include consideration of demographic factors such as production type and geographic location, and the potential influence of culturally unique husbandry practices. The approach used and the assumptions made should be fully documented, and the documentation retained for 7 years.

The points targets and *surveillance* point values in this chapter were obtained by applying the following factors to a statistical model:

- a) the design prevalence for Type A or Type B *surveillance*;
- b) a confidence level of 95%;
- c) the pathogenesis, and pathological and clinical expression of BSE:
 - i) sensitivity of diagnostic methods used;
 - ii) relative frequency of expression by age;
 - iii) relative frequency of expression within each subpopulation;
 - iv) interval between pathological change and clinical expression;
- d) demographics of the cattle population, including age distribution;
- e) influence of BSE on culling or attrition of animals from the cattle population via the four subpopulations;
- f) percentage of infected animals in the cattle population which are not detected.

Although the procedure accepts very basic information about a cattle population, and can be used with estimates and less precise data, careful collection and documentation of the data significantly enhance their value. Since samples from clinical suspect animals provide many times more information than samples from healthy or dead-of-unknown-cause animals, careful attention to the input data can substantially decrease the procedure's cost and the number of samples needed. The essential input data are:

- g) cattle population numbers stratified by age;
- h) the number of cattle tested for BSE stratified by age and by subpopulation.

Annex XXVIII (contd)

This chapter utilises Tables 1 and 2 to determine a desired *surveillance* points target and the point values of *surveillance* samples collected.

Within each of the subpopulations above in a country, *zone* or *compartment*, a Member may wish to target cattle identifiable as imported from countries or *zones* not free from BSE and cattle which have consumed potentially contaminated feedstuffs from countries or *zones* not free from BSE.

All clinical suspects should be investigated, regardless of the number of points accumulated. In addition, animals from the other subpopulations should be tested.

1. Type A surveillance

The application of Type A *surveillance* will allow the detection of BSE around a design prevalence of at least one case per 100,000 in the adult cattle population in the country, *zone* or *compartment* of concern, at a confidence level of 95%.

2. Type B surveillance

The application of Type B *surveillance* will allow the detection of BSE around a design prevalence of at least one case per 50,000 in the adult cattle population in the country, *zone* or *compartment* of concern, at a confidence level of 95%.

Type B *surveillance* may be carried out by countries, *zones* or *compartments* of negligible BSE risk status (Article 11.6.3.) to confirm the conclusions of the *risk assessment*, for example by demonstrating the effectiveness of the measures mitigating any risk factors identified, through *surveillance* targeted to maximise the likelihood of identifying failures of such measures.

Type B *surveillance* may also be carried out by countries, *zones* or *compartments* of controlled BSE risk status (Article 11.6.4.), following the achievement of the relevant points target using Type A *surveillance*, to maintain confidence in the knowledge gained through Type A *surveillance*.

3. Selecting the points target

The *surveillance* points target should be selected from Table 1, which shows target points for adult cattle populations of different sizes. The size of the adult cattle population of a country, *zone* or *compartment* may be estimated or may be set at one million because, for statistical reasons, one million is the point beyond which sample size does not further increase with population size.

4. Determining the point values of samples collected

Table 2 can be used to determine the point values of the *surveillance* samples collected. The approach assigns point values to each sample according to the likelihood of detecting *infection* based on the subpopulation from which the sample was collected and the age of the animal sampled. This approach takes into account the general principles of *surveillance* described in Chapter 1.4. and the epidemiology of BSE.

Because precise aging of the animals that are sampled may not be possible, Table 2 combines point values into five age categories. The point estimates for each category were determined as an average for the age range comprising the group. The age groups were selected on their relative likelihoods of expressing BSE according to scientific knowledge of the incubation of the *disease* and the world BSE experience. Samples may be collected from any combination of subpopulations and ages but should reflect the demographics of the cattle *herd* of the country, *zone* or *compartment*. In addition, Members should sample at least three of the four subpopulations.

Table 1. **Points targets for different adult cattle population sizes in a country, zone or compartment**

Points targets for country, zone or compartment		
Adult cattle population size (24 months and older)	Type A surveillance	Type B surveillance
>1,000,000	300,000	150,000
800,000-1,000,000	240,000	120,000
600,000-800,000	180,000	90,000
400,000-600,000	120,000	60,000
200,000-400,000	60,000	30,000
100,000-200,000	30,000	15,000
50,000-100,000	15,000	7,500
25,000 -50,000	7,500	3,750

If a country, *zone* or *compartment* determines, based on the demographics and epidemiological characteristics of its cattle population, that precise classification of the subpopulations 'casualty or emergency slaughter, or downer cattle' and 'fallen stock' is not possible, these subpopulations may be combined. In such a case, the *surveillance* point values accorded to the combined subpopulation would be that of 'fallen stock'.

The total points for samples collected may be accumulated over a period of a maximum of 7 consecutive years to achieve the target number of points determined in Table 1.

Surveillance points remain valid for 7 years (the 95th percentile of the incubation period).

Table 2. **Surveillance point values for samples collected from animals in the given subpopulation and age category**

Surveillance subpopulation			
Routine slaughter ¹	Fallen stock ²	Casualty slaughter ³	Clinical suspect ⁴
Age=1 year and <2years			
0.01	0.2	0.4	N/A
Age =2 years and <4 years (young adult)			
0.1	0.2	0.4	260
Age =4 years and <7 years (middle adult)			
0.2	0.9	1.6.	750
Age =7 years and <9 years (older adult)			
0.1	0.4	0.7	220
Age =9 years (aged)			
0.0	0.1	0.2	45

Annex XXVIII (contd)

Article 11.6.23.

BSE risk assessment: introduction

The first step in determining the BSE risk status of the cattle population of a country or *zone* is to conduct a *risk assessment* (reviewed annually), based on Section 2 of this *Terrestrial Code*, identifying all potential factors for BSE occurrence and their historic perspective.

1. Release assessment

Release assessment consists of assessing the likelihood that a BSE agent has been introduced via the importation of the following *commodities* potentially contaminated with a BSE agent:

- a) *meat-and-bone meal* or *greaves*;
- b) live animals;
- c) animal feed and feed ingredients;
- d) products of animal origin for human consumption.

2. Exposure assessment

Exposure assessment consists of assessing the likelihood of exposure of the BSE agent to cattle, through a consideration of the following:

- a) epidemiological situation concerning BSE agents in the country or *zone*;
- b) recycling and amplification of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;
- c) the origin and use of ruminant carcasses (including fallen stock), by-products and *slaughterhouse* waste, the parameters of the rendering processes and the methods of animal feed manufacture;
- d) implementation and enforcement of feed bans, including measures to prevent cross-contamination of animal feed; the status of the birth cohort of a case should be determined when investigating the implementation of feed bans thorough epidemiological investigations of any indigenous case born after the date of the implementation of feed bans should be conducted.

The following recommendations are intended to assist *Veterinary Services* in conducting such a *risk assessment*. They provide guidance on the issues that need to be addressed when conducting a country-based assessment of BSE risk. They apply equally to self-assessment in preparation of dossiers for categorisation of countries. The recommendations are supported by greater detail in the questionnaire used for the submission of data for country assessment.

Article 11.6.24.

The potential for the release of the BSE agent through the importation of meat-and-bone meal or greaves

This point is irrelevant if the exposure assessment outlined below in Article 11.6.27. indicates that *meat-and-bone meal* or *greaves* has not been fed, either deliberately or accidentally, in the past 8 years. Nevertheless, documentation should be provided on the control systems (including relevant legislation) in place to ensure that *meat-and-bone meal* or *greaves* has not been fed to ruminants.

Assumption: That *meat-and-bone meal* or *greaves* of ruminant origin plays the only significant role in BSE transmission.

Question to be answered: Has *meat-and-bone meal*, *greaves*, or feedstuffs containing either been imported within the past 8 years? If so, where from and in what quantities?

Rationale: Knowledge of the origin of *meat-and-bone meal*, *greaves* or feedstuffs containing either *meat-and-bone meal* or *greaves*, is necessary to assess the risk of release of BSE agent. *Meat-and-bone meal* and *greaves* originating in countries of high BSE risk pose a higher release risk than that from low risk countries. *Meat-and-bone meal* and *greaves* originating in countries of unknown BSE risk pose an unknown release risk.

Evidence required:

- Documentation to support claims that *meat-and-bone meal*, *greaves* or feedstuffs containing either *meat-and-bone meal* or *greaves* have not been imported, OR
- Where *meat-and-bone meal*, *greaves* or feedstuffs containing them have been imported, documentation of country of origin and, if different, the country of export.
- Documentation on annual volume, by country of origin, of *meat*, *greaves* or feedstuffs containing them imported during the past 8 years.
- Documentation describing the composition (on a species and class of stock basis) of the imported *meat-and-bone meal*, *greaves* or feedstuffs containing them.
- Documentation, from the country of production, supporting why the rendering processes used to produce *meat-and-bone meal*, *greaves* or feedstuffs containing them would have inactivated, or significantly reduced the titre of BSE agent, should it be present.
- Documentation describing the fate of imported *meat-and-bone meal* and *greaves*.

Article 11.6.25.

The potential for the release of the BSE agent through the importation of live animals potentially infected with BSE

Assumptions:

- Countries which have imported ruminants from countries infected with BSEs are more likely to experience BSE.
- Cattle pose the only known risk although other species are under study.
- Animals imported for breeding may pose a greater risk than animals imported for *slaughter* because of the hypothetical risk of maternal transmission and because they are kept to a greater age than animals imported for *slaughter*.
- Risk is influenced by the date at which imports occurred, relative to the BSE status of the country of origin.
- Risk is proportional to volume of imports (Article 2.1.3.).

Annex XXVIII (contd)

Question to be answered: Have live animals been imported within the past 7 years?

Rationale: The release risks are dependent on:

- country of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical *disease*, or following active *surveillance*, or assessment of geographical BSE risk;
- feeding and management of the animals in the country of origin;
- use to which the *commodity* has been put as apart from representing risk of developing clinical *disease*, the *slaughter*, rendering and recycling in *meat-and-bone meal* of imported animals represents a potential route of exposure of indigenous livestock even if *meat-and-bone meal* and *greaves*, or feedstuffs containing them, have not been imported;
- species;
- dairy versus meat breeds, where there are differences in exposure in the country of origin because feeding practices result in greater exposure of one category;
- age at *slaughter*.

Evidence required:

- Documentation on the country of origin of imports. This should identify the country of breeding of animals, the length of time they lived in that country and of any other country in which they have resided during their lifetime.
- Documentation describing origins, species and volume of imports.
- Documentation describing the fate of imported animals, including their age at *slaughter*.
- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Article 11.6.26.

The potential for the release of the BSE agent through the importation of products of animal origin potentially infected with BSE

Assumptions:

- Semen, embryos, hides and skins or milk are not considered to play a role in the transmission of BSE.
- Countries which have imported products of animal origin from countries with BSEs are more likely to experience BSE.
- Risk is influenced by the date at which imports occurred, relative to the BSE status of the country of origin.
- Risk is proportional to volume of imports (Article 2.1.3.).

Question to be answered: What products of animal origin have been imported within the past 7 years?

Rationale: The release risks are dependent on:

- the species of origin of the animal products and whether these products contain tissues known to contain BSE infectivity (Article 11.6.14.);
- country of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical *disease*, or following active *surveillance*, or assessment of geographical BSE risk;
- feeding and management of the animals in the country of origin;
- use to which the *commodity* has been put as apart from representing risk of developing clinical *disease*, the *slaughter*, rendering and recycling in *meat-and-bone meal* of imported animals represents a potential route of exposure of indigenous livestock even if *meat-and-bone meal* and *greaves*, or feedstuffs containing them, have not been imported;
- species;
- dairy versus meat breeds, where there are differences in exposure in the country of origin because feeding practices result in greater exposure of one category;
- age at *slaughter*.

Evidence required:

- Documentation on the country of origin of imports. This should identify the country of breeding of animals, the length of time they lived in that country and of any other country in which they have resided during their lifetime.
- Documentation describing origins, species and volume of imports.
- Documentation describing the end use of imported animal products, and the disposal of waste.
- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Article 11.6.27.

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

Assumptions:

- That the consumption by bovines of *meat-and-bone meal* or *greaves* of ruminant origin plays the only significant role in BSE transmission.
- That commercially-available products of animal origin used in animal feeds may contain *meat-and-bone meal* or *greaves* of ruminant origin.
- Milk and blood are not considered to play a role in the transmission of BSE.

Annex XXVIII (contd)

Question to be answered: Has *meat-and-bone meal* or *greaves* of ruminant origin been fed to cattle within the past 8 years (see Articles 11.6.3. and 11.6.4.)?

Rationale: If cattle have not been fed products of animal origin (other than milk or blood) potentially containing *meat-and-bone meal* or *greaves* of ruminant origin within the past 8 years, *meat-and-bone meal* and *greaves* can be dismissed as a risk.

Article 11.6.28.

The origin of animal waste, the parameters of the rendering processes and the methods of animal feed production

Assumptions:

- BSE has a long *incubation period* and insidious onset of signs, so cases may escape detection.
- Pre-clinical BSE infectivity cannot reliably be detected by any method and may enter rendering, in particular if specified risk materials are not removed.
- Tissues most likely to contain high titres of BSE infectivity (brain, spinal cord, eyes) may not be harvested for human consumption and may be rendered.
- BSE may manifest in sudden *death*, chronic disease, or recumbency, and may be presented as fallen stock or materials condemned as unfit for human consumption.
- BSE agent survival in rendering is affected by the method of processing. Adequate rendering processes are described in Article 11.6.19.
- BSE agent is present at much higher titres in central nervous system and reticulo-endothelial tissues (so-called 'Specified Risk Materials', or SRM).

Question to be answered: How has animal waste been processed over the past 8 years?

Rationale: If potentially infected animals or contaminated materials are rendered, there is a risk that the resulting *meat-and-bone meal* could retain BSE infectivity.

Where *meat-and-bone meal* is utilized in the production of any animal feeds, the risk of cross-contamination exists.

Evidence required:

- Documentation describing the collection and disposal of fallen stock and materials condemned as unfit for human consumption.
- Documentation describing the definition and disposal of specified risk material, if any.
- Documentation describing the rendering process and parameters used to produce *meat-and-bone meal* and *greaves*.
- Documentation describing methods of animal feed production, including details of ingredients used, the extent of use of *meat-and-bone meal* in any livestock feed, and measures that prevent cross-contamination of cattle feed with ingredients used in monogastric feed.
- Documentation describing monitoring and enforcement of the above.

Article 11.6.29.

Conclusions of the risk assessment

The overall risk of BSE in the cattle population of a country or *zone* is proportional to the level of known or potential exposure to BSE infectivity and the potential for recycling and amplification of the infectivity through livestock feeding practices. For the *risk assessment* to conclude that the cattle population of a country or *zone* is free from BSE risk, it ~~must~~ should have demonstrated that appropriate measures have been taken to manage any risks identified.

¹ See point 4) of Article 11.6.21.

² See point 3) of Article 11.6.21.

³ See point 2) of Article 11.6.21.

⁴ See point 1) of Article 11.6.21.

— text deleted

CHAPTER 11.7.

BOVINE TUBERCULOSIS

Article 11.7.1.

General provisions

The recommendations in this chapter are intended to manage the human and animal health risks associated with *Mycobacterium bovis* (*M. bovis*) infection in domestic (permanently captive and owned free-range) bovines including cattle (*Bos taurus*, *B. indicus* and *B. grunniens*), water buffaloes (*Bubalus bubalis*) and wood bison⁵ (*Bison bison* and *B. bonasus*).

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

Article 11.7.2.

Country or zone free from bovine tuberculosis

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

1. *M. bovis* infection in domestic (permanently captive and owned free-range) bovines including cattle, water buffalo and wood bison is a *notifiable disease* in the country;
2. an on-going awareness programme should be in place to encourage reporting of all cases suggestive of bovine tuberculosis;
3. regular and periodic testing of all cattle, water buffalo and wood bison *herds* demonstrated that *M. bovis* infection was not present in at least 99.8% of the *herds* and 99.9% of the cattle, water buffalo and wood bison in the country or *zone* for 3 consecutive years;
4. a *surveillance* programme should be in place to detect bovine tuberculosis in the country or *zone* through ante-mortem and post-mortem inspection as described in Chapter 6.2.;
5. if the *surveillance* programme described in points 3 and 4 above ~~has not detected infection with demonstrated that~~ *M. bovis* infection was not present in at least 99.8% of the *herds* and 99.9% of the cattle, water buffalo and wood bison in the country or *zone* for 5 consecutive years, *surveillance* may be maintained through ante-mortem and post-mortem inspection as described in Chapter 6.2.;
6. cattle, water buffalo and wood bison introduced into a country or *zone* free from bovine tuberculosis should be accompanied by a certificate from an *Official Veterinarian* attesting that they come from a country, *zone*, *compartment* or *herd* free from bovine tuberculosis or comply with the relevant provisions in Article 11.7.5. or in Article 11.7.6.

Article 11.7.3.

Compartment free from bovine tuberculosis

To qualify as a *compartment* free from bovine tuberculosis, all cattle, water buffalo or wood bison in a *compartment* should be certified by the *Veterinary Authority* as satisfying the following requirements:

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1. the cattle, water buffalo and wood bison:
 - a) showed no sign of bovine tuberculosis or lesions at ante-mortem or post-mortem inspection for at least 3 consecutive years;
 - b) were over 6 weeks of age at the time of the first test and have shown a negative result to at least two tuberculin tests or gamma interferon tests carried out at an interval of a minimum of 6 months, the first test being performed at least 6 months following the *slaughter* of the last affected animal;
 - c) met one of the following conditions:
 - i) showed a negative result to a biannual twice yearly tuberculin test or gamma interferon test to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is more than 1% of all *herds* in the country or *zone* during the last 2 years; or
 - ii) showed a negative result to an annual tuberculin test or gamma interferon test to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is more than 0.2% but not more than 1% of all *herds* in the country or *zone* during the last 2 years; or
 - iii) showed a negative result to a tuberculin test or gamma interferon test every 3 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.2% of all *herds* in the country or *zone* during the last 4 years; or
 - iv) showed a negative result to a tuberculin test or gamma interferon test every 4 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.1% of all *herds* in the country or *zone* during the last 6 years;
2. cattle, water buffalo and wood bison introduced into the *compartment* come from a *herd* free from bovine tuberculosis. This condition may be waived for animals which have been isolated for at least 90 days and which, prior to entry into the *compartment*, were subjected to at least two tuberculin tests or gamma interferon tests carried out at a 6-month interval with negative results with the second tuberculin test or gamma interferon test performed during the 30 days prior to entry into the *compartment*;
3. cattle, water buffalo and wood bison in a *compartment* free from bovine tuberculosis are protected from contact with wildlife reservoirs of bovine tuberculosis and are managed under a common biosecurity plan protecting them from contamination with *M. bovis*, and the *compartment* has been approved by the *Veterinary Authority* in accordance with Chapters 4.3. and 4.4.

Article 11.7.4.

Herd free from bovine tuberculosis

To qualify as free from bovine tuberculosis, a *herd* of cattle, water buffalo, or wood bison should satisfy the following requirements:

1. the *herd* is in a country, *zone* or *compartment* free from bovine tuberculosis and is certified free by the *Veterinary Authority*; or
2. cattle, water buffalo and wood bison in the *herd*
 - a) showed no signs of bovine tuberculosis or lesions at ante-mortem or post-mortem inspection for at least 3 consecutive one years;
 - b) were over 6 weeks of age at the time of the first test and have shown a negative result to at least two tuberculin tests or gamma interferon tests carried out at an interval of a minimum interval of 6 months; in case of regaining of free status after an outbreak, the first test being should be performed at least 6 months following the *slaughter* of the last affected animal;
 - c) to maintain the free status, met one of the following conditions:
 - i) showed a negative result to an annual tuberculin test or gamma interferon test to ensure the continuing absence of bovine tuberculosis; or
 - ii) showed a negative result to a tuberculin test or gamma interferon test every 2 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 1% of all *herds* in the country or *zone* during the last 2 years; or
 - iii) showed a negative result to a tuberculin test or gamma interferon test every 3 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.2% of all *herds* in the country or *zone* during the last 4 years; or
 - iv) showed a negative result to a tuberculin test or gamma interferon test every 4 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.1% of all *herds* in the country or *zone* during the last 6 years;
3. cattle, water buffalo and wood bison introduced into the *herd* come from a *herd* free from bovine tuberculosis. This condition may be waived for animals which have been isolated for at least 90 days and which, prior to entry into the *herd*, were subjected to at least two tuberculin tests or gamma interferon tests carried out at a 6-month interval with negative results with the second tuberculin test or gamma interferon test performed during the 30 days prior to entry into the herd.

Article 11.7.5.

Recommendations for the importation of cattle, water buffalo and wood bison for breeding or rearing

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

1. showed no signs of bovine tuberculosis on the day of shipment;
2. originate from a *herd* free from bovine tuberculosis that is in a country, *zone* or *compartment* free from bovine tuberculosis; or

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3. were subjected to the tuberculin test or gamma interferon test for bovine tuberculosis with negative results during the 30 days prior to shipment and come from a *herd* free from bovine tuberculosis; or
4. have been isolated for at least 90 days prior to entry into the *herd*, including protection from contact with wildlife reservoirs of bovine tuberculosis and were subjected to at least two tuberculin tests or gamma interferon tests carried out at a six-month interval with negative results with the second tuberculin test or gamma interferon test performed during the 30 days prior to entry into the *herd*.

Article 11.7.6.

Recommendations for the importation of cattle, water buffalo and wood bison for slaughter

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

1. showed no signs of bovine tuberculosis on the day of shipment;
2. originated from a *herd* free from bovine tuberculosis or were subjected to a tuberculin test or gamma interferon test for bovine tuberculosis with negative results during the 30 days prior to shipment;
3. were not being eliminated as part of an eradication programme against bovine tuberculosis.

Article 11.7.7.

Recommendations for the importation of semen of cattle, water buffalo and wood bison

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

1. the donor animals showed no signs of bovine tuberculosis on the day of collection of the semen and either:
 - a) were kept in an *artificial insemination centre* free from bovine tuberculosis in a country, *zone* or *compartment* free from bovine tuberculosis and which only accepts animals from free *herds* in a free country, *zone* or *compartment*; or
 - b) showed negative results to tuberculin tests or gamma interferon tests carried out annually and were kept in a *herd* free from bovine tuberculosis;
2. the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5. and Chapter 4.6.

Article 11.7.8.

Recommendations for the importation of embryos/ova of cattle, water buffalo and wood bison

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

1. the donor females and all other susceptible animals in the *herd* of origin showed no signs of bovine tuberculosis during the 24 hours prior to embryo collection; and either

- a) originated from a *herd* free from bovine tuberculosis in a country, *zone* or *compartment* free from bovine tuberculosis; or
 - b) were kept in a *herd* free from bovine tuberculosis, and were subjected to a tuberculin test or gamma interferon test for bovine tuberculosis with negative results during an isolation period of 30 days in the *establishment* of origin prior to collection;
2. the embryos/ova were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 11.7.9.

Recommendations for the importation of fresh meat and meat products of cattle, water buffalo, and wood bison

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* comes from animals which have been subjected to ante-mortem and post-mortem inspections as described in Chapter 6.2.

Article 11.7.10.

Recommendations for the importation of milk and milk products of cattle, water buffalo and wood bison

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

1. has been derived from animals in a *herd* free from bovine tuberculosis; or
2. was subjected to pasteurization; or
3. was subjected to a combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.

— text deleted

CHAPTER 11.8.

BOVINE TUBERCULOSIS OF FARMED CERVIDAE

Article 11.8.1.

General provisions

The recommendations in this chapter are intended to manage the human and animal health risks associated with *Mycobacterium bovis* (*M. bovis*) infection in domestic (permanently captive and owned free-range) farmed cervidae (red deer, wapiti, sika, sambar, rusa, fallow deer, white-tailed, black-tailed and mule deer [*Cervus elephas*, *C. canadensis*, *C. nippon*, *C. unicolor unicolor*, *C. timorensis*, *Dama dama dama*, *Odocoileus virginianus borealis*, *Odocoileus hemionus columbianus* and *Odocoileus hemionus hemionus*]). The chapter does not address the management of tuberculosis in wild cervid populations.

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

Article 11.8.2.

Country or zone free from bovine tuberculosis of farmed cervidae

To qualify as free from bovine tuberculosis of farmed cervidae, a country or zone should satisfy the following requirements:

1. *M. bovis* infection in domestic bovines and in farmed cervidae as specified in Article 11.8.1. is a *notifiable disease* in the country;
2. an on-going awareness programme should be in place to encourage reporting of all *cases* suggestive of tuberculosis;
3. regular and periodic testing of all *herds* of farmed cervidae has demonstrated that *M. bovis* infection was not present in at least 99.8% of the *herds* and 99.9% of the farmed cervidae in the country or zone for 3 consecutive years;
4. a *surveillance* programme should be in place to detect bovine tuberculosis in the country or zone through ante-mortem and post-mortem inspection as described in Chapter 6.2.;
5. if the *surveillance* programme described in points 3 and 4 above ~~has not detected infection with demonstrated that~~ *M. bovis* infection was not present in at least 99.8% of the herds and 99.9% of the farmed cervidae in the country or zone for 5 consecutive years, *surveillance* may be maintained through ante-mortem and post-mortem inspection as described in Chapter 6.2.;
6. farmed cervidae introduced into a country or zone free from bovine tuberculosis should be accompanied by a certificate from an *Official Veterinarian* attesting that they come from a country, zone, compartment or herd free from bovine tuberculosis or comply with the relevant provisions in Article 11.8.5. or in Article 11.8.6.

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Article 11.8.3.

Compartment free from bovine tuberculosis of farmed cervidae

To qualify as a *compartment* free from bovine tuberculosis of farmed cervidae, the *Veterinary Authority* should be able to certify that the following requirements are satisfied:

1. all farmed cervidae:
 - a) showed no sign of bovine tuberculosis or lesions at ante-mortem or post-mortem inspection for at least 3 consecutive years;
 - b) were over 6 weeks of age at the time of the first test and have shown a negative result to at least two tuberculin tests carried out at an interval of a minimum of 6 months, the first test being performed at least 6 months following the *slaughter* of the last affected animal;
 - c) met one of the following conditions:
 - i) showed a negative result to a **biannual twice yearly** tuberculin test to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is more than 1% of all *herds* in the country or *zone* during the last 2 years; or
 - ii) showed a negative result to an annual tuberculin test to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is more than 0.2% but not more than 1% of all *herds* in the country or *zone* during the last 2 years; or
 - iii) showed a negative result to a tuberculin test every 3 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.2% of all *herds* in the country or *zone* during the last 4 years; or
 - iv) showed a negative result to a tuberculin test every 4 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.1% of all *herds* in the country or *zone* during the last 6 years;
2. farmed cervidae introduced into the *compartment* come from a *herd* free from bovine tuberculosis. This condition may be waived for animals which have been isolated for at least 90 days and which, prior to entry into the *compartment*, were subjected to at least two tuberculin tests carried out at a 6-month interval with negative results with the second tuberculin test performed during the 30 days prior to entry into the *compartment*;
3. farmed cervidae in a *compartment* free from bovine tuberculosis are protected from contact with wildlife reservoirs of bovine tuberculosis and are managed under a common biosecurity plan protecting them from contamination with *M. bovis*, and the *compartment* has been approved by the *Veterinary Authority* in accordance with Chapters 4.3. and 4.4.

Article 11.8.4.

Herd free from bovine tuberculosis

To qualify as free from bovine tuberculosis, a *herd* of farmed cervidae should satisfy the following requirements:

1. the *herd* is in a country, a *zone* or a *compartment* free from bovine tuberculosis and is certified free by the *Veterinary Authority*, or
2. farmed cervidae in the *herd*
 - a) showed no sign of bovine tuberculosis or lesions at ante-mortem or post-mortem inspection for at least 3 consecutive years;
 - b) were over 6 weeks of age at the time of the first test and have shown a negative result to at least two tuberculin tests carried out at ~~an interval of~~ a minimum interval of 6 months; in case of regaining of free status after an outbreak, the first test being should be performed at least 6 months following the *slaughter* of the last affected animal;
 - c) to maintain the free status, met one of the following conditions:
 - i) showed a negative result to an annual tuberculin test to ensure the continuing absence of bovine tuberculosis; or
 - ii) showed a negative result to a tuberculin test every 2 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 1% of all *herds* in the country or *zone* during the last 2 years; or
 - iii) showed a negative result to a tuberculin test every 3 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.2% of all *herds* in the country or *zone* during the last 4 years; or
 - iv) showed a negative result to a tuberculin test every 4 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.1% of all *herds* in the country or *zone* during the last 6 years;
3. farmed cervidae introduced into the *herd* come from a *herd* free from bovine tuberculosis. This condition may be waived for animals which have been isolated for at least 90 days and which, prior to entry into the *herd*, were subjected to at least two tuberculin tests carried out at a 6-month interval with negative results with the second tuberculin test performed during the 30 days prior to entry into the herd.

Article 11.8.5.

Recommendations for the importation of farmed cervidae for breeding or rearing

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

1. showed no signs of bovine tuberculosis on the day of shipment;
2. originate from a *herd* free from bovine tuberculosis of farmed cervidae that is in a country, *zone* or *compartment* free from bovine tuberculosis of farmed cervidae; or
3. were subjected to the tuberculin test for bovine tuberculosis with negative results during the 30 days prior to shipment and come from a *herd* free from bovine tuberculosis of farmed cervidae; or
4. have been isolated for at least 90 days prior to entry into the *herd*, including protection from contact with wildlife reservoirs of bovine tuberculosis and were subjected to at least two tuberculin tests carried out at a six-month interval with negative results with ~~the~~ the second tuberculin test performed during the 30 days prior to entry into the *herd*.

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Article 11.8.6.

Recommendations for the importation of farmed cervidae for slaughter

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

1. showed no signs of bovine tuberculosis on the day of shipment;
2. originated from a *herd* free from bovine tuberculosis of farmed cervidae or were subjected to a tuberculin test for bovine tuberculosis with negative results during the 30 days prior to shipment;
3. were not being eliminated as part of an eradication programme against bovine tuberculosis.

Article 11.8.7.

Recommendations for the importation of semen of farmed cervidae

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

1. the donor animals showed no signs of bovine tuberculosis on the day of collection of the semen; and either:
 - a) were kept in a *herd* free from bovine tuberculosis in any species, in a country, *zone* or *compartment* free from bovine tuberculosis of farmed cervidae, and which only accepts animals from free *herds* in a free country, *zone* or *compartment*; or
 - b) showed negative results to tuberculin tests carried out annually and were kept in a *herd* free from bovine tuberculosis;
2. the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5. and Chapter 4.6.

Article 11.8.8.

Recommendations for the importation of embryos/ova of farmed cervidae

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

1. the donor females and all other susceptible animals in the *herd* of origin showed no signs of bovine tuberculosis during the 24 hours prior to embryo collection; and either
 - a) originated from a *herd* free from bovine tuberculosis of farmed cervidae in a country, *zone* or *compartment* free from bovine tuberculosis; or
 - b) were kept in a *herd* free from bovine tuberculosis of farmed cervidae and were subjected to a tuberculin test for bovine tuberculosis with negative results during an isolation period of 30 days in the *establishment* of origin prior to collection;
2. the embryos/ova were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 11.8.9.

Recommendations for the importation of fresh meat and meat products of farmed cervidae

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* comes from animals which have been subjected to ante-mortem and post-mortem inspections as described in Chapter 6.2.

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CHAPTER 11.9.

CONTAGIOUS BOVINE PLEUROPNEUMONIA

Article 11.9.1.

General provisions

For the purposes of the *Terrestrial Code*, the *incubation period* for contagious bovine pleuropneumonia (CBPP) shall be 6 months.

For the purpose of this chapter, a *case* of CBPP means an animal infected with *Mycoplasma mycoides* subsp. *mycoides* SC (*MmmSC*), and freedom from CBPP means freedom from *Mmm* SC infection.

For the purpose of this chapter, susceptible animals include **domestic** cattle (*Bos indicus* and *B. taurus*) and water buffalo (*Bubalus bubalis*).

For the purposes of *international trade*, this chapter deals not only with the occurrence of clinical signs caused by *MmmSC*, but also with the presence of infection with *MmmSC* in the absence of clinical signs.

The following defines the occurrence of *MmmSC* infection:

1. *MmmSC* has been isolated and identified as such from an animal, embryos, oocytes or semen; or
2. antibodies to *MmmSC* antigens which are not the consequence of vaccination, or *MmmSC* DNA, have been identified in one or more animals showing pathological lesions consistent with infection with *MmmSC* with or without clinical signs, and epidemiological links to a confirmed *outbreak* of CBPP in susceptible animals.

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

When authorising import or transit of other *commodities* listed in this chapter, **with the exception of those listed in Article 11.9.2.** *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the CBPP status of the domestic cattle and water buffalo population of the *exporting country, zone or compartment*.

Article 11.9.2.

Trade in Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any CBPP related conditions, regardless of the CBPP status of the domestic cattle and water buffalo population of the *exporting country, zone or compartment*:

1. *milk* and *milk products*;
2. *hides* and *skins*;
3. *meat* and *meat products* (excluding *lung*).

~~When authorising import or transit of other *commodities* listed in this chapter, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the CBPP status of the domestic cattle and water buffalo population of the *exporting country, zone or compartment*.~~

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Article 11.9.3.

CBPP free country, zone or compartment

To qualify for inclusion in the existing list of CBPP free countries, a Member should:

1. have a record of regular and prompt animal disease reporting;
2. send a declaration to the OIE stating that:
 - a) there has been no *outbreak* of CBPP during the past 24 months;
 - b) no evidence of CBPP infection has been found during the past 24 months;
 - c) no vaccination against CBPP has been carried out during the past 24 months,

and supply documented evidence that *surveillance* for CBPP in accordance with this chapter is in operation and that regulatory measures for the prevention and control of CBPP have been implemented;

3. not have imported since the cessation of vaccination any animals vaccinated against CBPP.

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

Article 11.9.4.

Recovery of free status

When a CBPP *outbreak* occurs in a CBPP free country, *zone* or *compartment*, one of the following waiting periods is required to regain the status of CBPP free country, *zone* or *compartment*:

1. 12 months after the last *case* where a *stamping-out policy* and serological *surveillance* and strict movement control are applied in accordance with this chapter;
2. if vaccination was used, 12 months after the *slaughter* of the last vaccinated animal.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply but Article 11.9.3. applies.

Article 11.9.5.

CBPP infected country or zone

When the requirements for acceptance as a CBPP free country or *zone* are not fulfilled, a country or *zone* shall be considered as infected.

Article 11.9.6.

Recommendations for importation from CBPP free countries, zones or compartmentsfor domestic cattle and water buffaloes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals showed no clinical sign of CBPP on the day of shipment.

Article 11.9.7.

Recommendations for importation from CBPP infected countries or zones

for domestic cattle and water buffaloes for slaughter

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

1. showed no clinical sign of CBPP on the day of shipment;
2. originate from an *establishment* where no *case* of CBPP was officially reported for the past 6 months, and
3. are transported directly to the *slaughterhouse* in sealed *vehicles*.

Article 11.9.8.

Recommendations for importation from CBPP free countries, zones or compartments

for bovine semen

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

1. the donor animals:
 - a) showed no clinical sign of CBPP on the day of collection of the semen;
 - b) were kept in a CBPP free country since birth or for at least the past 6 months;
2. the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5. and Chapter 4.6.

Article 11.9.9.

Recommendations for importation from CBPP infected countries or zones

for bovine semen

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

1. the donor animals:
 - a) showed no clinical sign of CBPP on the day of collection of the semen;
 - b) were subjected to the complement fixation test for CBPP with negative results, on two occasions, with an interval of not less than 21 days and not more than 30 days between each test, the second test being performed within 14 days prior to collection;
 - c) were isolated from other domestic bovidae from the day of the first complement fixation test until collection;

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- d) were kept since birth, or for the past 6 months, in an *establishment* where no *case* of CBPP was reported during that period, and that the *establishment* was not situated in a CBPP *infected zone*;
- e) AND EITHER:
 - i) have not been vaccinated against CBPP;

OR

 - ii) were vaccinated using a vaccine complying with the standards described in the *Terrestrial Manual* not more than 4 months prior to collection; in this case, the condition laid down in point b) above is not required;
- 2. the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5. and Chapter 4.6.

Article 11.9.10.

Recommendations for importation from CBPP free countries, zones or compartments

for *in vivo* derived or *in vitro* produced embryos/oocytes of bovidae

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

- 1. the donor animals:
 - a) showed no clinical sign of CBPP on the day of collection of the embryos/oocytes;
 - b) were kept in a CBPP free country since birth or for at least the past 6 months;
- 2. the oocytes were fertilised with semen meeting the conditions of Article 11.9.8.;
- 3. the embryos/oocytes was collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 11.9.11.

Recommendations for importation from CBPP infected countries or zones

for *in vivo* derived or *in vitro* produced embryos/oocytes of bovidae

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

- 1. the donor animals:
 - a) showed no clinical sign of CBPP on the day of collection of the embryos/oocytes;
 - b) were subjected to the complement fixation test for CBPP with negative results, on two occasions, with an interval of not less than 21 days and not more than 30 days between each test, the second test being performed within 14 days prior to collection;
 - c) were isolated from other domestic bovidae from the day of the first complement fixation test until collection;

- d) were kept since birth, or for the past 6 months, in an *establishment* where no *case* of CBPP was reported during that period, and that the *establishment* was not situated in a CBPP *infected zone*,
- e) AND EITHER:
 - i) have not been vaccinated against CBPP;

OR

 - ii) were vaccinated using a vaccine complying with the standards described in the *Terrestrial Manual* not more than 4 months prior to collection; in this case, the condition laid down in point b) above is not required;
- 2. the oocytes were fertilised with semen meeting the conditions of Article 11.9.9.;
- 3. the embryos/oocytes was collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 11.9.12.

Surveillance: introduction

Articles 11.9.12. to 11.9.17. define the principles and provides a guide for the *surveillance of for* CBPP in accordance with Chapter 1.4. applicable to Members seeking establishment of freedom from CBPP. Guidance is provided for Members seeking reestablishment of freedom from CBPP for the entire country or for a *zone* or *compartment*, following an *outbreak* and for the maintenance of CBPP free status.

The impact and epidemiology of CBPP differ widely in different regions of the world and therefore it is impossible to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from CBPP at an acceptable level of confidence will need to be adapted to the local situation. It is incumbent upon the applicant Member to submit a dossier to the OIE in support of its application that not only explains the epidemiology of CBPP in the region concerned but also demonstrates how all the risk factors are managed. This should include provision of scientifically-based supporting data. There is therefore considerable latitude available to OIE Members to provide a well-reasoned argument to prove that the absence of CBPP infection is assured at an acceptable level of confidence.

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

Article 11.9.13.

Surveillance: general conditions and methods

1. A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. A procedure should be in place for the rapid collection and transport of samples from suspect *cases* of CBPP to a *laboratory* for CBPP diagnoses as described in the *Terrestrial Manual*.

Annex XXX (contd)2. The CBPP *surveillance* programme should:

- a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious *cases*. Farmers and workers (such as community animal health workers) who have day-to-day contact with livestock, *meat* inspectors as well as *laboratory* diagnosticians, should report promptly any suspicion of CBPP. They should be integrated directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) into the *surveillance* system. All suspect *cases* of CBPP should be investigated immediately. Where suspicion cannot be resolved by epidemiological and clinical investigation, samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment are available for those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in CBPP diagnosis and control;
- b) implement, when relevant, regular and frequent clinical inspection and testing of high-risk groups of animals, such as those adjacent to a CBPP infected country or *infected zone* (for example, areas of transhumant production systems);
- c) take into consideration additional factors such as animal movement, different production systems, geographical and socio-economic factors that may influence the risk of *disease* occurrence.

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

Article 11.9.14.

Surveillance strategies1. Introduction

The target population for *surveillance* aimed at identifying *disease* and *infection* should cover all the susceptible species (*Bos taurus*, *B. indicus* and *Bubalus bubalis*) within the country, *zone* or *compartment*.

Given the limitations of the diagnostic tools available, the interpretation of *surveillance* results should be at the *herd* level rather than at the individual animal level.

Randomised *surveillance* may not be the preferred approach given the epidemiology of the *disease* (usually uneven distribution and potential for occult foci of *infection* in small populations) and the limited sensitivity and specificity of currently available tests. Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in particular localities or species, focusing on *slaughter* findings, and active clinical *surveillance*) may be the most appropriate strategy. The applicant Member should justify the *surveillance* strategy chosen as adequate to detect the presence of CBPP infection in accordance with Chapter 1.4. and the epidemiological situation.

Targeted *surveillance* may involve testing of the entire target subpopulation or a sample from it. In the latter case the sampling strategy will need to incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect *infection* if it were to occur at a predetermined minimum rate. The sample size and expected disease prevalence determine the level of confidence in the results of the survey. The applicant Member **must should** justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated.

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

2. Clinical surveillance

Clinical *surveillance* aims at detecting clinical signs of CBPP in a *herd* by close physical examination of susceptible animals. Clinical inspection will be an important component of CBPP *surveillance* contributing to reach the desired level of confidence of detection of *disease* if a sufficiently large number of clinically susceptible animals is examined.

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

3. Pathological surveillance

Systematic pathological *surveillance* for CBPP is the most effective approach and should be conducted at *slaughterhouses* and other *slaughter* facilities. Suspect pathological findings should be confirmed by agent identification. Training courses for *slaughter* personnel and *meat* inspectors are recommended.

4. Serological testing

Serological *surveillance* is not the preferred strategy for CBPP. However, in the framework of epidemiologic investigations, serological testing may be used.

The limitations of available serological tests for CBPP will make the interpretation of results difficult and useful only at the *herd* level. Positive findings should be followed-up by clinical and pathological investigations and agent identification.

Clustering of seropositive reactions should be expected in CBPP infections and will be usually accompanied by clinical signs. As clustering may signal field strain *infection*, the investigation of all instances **must should** be incorporated in the *surveillance* strategy.

Following the identification of a CBPP infected *herd*, contact *herds* need to be tested serologically. Repeated testing may be necessary to reach an acceptable level of confidence in *herd* classification.

5. Agent surveillance

Agent *surveillance* using tests described in the *Terrestrial Manual* should be conducted to follow-up and confirm or exclude suspect *cases*. Isolates should be typed to confirm *MmmSC*.

Article 11.9.15.

Countries or zones applying for recognition of freedom from CBPP

In addition to the general conditions described in this chapter, an OIE Member applying for recognition of CBPP freedom for the country or a *zone* should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and will be planned and implemented according to general conditions and methods in this chapter, to demonstrate absence of CBPP infection, during the preceding 24 months in susceptible populations. This requires the support of a national or other *laboratory* able to undertake identification of CBPP infection using methods described in the *Terrestrial Manual*.

Article 11.9.16.

Compartments seeking recognition of freedom from CBPP

The bilateral recognition of CBPP free *compartments* should follow the principles laid in this chapter, Chapter 4.3. and Chapter 4.4.

Article 11.9.17.

Countries or zones re-applying for recognition of freedom from CBPP following an outbreak

In addition to the general conditions described in this chapter, a Member re-applying for recognition of country or *zone* freedom from CBPP should show evidence of an active *surveillance* programme for CBPP, following the recommendations of this chapter.

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

1. *slaughter* of all clinically affected and in-contact susceptible animals;
2. vaccination used without subsequent *slaughter* of vaccinated animals.

The time periods before which an application can be made for re-instatement of freedom from CBPP depends on which of these alternatives is followed. The time periods are prescribed in Article 11.9.4.

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CHAPTER 11.11.

ENZOOTIC BOVINE LEUKOSIS

Article 11.11.1.

General provisions

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

For the purpose of this chapter, susceptible animals include domestic cattle (*Bos indicus* and *Bos taurus*).

Article 11.11.2.

Country or zone free from enzootic bovine leukosis1. Qualification

To qualify as free from enzootic bovine leukosis (EBL), a country or zone ~~must~~ should satisfy the following requirements for at least 3 years:

- a) all tumours, suspected to be lymphosarcoma, are reported to the *Veterinary Authority*, and are examined at a *laboratory* by appropriate diagnostic techniques;
- b) all ~~animals~~ cattle with tumours in which EBL has been confirmed or cannot be ruled out are traced back to the *herds* in which they have been kept since birth; all cattle over 24 months of age in these *herds* are subjected to an individual diagnostic test for EBL;
- c) at least 99.8% of the *herds* are qualified as EBL free.

2. Maintenance of free status

For a country or zone to maintain its EBL free status:

- a) a serological survey ~~must~~ should be carried out annually on a random sample of the cattle population of the country or zone sufficient to provide a 99% level of confidence of detecting EBL if it is present at a prevalence rate exceeding 0.2% of the *herds*;
- b) all imported bovines cattle (except for *slaughter*) comply with the provisions of Article 11.11.4.;
- c) all imported bovine semen and embryos/ova fulfil the requirements referred to in Article 11.11.5. and in Article 11.11.6., respectively.

Article 11.11.2.bis**Compartment free from enzootic bovine leukosis****1. Qualification**

To qualify as free from EBL, a *compartment* should satisfy the following requirements:

All *herds* in the *compartment* have satisfied the requirements of Article 11.11.3. and:

- a) all cattle introduced into the *compartment* come from a free *herd*
- b) all bovine semen and embryos/ova introduced into the *compartment* after the first test have fulfilled the conditions referred to in Article 11.11.5. and in Article 11.11.6., respectively;
- c) the *compartment* is managed under a common biosecurity plan complying with Article 4.3.3. and Article 4.4.3., which protects the cattle from contact with EBL virus, which might occur from introduction of infected cattle, cattle products or material and through practices such as vaccinations and other injections, collection of blood and other biological samples, dehorning, ear-tagging, pregnancy diagnosis, etc.;
- d) the *compartment* has been approved by the *Veterinary Authority* in accordance with Chapters 4.3. and 4.4.

2. Maintenance of free status

For a *compartment* to maintain its EBL free status, all *herds* in the *compartment* should remain free according to Article 11.11.3. and specific *surveillance* implemented according to Article 4.4.5. has not detected the agent.

3. Revocation and re-approval of free status

If in an EBL free *compartment* any cattle react positively to a diagnostic test for EBL as described in the *Terrestrial Manual*, the status of the *compartment* shall be revoked until all *herds* have recovered their free status according to Article 11.11.3. and the *compartment* has been re-approved according to Chapters 4.3 and 4.4.

Article 11.11.3.

Herd free from enzootic bovine leukosis**1. Qualification**

To qualify as free from EBL, a *herd* ~~must~~ should satisfy the following requirements:

- a) there has been no evidence of EBL either clinical, post-mortem, or as a result of a diagnostic test for EBL within the previous 2 years;
- b) all ~~animals~~ cattle over 24 months of age have been subjected to a diagnostic test for EBL on two occasions with negative results, at an interval of not less than 4 months during the preceding 12 months;
- c) ~~animals~~ cattle introduced into the *herd* after the first test have fulfilled the conditions of Article 11.11.4.;
- d) all bovine semen and embryos/ova introduced into the *herd* after the first test have fulfilled the conditions referred to in Article 11.11.5. and in Article 11.11.6., respectively.

2. Maintenance of free status

For a *herd* to maintain its EBL free status, the ~~animals~~ cattle in the *herd* over 24 months of age on the day of sampling ~~must~~ should be subjected to a diagnostic test for EBL with negative results at intervals of no more than 36 months and the conditions referred to in points 1a), 1c) and 1d) above continue to be fulfilled.

3. Suspension and restoration of free status

If in an EBL free *herd* any ~~animals~~ cattle react positively to a diagnostic test for EBL as described in the *Terrestrial Manual* or a virological test (under study) for bovine leukosis virus, the status of the *herd* shall be suspended until the following measures have been taken:

- a) the ~~animals~~ cattle which have reacted positively, and their progeny since the last negative test, ~~must~~ should be removed from the *herd* immediately; however, any ~~animal~~ cattle within the progeny which ~~has~~ have been subjected to a PCR test with negative results (under study) may be retained in the *herd*;
- b) the remaining ~~animals~~ cattle ~~must~~ should have been subjected to a diagnostic test for EBL carried out as described in point 1b) above with negative results at least 4 months after removal of the positive ~~animals~~ cattle and their progeny.

Article 11.11.4.

Recommendations for the importation of cattle for breeding or rearing

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

Annex XXXI (contd)

1. come from a country, ~~or~~ zone or compartment free from EBL; or
2. come from an EBL free *herd*; or
3. meet the following three conditions:
 - a) the ~~animals~~ cattle were kept in a *herd* in which:
 - i) there has been no evidence of EBL either clinical, post-mortem, or as a result of a diagnostic test for EBL within the previous 2 years;
 - ii) all ~~animals~~ cattle over 24 months of age have been subjected to a diagnostic test for EBL on a blood sample on two occasions with negative results during the preceding 12 months, at an interval of at least 4 months, or were tested on two occasions while segregated from the *herd* in an isolation unit approved by the *Veterinary Authority* at an interval of at least 4 months;
 - b) the ~~animals~~ cattle were subjected to a diagnostic test for EBL within 30 days prior to shipment with negative results;
 - c) if less than 2 years of age, the ~~animals~~ cattle come from 'uterine' dams which have been subjected to a diagnostic test for EBL on a blood sample on two occasions at intervals of at least 4 months within the preceding 12 months, with negative results.

Article 11.11.5.

Recommendations for the importation of bovine semen

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

1. the donor bull was resident at the time of semen collection in an EBL free *herd*; and
2. if less than 2 years of age, the bull came from a serologically negative 'uterine' dam; or
3. the bull was subjected to diagnostic tests for EBL on blood samples on two occasions with negative results, the first test being carried out at least 30 days before and the second test at least 90 days after collection of the semen;
4. the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5. and Chapter 4.6.

Article 11.11.6.

Recommendations for the importation of bovine embryos/ova

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the embryos/ova have been collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

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CHAPTER 11.13.

INFECTIOUS BOVINE RHINOTRACHEITIS / INFECTIOUS PUSTULAR VULVOVAGINITIS

Article 11.13.1.

General provisions

For the purposes of the *Terrestrial Code*, the *incubation period* for infectious bovine rhinotracheitis/infectious pustular vulvovaginitis (IBR/IPV) shall be 21 days.

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

Article 11.13.2.

Country or zone free from IBR/IPV1. Qualification

To qualify as free from IBR/IPV, a country or zone **must should** satisfy the following requirements:

- a) the *disease* or suspicion of the *disease* is notifiable;
- b) no animal has been vaccinated against IBR/IPV for at least 3 years;
- c) at least 99.8% of the *herds* are qualified as free from IBR/IPV.

2. Maintenance of free status

For a country or zone to maintain its status free from IBR/IPV:

- a) a serological survey should be carried out annually on a random sample of the cattle population of the country or zone sufficient to provide a 99% level of confidence of detecting IBR/IPV if it is present at a prevalence rate exceeding 0.2% of the *herds*;
- b) all imported bovines comply with the provisions of Article 11.13.4.;
- c) all imported bovine semen and embryos/ova fulfil the requirements referred to in Articles 11.13.6. or 11.13.7., and in Article 11.13.8., respectively.

Article 11.13.3.

Herd free from IBR/IPV1. Qualification

To qualify as free from IBR/IPV, a herd of cattle **must should** satisfy the following requirements:

- a) all the animals in the *herd* have been subjected to a diagnostic test for IBR/IPV on a blood sample on two occasions with negative results, at an interval of not less than 2 months and not more than 12 months; or

Annex XXXII (contd)

- b) if the *herd* contains only dairy cattle of which at least a quarter are lactating cows, each of the latter has been subjected to a diagnostic test on individual milk samples carried out on three occasions at intervals of 2 months with negative results;
- c) animals introduced into the *herd* after the first tests referred to in point a) or point b) as relevant have been:
 - i) kept in an IBR/IPV free *herd*, or
 - ii) placed in isolation for a period of 30 days, and during this period have been subjected to a diagnostic test for IBR/IPV on a blood sample on two occasions with negative results, at an interval of not less than 21 days;
- d) all bovine semen and embryos/ova introduced into the *herd* after the first tests referred to in point a) or point b) as relevant have fulfilled the conditions provided in Articles 11.13.6. or 11.13.7. and in Article 11.13.8., respectively.

2. Maintenance of free status

For a *herd* to maintain its status free from IBR/IPV, it ~~must~~ should be subjected to the following tests with negative results:

EITHER

- a) diagnostic tests for IBR/IPV on blood samples for all the animals repeated at maximum intervals of 12 months; in *herds* composed entirely of fattening animals, blood sampling may be limited to animals sent for *slaughter*;

OR

- b) diagnostic tests on individual milk samples from all lactating cows repeated at intervals of 6 months; *Veterinary Authorities* applying an IBR/IPV eradication programme may extend these intervals (under study) if more than 98% of *herds* have been free from the *disease* for at least 3 years; and
- c) diagnostic tests on blood samples for IBR/IPV of all breeding bulls repeated at maximum intervals of 12 months;

AND

- d) diagnostic tests on blood samples for IBR/IPV of all cattle having aborted after more than 3 months of gestation.

Animals introduced into the *herd* ~~must~~ should satisfy the conditions provided in point 1c) above, and semen and embryos/ova used in the *herd* ~~must~~ should satisfy the conditions provided in Articles 11.13.6. or 11.13.7. and in Article 11.13.8., respectively.

Article 11.13.4.

Recommendations for the importation of cattle destined for IBR/IPV free herds

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

1. showed no clinical sign of IBR/IPV on the day of shipment;
2. come from an IBR/IPV free *herd*, or
3. were kept in a *quarantine station* for the 30 days prior to shipment and were subjected to a diagnostic test for IBR/IPV on a blood sample on two occasions with negative results, at an interval of not less than 21 days.

Article 11.13.5.

Recommendations for the importation of cattle intended for herds not qualified as free from IBR/IPV

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

1. showed no clinical sign of IBR/IPV on the day of shipment;
2. were vaccinated with an inactivated virus vaccine not less than one month and not more than 6 months prior to shipment.

Article 11.13.6.

Recommendations for the importation of fresh semen

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

1. the donor animals were kept in an IBR/IPV free *herd* at the time of collection of the semen;
2. the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5. and Chapter 4.6.

Article 11.13.7.

Recommendations for the importation of frozen semen

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

1. the donor animals were kept in an IBR/IPV free *herd* at the time of collection of the semen; or
2. the donor animals were held in isolation during the period of collection and for the 30 days following collection and were subjected to a diagnostic test for IBR/IPV on a blood sample taken at least 21 days after collection of the semen, with negative results; or

Annex XXXII (contd)

3. if the serological status of the bull is unknown or if the bull is serologically positive, an aliquot of each semen collection was subjected to a virus isolation test or PCR, performed in accordance with the *Terrestrial Manual*, with negative results; and
4. the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5. and Chapter 4.6.

Article 11.13.8.

Recommendations for the importation of embryos/ova

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the embryos/ova were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

— text deleted

CHAPTER 11.14.

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

Article 11.14.1.

General provisions

For the purposes of the *Terrestrial Code*, the *incubation period* for lumpy skin disease (LSD) shall be 28 days.

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

Article 11.14.2.

LSD free country

A country may be considered free from LSD when:

1. LSD is notifiable in the country;
2. no *case* of LSD has been confirmed for at least the past 3 years.

Article 11.14.3.

Trade in commodities

Veterinary Authorities of LSD free countries may prohibit importation or transit through their territory, from countries considered infected with LSD, of the following *commodities*:

1. domestic and wild animals of the bovine species;
2. semen of animals of the bovine species.

Article 11.14.4.

Recommendations for importation from LSD free countriesfor domestic **bovines cattle**

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

1. showed no clinical sign of LSD on the day of shipment;
2. come from an LSD free country.

Article 11.14.5.

Recommendations for importation from LSD free countriesfor wild **bovines cattle**

Annex XXXIII (contd)

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

1. showed no clinical sign of LSD on the day of shipment;
2. come from an LSD free country;

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

3. were kept in a *quarantine station* for the 28 days prior to shipment.

Article 11.14.6.

Recommendations for importation from countries considered infected with LSD

for domestic bovines cattle

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

1. showed no clinical sign of LSD on the day of shipment;
2. were not vaccinated against LSD during the 30 days prior to shipment; or
3. were vaccinated against LSD not more than 3 months prior to shipment;
4. were kept since birth, or for the past 28 days, in an *establishment* where no *case* of LSD was officially reported during that period; or
5. were kept in a *quarantine station* for the 28 days prior to shipment.

Article 11.14.7.

Recommendations for importation from countries considered infected with LSD

for wild bovines cattle

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

1. showed no clinical sign of LSD on the day of shipment;
2. were kept in a *quarantine station* for the 28 days prior to shipment.

Article 11.14.8.

Recommendations for importation from LSD free countries

for semen of bovines cattle

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

1. the donor animals:
 - a) showed no clinical sign of LSD on the day of collection of the semen ~~and for the following 28 days;~~
 - ~~2-b)~~ were kept for at least 28 days prior to collection in an LSD free country;
2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 11.14.9.

Recommendations for importation from countries considered infected with LSD

for semen of bovines cattle

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

1. the donor animals:
 - a) showed no clinical sign of LSD on the day of collection of the semen and for the following 28 days;
 - ~~2-b)~~ were kept in the *exporting country* for the 28 days prior to collection, in an *establishment* or *artificial insemination centre* where no *case* of LSD was officially reported during that period, and that the *establishment* or *artificial insemination centre* was not situated in an LSD *infected zone*;
2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 11.14.9.bis

Recommendations for importation from LSD free countries

for embryos/oocytes of cattle

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

1. the donor animals showed no clinical sign of LSD on the day of collection of the embryos/oocytes; and.
2. the embryos/oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 11.14.9.tris

Recommendations for importation from countries considered infected with LSD

for embryos/oocytes of cattle

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

Annex XXXIII (contd)1. the donor animals:

- a) were kept in an establishment where no case of LSD has been reported during the 28 days prior to collection; and
- b) showed no clinical sign of LSD on the day of collection;
- c) and either:
 - i) were vaccinated against LSD between 30 days and 90 days before collection; or
 - ii) were tested with negative results according to the *Terrestrial Manual*; or
 - iii) showed serostability (not more than a two-fold rise in titre) on paired samples to indirect ELISA tests, tested side by side, carried out in isolation, 14–60 days apart with one of the samples taken on the day of collection of the embryos/oocytes;

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

Article 11.14.10.

Recommendations for importation from LSD free countriesfor products of animal origin (from bovines cattle) intended for agricultural or industrial use

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products come from animals which have been kept in an LSD free country since birth or for at least the past 28 days.

Article 11.14.11.

Recommendations for importation from countries considered infected with LSDfor products of animal origin (from bovines cattle) intended for agricultural or industrial use

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of the LSD virus.

Article 11.14.12.

Recommendations for importation from countries considered infected with LSDfor raw hides of bovines cattle

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products were stored for at least 40 days before shipment.

— text deleted

CHAPTER 12.7.

EQUINE INFLUENZA

Article 12.7.1.

General provisions

For the purposes of the *Terrestrial Code*, equine influenza (EI) is defined as an *infection* of domestic horses, donkeys and mules.

For the purposes of *international trade*, this chapter deals not only with the occurrence of clinical signs caused by equine influenza virus (EIV), but also with the presence of *infection* with EIV in the absence of clinical signs.

For the purposes of this chapter, isolation is defined as ‘the separation of horses domestic equids from horses domestic equids of a different equine influenza health status, utilising appropriate biosecurity measures, with the purpose of preventing the transmission of *infection*’.

For the purposes of the *Terrestrial Code*, the *infective period* for equine influenza EI is 21 days.

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

When authorising import or transit of other commodities listed in this chapter, with the exception of those listed in Article 12.7.2., Veterinary Authorities should require the conditions prescribed in this chapter relevant to the EI status of the equine population of the exporting country, zone or compartment.

Article 12.7.2.

Trade in Safe commodities

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

1. semen;
2. *in vivo* derived equine embryos collected, processed and stored in conformity with the provisions of Chapter 4.7. or Chapter 4.9. (under study).

~~When authorising import or transit of other commodities listed in this chapter, Veterinary Authorities should require the conditions prescribed in this chapter relevant to the EI status of the equine population of the exporting country, zone or compartment.~~

Article 12.7.3.

Determination of the EI status of a country, a zone or a compartment

The EI status of a country, a *zone* or a *compartment* can be determined on the basis of the following criteria:

1. the outcome of a *risk assessment* identifying all potential factors for EI occurrence and their historic perspective;

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2. whether EI is notifiable in the whole country, an on-going EI awareness programme is in place, and all notified suspect occurrences of EI are subjected to field and, where applicable, laboratory investigations;
3. appropriate *surveillance* is in place to demonstrate the presence of *infection* in the absence of clinical signs in horses domestic equids.

Article 12.7.4.

Equine influenza EI free country, zone or compartment

A country ~~or~~ a zone or a compartment may be considered free from EI provided the *disease* is notifiable in the whole country and it shows evidence through ~~of~~ an effective *surveillance* programme, planned and implemented according to the general principles in Chapter 1.4, that no case of EI occurred in the past two years. The *surveillance* may need to be adapted to parts of the country, zone or compartment depending on historical or geographical factors, industry structure, population data, movements of equids into the country, zone or compartment, wild equid populations or proximity to recent *outbreaks*.

A country ~~or~~ a zone or a compartment seeking freedom from EI, in which vaccination is practised, should also demonstrate that EIV has not been circulating in the population of domestic and wild equidae during the past 12 months, through *surveillance*, in accordance with Chapter 1.4. In a country in which vaccination is not practised, *surveillance* ~~could~~ may be conducted using serological testing alone. In countries where vaccination is practised, the *surveillance* should include agent identification methods of virus detection described in the Terrestrial Manual for evidence of infection.

If an *outbreak* of clinical equine influenza EI occurs in a previously free country, zone or compartment, free status can be regained 12 months after the last clinical *case*, providing that *surveillance* for evidence of *infection* has been carried out during that 12-month period in accordance with Chapter 1.4.

Article 12.7.5.

Recommendations for the importation of horses domestic equids for immediate slaughter

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the horses domestic equids showed no clinical sign of EI on the day of shipment.

Article 12.7.6.

Recommendations for the importation of horses domestic equids for unrestricted movement

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

1. came from an EI free country, zone or compartment in which they had been resident for at least 21 days; in the case of a vaccinated horse domestic equid, information on its vaccination status should be included in the veterinary certificate;

OR

2. came from a country, zone or compartment not known to be free from EI, were subjected to pre-export isolation for 21 days and showed no clinical sign of EI during isolation nor on the day of shipment; and

CHAPTER 12.10.

EQUINE VIRAL ARTERITIS

Article 12.10.1.

General provisions

The *infective period* for equine viral arteritis (EVA) shall be 28 days for all categories of equine except sexually mature stallion where the *infective period* may be for the life of the animal. Because the *infective period* may be extended in the case of virus shedding in semen, the status of seropositive stallions should be checked to ensure that they do not shed virus in their semen.

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

Article 12.10.2.

Recommendations for the importation of uncastrated male equines

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the animals showed no clinical sign of EVA on the day of shipment and during the 28 days prior to shipment and met one of the following requirements:

1. were isolated for the 28 days prior to shipment and were subjected, to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out on a single blood sample collected during the 21 days prior to shipment with negative result; or
2. were subjected between 6 and 9 months of age to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out on two blood samples collected at least 14 days apart with stable or decreasing titre, immediately vaccinated for EVA and regularly revaccinated according to the manufacturer's instructions; or
3. met the following requirements:
 - a) were isolated ~~for 28 days~~; and
 - b) not earlier than 7 days of commencing isolation were tested, with negative results, with a test for EVA as prescribed in the *Terrestrial Manual*; and
 - c) were then immediately vaccinated; and
 - d) were kept separated from other equidae for 21 days following vaccination; and
 - e) were revaccinated regularly according to the manufacturer's instructions; or
4. have been subjected to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out on a blood sample with positive results and then: either
 - a) were subsequently test mated to two mares within ~~12-6~~ months prior to shipment which were subjected to two tests for EVA as prescribed in the *Terrestrial Manual* with negative results on blood samples collected at the time of test mating and again 28 days after the mating; or

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- b) were subjected to a test for equine arteritis virus as prescribed in the *Terrestrial Manual* with negative results, carried out on semen collected during the ~~28 days~~ 6 months prior to shipment; or
- c) were subjected to a test for equine arteritis virus as prescribed in the *Terrestrial Manual* with negative results, carried out on semen collected within 6 months after the blood sample was tested, then immediately vaccinated, and revaccinated regularly.

Article 12.10.3.

Recommendations for the importation of equines other than uncastrated males

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the animals showed no clinical sign of EVA on the day of shipment and

EITHER

1. were kept in an *establishment* where no animals have shown any signs of EVA for the 28 days prior to shipment; and ~~either~~
- 1a) ~~were isolated for the 28 days prior to shipment and~~ were subjected to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out ~~either:~~
- a. ~~on a single blood sample collected during the 28 days prior to shipment with negative results, or~~
- b. on blood samples collected on two occasions at least 14 days apart within 28 days prior to shipment, which demonstrated stable or declining antibody titres; or
- b) regularly vaccinated according to the manufacturer's instructions;

OR

2. were isolated for the 28 days prior to shipment and during this period the animals showed no signs of EVA and were subjected, between 6 and 9 months of age, to a diagnostic test for EVA, as prescribed in the *Terrestrial Manual*, carried out on two blood samples collected at least 14 days apart, on a single blood sample with negative results or stable or declining titre, and immediately vaccinated for EVA and regularly revaccinated according to the manufacturer's instructions.

Article 12.10.4.

Recommendations for the importation of semen

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the animal donors were kept for the 28 days prior to semen collection in an *establishment* where no equine has shown any clinical sign of EVA during that period and showed no clinical sign of EVA on the day of semen collection; and

1. were subjected between 6 and 9 months of age to a test for EVA as prescribed in the *Terrestrial Manual* on two blood samples with stable or decreasing titre, immediately vaccinated for EVA and regularly revaccinated according to the manufacturer's instructions; or

2. were isolated and not earlier than 7 days of commencing isolation were subjected to a test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results, immediately vaccinated for EVA, kept for 21 days following vaccination separated from other equidae and regularly revaccinated according to the manufacturer's instructions; or
3. were subjected to a test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results within 14 days prior to semen collection, and had been separated from other equidae not of an equivalent EVA status for 14 days prior to blood sampling from the time of the taking of the blood sample until the end of semen collection; or
4. have been subjected to a test for EVA as prescribed in the *Terrestrial Manual* carried out on a blood sample with positive results and then: either
 - a) were subsequently test mated to two mares within ~~12~~ 6 months prior to semen collection, which were subjected to two tests for EVA as prescribed in the *Terrestrial Manual* with negative results on blood samples collected at the time of test mating and again ~~28 days~~ 6 months ~~28 days~~ after the test mating, or
 - b) were subjected to a test for equine arteritis virus as prescribed in the *Terrestrial Manual* with negative results, carried out on semen collected within ~~one year~~ 6 months prior to collection of the semen to be exported; or
 - c) were subjected to a test for equine arteritis virus as prescribed in the *Terrestrial Manual* with negative results, carried out on semen collected within 6 months after the blood sample was tested, then immediately vaccinated, and revaccinated regularly; or
5. were, for frozen semen, subjected with negative results either:
 - a) to a test for EVA as prescribed in the *Terrestrial Manual* carried out on a blood sample taken not earlier than 14 days and not later than 12 months after the collection of the semen for export; or
 - b) to a test for equine arteritis virus as prescribed in the *Terrestrial Manual* carried out on an aliquot of the semen collected immediately prior to processing or on an aliquot of semen collected within 14 to 30 days after the first collection of the semen to be exported.

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CHAPTER 14.9.

SCRAPIE

Article 14.9.1.

General provisions and safe commodities

Scrapie is a neurodegenerative *disease* of sheep and goats. The main mode of transmission is from mother to offspring immediately after birth and to other susceptible neonates exposed to the birth fluids and tissues of an infected animal. Transmission occurs at a much lower frequency to adults exposed to the birth fluids and tissues of an infected animal. A variation in genetic susceptibility of sheep has been recognised. The *incubation period* of the *disease* is variable; however, it is usually measured in years. The duration in *incubation period* can be influenced by a number of factors including host genetics and strain of agent.

Scrapie ~~is~~ does is not ~~considered to~~ considered to pose a risk to human health. The recommendations in this chapter are intended to manage the animal health risks associated with the presence of the scrapie agent in sheep and goats. The chapter does not cover so-called 'atypical' scrapie which is clinically, pathologically, biochemically and epidemiologically unrelated to 'classical' scrapie, may not be contagious and may, in fact, be a spontaneous degenerative condition of older sheep.

1. When authorising import or transit of the following *commodities* derived from sheep or goats and any products made from these *commodities* and containing no other tissues from sheep or goats derived, *Veterinary Authorities* should not require any scrapie-related conditions, regardless of the scrapie risk status of the sheep and goat populations of the *exporting country, zone or compartment*:
 - a) ~~semen collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.~~ in vivo derived sheep embryos handled in accordance with Chapter 4.7 of this *Terrestrial Code*
 - b) meat (excluding materials as referred to in Article 14.9.12.);
 - c) hides and skins;
 - d) gelatine;
 - e) collagen prepared from hides or skins;
 - f) tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;
 - g) dicalcium phosphate (with no trace of protein or fat);
 - h) wool or fibre.
2. When authorising import or transit of other *commodities* listed in this chapter, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the scrapie risk status of the sheep and goat populations of the *exporting country, zone or compartment*.

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

Article 14.9.2.

Determination of the scrapie status of a country, zone, compartment or establishment

The scrapie status of the sheep and goat populations of a country, *zone*, *compartment* or *establishment* should be determined on the basis of the following criteria:

1. the outcome of a *risk assessment* identifying all potential factors for scrapie occurrence and their historic perspective, in particular the:
 - a) importation or introduction of sheep and goats or their ~~semen or~~ semen, in vivo derived goat embryos or their in vitro processed sheep and goat embryos/oocytes potentially infected with scrapie;
 - b) extent of knowledge of the population structure and husbandry practices of sheep and goats;
 - c) feeding practices, including consumption of *meat-and-bone meal* or *greaves* derived from ruminants;
 - d) importation of *milk* and *milk products* of sheep or goats origin intended for use in feeding of sheep and goats;
2. an on-going awareness programme for *veterinarians*, farmers, and workers involved in transportation, marketing and *slaughter* of sheep and goats to facilitate recognition and encourage reporting of all animals with clinical signs compatible with scrapie;
3. a *surveillance* and monitoring system including the following:
 - a) official veterinary *surveillance*, reporting and regulatory control in accordance with the provisions of Chapter 1.4.;
 - b) a *Veterinary Authority* with current knowledge of, and authority over, all *establishments* which contain sheep and goats in the whole country;
 - c) compulsory notification and clinical investigation of sheep and goats showing clinical signs compatible with scrapie;
 - d) examination, in accordance with the *Terrestrial Manual*, in a *laboratory* of appropriate material from sheep and goats older than 18 months displaying clinical signs compatible with scrapie;
 - e) maintenance of records including the number and results of all investigations for at least 7 years.

Article 14.9.3.

Scrapie free country or zone

Countries or *zones* may be considered free from scrapie if within the said territory:

1. a *risk assessment*, as described in point 1 of Article 14.9.2., has been conducted, and it has been demonstrated that appropriate measures are currently in place and have been taken for the relevant period of time to manage any *risk* identified and points 2 and 3 have been complied with for the preceding 7 years;

AND

2. one of the following conditions should be met:

- a) the country or the *zone* have demonstrated historical freedom as follows: taking into account the recommendations in Articles 14.9.14. and 14.9.15. (under study); or
- i) scrapie has been notifiable for at least 25 years; and
 - ii) a formal programme of targeted surveillance and monitoring, which includes testing of sheep and goats displaying clinical signs compatible with scrapie and those over 18 months of age slaughtered, culled or found dead on farm, can be documented as having been in place for at least 10 years; and
 - iii) appropriate measures to prevent scrapie introduction can be documented as having been in place for at least 25 years; and
 - either scrapie has never been reported; or
 - no case of scrapie has been reported for at least 25 years.
- b) for at least 7 years, sheep and goats displaying clinical signs compatible with scrapie have been tested. Also a sufficient number of representative mature culled sheep and goats over 18 months of age, representative of slaughtered, culled and/or found dead on farm, have been tested annually, to provide a 95% level of confidence of detecting scrapie if it is present in that population at a prevalence rate exceeding 0.01% 0.1% out of the total number of all chronic-wasting conditions in the population of sheep and goats older than 18 months of age and no case of scrapie has been reported during this period; it is assumed that the occurrence rate of chronic-wasting conditions within the population of sheep and goats older than 18 months of age is at least 1% (under study); or
- c) all *establishments* containing sheep or goats have been accredited free as described in Article 14.9.5.;

AND

3. the feeding to sheep and goats of *meat-and-bone meal* or *greaves* of ruminant origin has been banned and effectively enforced in the whole country for at least 7 years;

AND

4. introductions of sheep and goats or ~~their semen or~~ their semen, in vivo derived goat embryos or their in vitro processed sheep and goat embryos/oocytes from countries or *zones* not free from scrapie are carried out in accordance with Articles 14.9.6., 14.9.7., ~~14.9.8.~~ 14.9.8. or 14.9.9., as relevant.

Article 14.9.4.

Compartment free from sScrapie free compartment

To qualify as a A compartment free from scrapie, may be considered free from scrapie if the following conditions are fulfilled all sheep and goats in a compartment should be certified by the Veterinary Authority as satisfying the following requirements:

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1. all establishments within the compartment are free from scrapie according to Article 14.9.5.;
2. all establishments within the compartment are managed under a common biosecurity plan protecting them from introduction of scrapie, and the compartment has been approved by the Veterinary Authority in accordance with Chapters 4.3. and 4.4.;
3. introductions of sheep and goats are allowed only from accredited free establishments or free countries;
4. introductions of in vivo derived goat embryos and in vitro processed sheep and goat embryos/oocytes are allowed either from accredited free establishments or in accordance with Article 14.9.9.;
5. sheep and goat semen should be introduced into the compartment should have been collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6. in accordance with Article 14.9.8.;
6. sheep and goats in the compartment should have no direct or indirect contact, including shared grazing, with sheep or goats from establishments not within the compartment.

~~One or more establishments may be considered eligible for accreditation as a scrapie free compartment if:~~

- ~~1. in the country or zone where the establishments are situated, the following conditions are fulfilled:

 - ~~a. the disease is compulsorily notifiable;~~
 - ~~b. an awareness, surveillance and monitoring system as referred to in Article 14.9.2. is in place;~~
 - ~~c. affected sheep and goats are slaughtered and completely destroyed;~~
 - ~~d. the feeding to sheep and goats of meat and bone meal or greaves of ruminant origin has been banned and effectively enforced in the whole country;~~
 - ~~e. an official accreditation scheme is in operation under the supervision of the Veterinary Authority, including the measures described in point 2 below;~~~~
- ~~2. in the establishments the following conditions have been complied with for at least 7 years:

 - ~~a. sheep and goats are permanently identified and records maintained, to enable trace back to their establishment of birth;~~
 - ~~b. records of movements of sheep and goats in and out of the establishment are maintained;~~
 - ~~c. introductions of sheep and goats are allowed only from free establishments of an equal or higher stage in the process of accreditation; however, rams and bucks complying with the provisions in point 1 of Article 14.9.8. may also be introduced;~~
 - ~~d. an Official Veterinarian inspects sheep and goats in the establishments and audits the records at least once a year;~~
 - ~~e. no case of scrapie has been reported;~~
 - ~~f. sheep and goats of the establishments should have no direct or indirect contact, including shared grazing, with sheep or goats from establishments of a lower status;~~~~

- g. ~~all culled sheep and goats over 18 months of age are inspected by an Official Veterinarian, and a proportion of those exhibiting wasting signs and all those exhibiting neurological signs are tested in a laboratory for scrapie. The selection of the sheep and goats to be tested should be made by the Official Veterinarian. Sheep and goats over 18 months of age that have died or have been killed for reasons other than routine slaughter should also be tested (including 'fallen' stock and those sent for emergency slaughter).~~
3. ~~cattle, water buffalo and wood bison in a compartment free from bovine tuberculosis are protected from contact with wildlife reservoirs of bovine tuberculosis and are managed under a common biosecurity plan protecting them from contamination with *M. bovis*, and the compartment has been approved by the Veterinary Authority in accordance with Chapters 4.3. and 4.4.~~

Article 14.9.5.

Scrapie free establishment

~~To qualify as free from scrapie, an establishment of sheep and goats may be considered eligible for accreditation as a scrapie free establishment if~~ should satisfy the following requirements:

1. in the country or zone where the establishment is situated, the following conditions are fulfilled:
 - a) the disease is compulsorily notifiable;
 - b) an awareness, surveillance and monitoring system as referred to in Article 14.9.2. is in place;
 - c) affected sheep and goats are ~~slaughtered~~ killed and completely destroyed;
 - d) the feeding to sheep and goats of *meat-and-bone meal* or *greaves* of ruminant origin has been banned and effectively enforced in the whole country for at least 7 years;
 - e) an official accreditation scheme is in operation under the supervision of the Veterinary Authority, including the measures described in point 2 below;
2. in the establishment the following conditions have been complied with for at least 7 years:
 - a) sheep and goats are permanently identified and records maintained, to enable trace back to their establishment of birth;
 - b) records of movements of sheep and goats in and out of the establishment are maintained;
 - c) introductions of sheep and goats are allowed only from free establishments or establishments at an equal or higher stage in the process of accreditation;
 - d) introduction of in vivo derived goat embryos and in vitro processed sheep and goat embryos /oocytes should comply with Article 14.9.9.;
 - e) sheep and goat semen should be introduced into the establishment should have been collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6. in accordance with Article 14.9.8.;
 - f) an Official Veterinarian inspects sheep and goats in the establishments and audits the records at least once a year;
 - g) no case of scrapie has been reported;

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- ~~h~~ sheep and goats of the *establishments* should have no direct or indirect contact, including shared grazing, with sheep or goats from *establishments* of a lower status;
- ~~g~~ all culled sheep and goats over 18 months of age are inspected by an *Official Veterinarian*, and a proportion of those exhibiting wasting signs and all those exhibiting neurological signs are tested in a *laboratory* for scrapie. The selection of the sheep and goats to be tested should be made by the *Official Veterinarian*. Sheep and goats over 18 months of age that have died or have been killed for reasons other than routine *slaughter* should also be tested (including 'fallen' stock and those sent for emergency *slaughter*).

Article 14.9.6.

**Recommendations for importation from countries or zones not considered free from scrapie
for sheep and goats for breeding or rearing**

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals come from an *establishment* free from scrapie as described in Article 14.9.5.

OR

~~In cases where the animals do not come from an *establishment* free from scrapie as described in Article 14.9.5., the *importing country* may require the placing of the animals in a *quarantine station* located on its territory, in conformity with the conditions stipulated in its animal health legislation.~~

Article 14.9.7.

**Recommendations for importation from countries or zones not considered free from scrapie
for sheep and goats for slaughter**

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

1. in the country or *zone*
 - a) the *disease* is compulsorily notifiable;
 - b) an awareness, *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;
 - c) affected sheep and goats are **slaughtered** **killed** and completely destroyed;
2. the sheep and goats selected for export showed no clinical sign of scrapie on the day of shipment.

Article 14.9.8.

**Recommendations for importation from countries or zones not considered free from scrapie
for semen of sheep and goats**

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

- ~~1. the donor animals:

 - a) are permanently identified to enable trace back to their *establishment* of origin;~~

- b) ~~have been kept since birth in establishments in which no case of scrapie had been confirmed during their residency;~~
- c) ~~showed no clinical sign of scrapie at the time of semen collection;~~
- 2. ~~the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5. and Chapter 4.6.~~

Article 14.9.8.

Recommendations for importation from countries or zones not considered free from scrapie for semen of sheep and goats

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

1. the donor animals:

- a) are permanently identified to enable trace back to their establishment of origin;
- b) showed no clinical sign of scrapie at the time of semen collection;

2. the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5. and Chapter 4.6.

Article 14.9.9.

Recommendations for importation from countries or zones not considered free from scrapie for in vivo derived goat embryos and in vitro processed sheep and goat embryos/oocytes

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

1. in the country or zone
 - a) the disease is compulsorily notifiable;
 - b) an awareness, surveillance and monitoring system as referred to in Article 14.9.2. is in place;
 - c) affected sheep and goats are ~~slaughtered~~ **killed** and completely destroyed;
 - d) the feeding to sheep and goats of *meat-and-bone meal* or *greaves* of ruminant origin has been banned and effectively enforced in the whole country;
2. the donor animals either have been kept since birth in a free establishment, or meet the following conditions:
 - a) are permanently identified to enable trace back to their establishment of origin;
 - b) have been kept since birth in establishments in which no case of scrapie had been confirmed during their residency;
 - c) showed no clinical sign of scrapie at the time of embryo/oocyte collection;

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

Article 14.9.10.

Recommendations for importation from countries or zones not considered free from scrapie

for milk and milk products of sheep or goat origin intended for use in feeding of sheep and goats

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *milk* and *milk products* come from scrapie free *establishments*.

Article 14.9.11.

Recommendations on meat-and-bone meal

Meat-and-bone meal containing any sheep or goat protein, or any feedstuffs containing that type of *meat-and-bone meal*, which originate from countries not considered free of scrapie should not be traded between countries for ruminant feeding.

Article 14.9.12.

Recommendations for importation from countries or zones not considered free from scrapie

for skulls including brains, ganglia and eyes, vertebral column including ganglia and spinal cord, tonsils, thymus, spleen, intestine, adrenal gland, pancreas, or liver, and protein products derived therefrom, from sheep and goats

1. these commodities should not be traded for use in ruminant feeds;
2. for purposes other than ruminant feeding. *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:
 - 1a) in the country or *zone*:
 - Ai) the *disease* is compulsorily notifiable;
 - Bii) an awareness, *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;
 - eiii) affected sheep and goats are slaughtered killed and completely destroyed;
 - 2b) the materials come from sheep and goats that showed no clinical sign of scrapie on the day of *slaughter*.

Article 14.9.13.

Recommendations for the importation of ovine and caprine materials destined for the preparation of biologicals

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products originate from sheep and goats born and raised in a scrapie free country, *zone*, *compartment* or *establishment*.

~~Article 14.9.14.~~~~**Principles for declaring a country or zone historically free from scrapie**~~~~Articles 14.9.14. and 14.9.15. outline principles for declaring a country or zone free from scrapie.~~~~An essential prerequisite to provide the guarantees required for the recognition of freedom from disease/infection is that the Veterinary Services of the Member comply with the provisions of Chapter 3.1. on evaluation of Veterinary Services, and, if relevant, with the provisions of Chapter 4.3. on zoning and compartmentalisation.~~~~The provisions of the above mentioned articles are based on the principles developed in Chapter 1.4. and the following premises:~~

- ~~1. the sheep population of the country or zone includes a range of genotypes known to be susceptible to scrapie;~~
- ~~2. the Veterinary Services have the competence, capacity and mandate to investigate, diagnose and report scrapie, if present;~~
- ~~3. the absence of scrapie over a long period of time can be substantiated by effective disease investigation and reporting by the Veterinary Services of an OIE Member.~~

~~Article 14.9.15.~~~~**Requirements to declare a country or zone historically free from scrapie**~~~~A country or zone may be recognised free from scrapie without having applied the requirements of Article 14.9.3. when:~~

- ~~1. scrapie has been notifiable for at least 25 years; and~~
- ~~2. a formal programme of targeted surveillance and monitoring, which includes clinical suspects, animals dead on farm and aged sheep and goats, can be documented as having been in place for at least 10 years; and~~
- ~~3. the presence of a range of scrapie susceptible genotypes in this sheep population can be documented; and~~
- ~~4. appropriate measures to prevent scrapie introduction can be documented as having been in place for at least 25 years; and~~
 - ~~a) either scrapie has never been reported; or~~
 - ~~b) no case of scrapie has been reported for at least 25 years.~~

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CHAPTER 15.3 .

CLASSICAL SWINE FEVER

Article 15.3.1.

General provisions

For the purposes of *international trade*, classical swine fever (CSF) is defined as an *infection* of domestic pigs.

Domestic pig is defined as 'all domesticated pigs, permanently captive or farmed free range, used for the production of *meat* for consumption, for the production of other commercial products or for breeding these categories of pigs.

The pig is the only natural host for classical swine fever (CSF) virus. The definition of pig includes all varieties of *Sus scrofa*, both domestic and wild. For the purposes of this chapter, a distinction is made between domestic pig and wild pig (including feral pigs) populations.

Pigs exposed to CSF virus prenatally may be persistently infected throughout life and may have an *incubation period* of several months before showing signs of *disease*. Pigs exposed postnatally have an *incubation period* of 2-14 days, and are usually infective between post-infection days 5 and 14, but up to 3 months in cases of chronic *infections*.

For the purposes of *international trade*, a Member should not impose trade bans in response to a notification of *infection* with classical swine fever virus in wild pigs according to Article 1.2.3. of the *Terrestrial Code* after the Member confirms that Article 15.3.2. is appropriately implemented.

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

Article 15.3.2.

Determination of the CSF status of a country, zone or compartment

The CSF status of a country, *zone* or *compartment* can only be determined after considering the following criteria in domestic and wild pigs, as applicable:

1. CSF should be notifiable in the whole territory, and all clinical signs suggestive of CSF should be subjected to appropriate field and/or *laboratory* investigations;
2. an on-going awareness programme should be in place to encourage reporting of all *cases* suggestive of CSF;
3. the *Veterinary Authority* should have current knowledge of, and authority over, all domestic pigs in the country, *zone* or *compartment*;
4. the *Veterinary Authority* should have current knowledge about the population and habitat of wild pigs in the country or *zone*;
5. for domestic pigs, appropriate *surveillance*, capable of detecting the presence of *infection* even in the absence of clinical signs, and the risk posed by wild pigs, is in place; this may be achieved through a *surveillance* programme in accordance with Articles 15.3.23. to 15.3.28.

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6. for wild pigs, if present in the country or *zone*, a *surveillance* programme is in place according to Article 15.3.28., taking into account the presence of natural and artificial boundaries, the ecology of the wild pig population, and an assessment of the risks of disease spread.
7. Based on the assessed risk of spread within the wild pig population, and according to Article 15.3.26., the domestic pig population should be separated from the wild pig population by appropriate biosecurity measures to prevent transmission of CSF from wild to domestic pigs.

Article 15.3.3.

CSF free country, zone or compartment

A country, *zone* or *compartment* may be considered free from CSF when *surveillance* in accordance with Articles 15.3.23. to 15.3.28. has been in place for at least 12 months, and when:

1. there has been no *outbreak* of CSF in domestic pigs during the past 12 months;
2. no evidence of CSFV infection has been found in domestic pigs during the past 12 months;
3. no vaccination against CSF has been carried out in domestic pigs during the past 12 months unless there are means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs;
4. imported domestic pigs comply with the requirements in Article 15.3.5. or Article 15.3.6.

Article 15.3.4.

Recovery of free status

Should a CSF *outbreak* occur in a free country, *zone* or *compartment*, the free status may be restored where *surveillance* in accordance with Articles 15.3.23. to 15.3.28. has been carried out with negative results either:

1. 3 months after the last *case* where a *stamping-out policy* without vaccination is practised;

OR

2. where a *stamping-out policy* with emergency vaccination is practised:
 - a) 3 months after the last *case* and the *slaughter* of all vaccinated animals, or
 - b) 3 months after the last *case* without the *slaughter* of vaccinated animals where there are means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs;

OR

3. where a *stamping-out policy* is not practised, the provisions of Article 15.3.3. should be followed.

Article 15.3.5.

Recommendations for importation from countries, zones or compartments free of CSF

for domestic pigs

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

1. showed no clinical sign of CSF on the day of shipment;
2. were kept in a country, *zone* or *compartment* free of CSF since birth or for at least the past 3 months;
3. have not been vaccinated against CSF, nor are they the progeny of vaccinated sows, unless there are means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs.

Article 15.3.6.

Recommendations for importation from CSF infected countries or zones

for domestic pigs

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

1. showed no clinical sign of CSF on the day of shipment;
2. were kept since birth or for the past 3 months in a CSF free *compartment*;
3. have not been vaccinated against CSF nor are they the progeny of vaccinated sows, unless there are means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs.

Article 15.3.7.

Recommendations for the importation of wild pigs

Regardless of the CSF status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of CSF on the day of shipment;
2. were kept in a *quarantine station* for 40 days prior to shipment, and were subjected to a virological test and a serological test performed at least 21 days after entry into the *quarantine station*, with negative results;
3. have not been vaccinated against CSF, unless there are means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs.

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Article 15.3.8.

Recommendations for importation from countries, zones or compartments free of CSFfor semen of domestic pigs

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

1. the donor animals:
 - a) were kept in a country, *zone* or *compartment* free of CSF since birth or for at least 3 months prior to collection;
 - b) showed no clinical sign of CSF on the day of collection of the semen;
2. the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5. and Chapter 4.6.

Article 15.3.9.

Recommendations for importation from CSF infected countries or zonesfor semen of domestic pigs

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

1. the donor animals:
 - a) were kept in a *compartment* free of CSF since birth or for at least 3 months prior to collection;
 - b) showed no clinical sign of CSF on the day of collection of the semen and for the following 40 days;
 - c) met one of the following conditions:
 - i) have not been vaccinated against CSF and were subjected to a serological test performed at least 21 days after collection, with negative results; or
 - ii) have been vaccinated against CSF and were subjected to a serological test in accordance with the *Terrestrial Manual* performed at least 21 days after collection and it has been conclusively demonstrated that any antibody is due to the vaccine; or
 - iii) have been vaccinated against CSF and were subjected to a virological test performed in accordance with the *Terrestrial Manual* on a sample taken on the day of collection and it has been conclusively demonstrated that the boar is negative for virus genome;
2. the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5. and Chapter 4.6.

Article 15.3.10.

Recommendations for importation from countries, zones or compartments free of CSFfor *in vivo* derived embryos of domestic pigs

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

1. the donor females showed no clinical sign of CSF on the day of collection of the embryos;
2. the embryos were collected, processed and stored in conformity with the provisions of Chapter 4.7. or Chapter 4.9., as relevant.

Article 15.3.11.

Recommendations for importation from CSF infected countries or zonesfor *in vivo* derived embryos of domestic pigs

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

1. the donor females:
 - a) were kept in a *compartment* free of CSF since birth or for at least 3 months prior to collection;
 - b) showed no clinical sign of CSF on the day of collection of the embryos and for the following 40 days;
 - c) and either:
 - i) have not been vaccinated against CSF and were subjected, with negative results, to a serological test performed at least 21 days after collection; or
 - ii) have been vaccinated against CSF and were subjected to a serological test performed at least 21 days after collection and it has been conclusively demonstrated by means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), that any antibody is due to the vaccine;
2. the embryos were collected, processed and stored in conformity with the provisions of Chapter 4.7. or Chapter 4.9., as relevant.

Article 15.3.12.

Recommendations for importation from countries, zones or compartments free of CSFfor fresh meat of domestic pigs

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

1. have been kept in a country, *zone* or *compartment* free of CSF ~~since birth or for at least the past 3 months~~, or which have been imported in accordance with Article 15.3.5. or Article 15.3.6.;

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2. have been slaughtered in an approved *abattoir*, have been subjected to ante-mortem and post-mortem inspections in accordance to Chapter 6.2. and have been found free of any sign suggestive of CSF.

Article 15.3.13.

Recommendations for the importation of fresh meat of wild pigs

Regardless of the CSF status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting the entire consignment of *meat* comes from animals:

1. which have been subjected to a post-mortem inspection in accordance with Chapter 6.2. in an approved examination centre, and have been found free of any sign suggestive of CSF;
2. from each of which a sample has been collected and has been subjected to a virological test and a serological test for CSF, with negative results.

Article 15.3.14.

Recommendations for the importation of meat and meat products of pigs, or for products of animal origin (from fresh meat of pigs) intended for use in animal feeding, for agricultural or industrial use, or for pharmaceutical or surgical use

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

1. have been prepared:
 - a) exclusively from *fresh meat* meeting the conditions laid down in Article 15.3.12.;
 - b) in a processing establishment:
 - i) approved by the *Veterinary Authority* for export purposes;
 - ii) processing only *meat* meeting the conditions laid down in Article 15.3.12.;

OR

2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSF virus in conformity with one of the procedures referred to in Article 15.3.21. and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus

Article 15.3.15.

Recommendations for the importation of products of animal origin (from pigs, but not derived from fresh meat) intended for use in animal feeding

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

1. originated from domestic pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or

2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSF virus in accordance with Article 15.3.20. and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 15.3.16.

Recommendations for the importation of products of animal origin (from pigs, but not derived from fresh meat) intended for agricultural or industrial use

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

1. originated from domestic pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or
2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSF virus (under study) and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 15.3.17.

Recommendations for the importation of bristles

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

1. originated from domestic pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or
2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSF virus (under study) and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 15.3.18.

Recommendations for the importation of litter and manure

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

1. originated from domestic pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or
2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSF virus (under study) and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 15.3.19.

Recommendations for the importation of skins and trophies derived from wild pigs

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

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1. originated from domestic pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or
2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSF virus in conformity with one of the procedures referred to in Article 15.3.22. and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 15.3.20.

Procedures for the inactivation of the CSF virus in swill

For the inactivation of classical swine fever (CSF) viruses likely to be present in swill, one of the following procedures should be used:

1. the swill should be maintained at a temperature of at least 90°C for at least 60 minutes, with continuous stirring; or
2. the swill should be maintained at a temperature of at least 121°C for at least 10 minutes at an absolute pressure of 3 bar.

Article 15.3.21.

Procedures for the inactivation of the CSF virus in meat

For the inactivation of viruses present in *meat*, one of the following procedures should be used:

1. Heat treatment

Meat shall be subjected to one of the following treatments:

- a) heat treatment in a hermetically sealed container with a Fo value of 3.00 or more;
- b) heat treatment at a minimum temperature of 70°C, which **must** should be reached throughout the *meat*.

2. Natural fermentation and maturation

The *meat* should be subjected to a treatment consisting of natural fermentation and maturation having the following characteristics:

- a) an aw value of not more than 0.93, or
- b) a pH value of not more than 6.0.

Hams should be subjected to a natural fermentation and maturation process for at least 190 days and loins for 140 days.

3. Dry cured pork meat

- a) Italian style hams with bone-in should be cured with salt and dried for a minimum of 313 days.
- b) Spanish style pork *meat* with bone-in should be cured with salt and dried for a minimum of 252 days for Iberian hams, 140 days for Iberian shoulders, 126 days for Iberian loin, and 140 days for Serrano hams.

Article 15.3.22.

Procedures for the inactivation of the CSF virus in trophies

For the inactivation of CSF viruses likely to be present in trophies, one of the following procedures should be used:

1. boiling in water for an appropriate time so as to ensure that any matter other than bone, tusks or teeth is removed;
2. gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher);
3. soaking, with agitation, in a 4% (w/v) solution of washing soda (sodium carbonate - Na₂CO₃) maintained at pH 11.5 or above for at least 48 hours;
4. soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained at below pH 3.0 for at least 48 hours; wetting and dressing agents may be added;
5. in the case of raw hides, salting for at least 28 days with sea salt containing 2% washing soda (sodium carbonate - Na₂CO₃).

Article 15.3.23.

Surveillance: introduction

Articles 15.3.23. to 15.3.28. define the principles and provide a guide on the *surveillance* for CSF, complementary to Chapter 1.4., applicable to Members seeking to determine their CSF status. This may be for the entire country or a *zone*. Guidance for Members seeking free status following an *outbreak* and for the maintenance of CSF status is also provided.

The impact and epidemiology of CSF differ widely in different regions of the world, and it is, therefore, impossible to provide specific recommendations for all situations. The *surveillance* strategies employed for demonstrating freedom from CSF at an acceptable level of confidence will need to be adapted to the local situation. For example, the approach **must should** be tailored in order to prove freedom from CSF for a country or *zone* where wild pigs provide a potential reservoir of *infection*, or where CSF is present in adjacent countries. The method **must should** examine the epidemiology of CSF in the region concerned and adapt to the specific risk factors encountered. This should include provision of scientifically based supporting data. There is, therefore, latitude available to Members to provide a well-reasoned argument to prove that absence of classical swine fever virus (CSFV) infection is assured at an acceptable level of confidence.

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Surveillance for CSF should be in the form of a continuing programme designed to establish that a population in a country, *zone* or *compartment* is free from CSFV infection or to detect the introduction of CSFV into a population already recognized as free. Consideration should be given to the specific characteristics of CSF epidemiology which include: the role of swill feeding and the impact of different production systems on *disease* spread, the role of semen in transmission of the virus, the lack of pathognomonic gross lesions and clinical signs, the frequency of clinically inapparent *infections*, the occurrence of persistent and chronic *infections*, and the genotypic, antigenic, and virulence variability exhibited by different strains of CSFV. Serological cross-reactivity with other pestiviruses has to be taken into consideration when interpreting data from serological surveys. A common route by which ruminant pestiviruses can infect pigs is the use of vaccines contaminated with bovine viral diarrhoea virus (BVDV).

For the purposes of this chapter, virus *infection* means presence of CSFV as demonstrated directly by virus isolation, the detection of virus antigen or virus nucleic acid, or indirectly by seroconversion which is not the result of vaccination.

Article 15.3.24.

Surveillance: general conditions and methods

1. A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. A procedure should be in place for the rapid collection and transport of samples to an accredited *laboratory* as described in the *Terrestrial Manual*.
2. The CSF *surveillance* programme should:
 - a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious *cases*. Farmers and workers, who have day-to-day contact with livestock, as well as diagnosticians, should report promptly any suspicion of CSF to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. Since many strains of CSFV do not induce pathognomonic gross lesions or clinical signs, cases in which CSF cannot be ruled out should be immediately investigated employing clinical, pathological, and *laboratory* diagnosis. This requires that sampling kits and other equipment are available to those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in CSF diagnosis, epidemiological evaluation, and control;
 - b) implement, when relevant, regular and frequent clinical inspections and serological testing of high-risk groups of animals (for example, where swill feeding is practised), or those adjacent to a CSF infected country or *zone* (for example, bordering areas where infected wild pigs are present).

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

Article 15.3.25.

Surveillance strategies1. Introduction

There are two basic strategies that can be employed for CSF *surveillance* depending on the purpose of the Member for seeking recognition of freedom from CSF. In countries free of CSF, *surveillance* programmes should be designed to detect the introduction of CSFV into domestic or wild swine. The optimal strategy to meet this objective is most often targeted *surveillance*.

The population covered by *surveillance* aimed at detecting *disease* and *infection* should include domestic and wild pig populations within the country or *zone* to be recognised as free from CSFV infection. Such *surveillance* may involve opportunistic testing of samples submitted for other purposes, but a more efficient and effective strategy is one which includes targeted *surveillance*.

Surveillance is targeted to the pig population which presents the highest risk of *infection* (for example, swill fed farms, pigs reared outdoors or farms in proximity to infected wild pigs). Each Member will need to identify its individual risk factors. These may include: temporal and spatial distribution of past *outbreaks*, pig movements and demographics, etc.

For reasons of cost, the longevity of antibody levels, as well as the existence of clinically inapparent *infections* and difficulties associated with differential diagnosis of other *diseases*, serology is often the most effective and efficient *surveillance* methodology. In some circumstances, which will be discussed later, clinical and virological *surveillance* may also have value.

The Member should justify the *surveillance* strategy chosen as adequate to detect the presence of CSFV infection in accordance with Chapter 1.4. and the epidemiological situation. Cumulative survey results in combination with the results of passive *surveillance*, over time, will increase the level of confidence in the *surveillance* strategy. If a Member wishes to apply for recognition by other Members of a specific *zone* within the country as being free from CSFV infection, the design of the *surveillance* strategy and the basis for any sampling process would need to be aimed at the population within the *zone*.

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

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

Annex XXXVI (contd)

Irrespective of the testing system employed, the *surveillance* system design should anticipate the occurrence of false positive reactions. This is especially true of the serological diagnosis of CSF because of the recognized cross-reactivity with ruminant pestiviruses. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether or not they are indicative of CSFV infection. This should involve confirmatory and differential tests for pestiviruses, as well as further investigations concerning the original sampling unit as well as animals which may be epidemiologically linked.

2. Clinical and virological surveillance

Beyond their role in targeted *surveillance*, clinical and virological *surveillance* for CSF has two aims: a) to shorten the period between introduction of CSF virus into a *disease* free country or *zone* and its detection, and b) to confirm that no unnoticed *outbreaks* have occurred.

In the past, clinical identification of *cases* was the cornerstone of early detection of CSF. However, emergence of low virulence strains of CSF, as well as new *diseases* - such as post-weaning multisystemic wasting syndrome and porcine dermatitis and nephropathy syndrome - have made such reliance less effective, and, in countries where such *diseases* are common, can add significant risk of masking the presence of CSF.

The spectrum of *disease* signs and gross pathology seen in CSF infections, along with the plethora of other agents that can mimic CSF, renders the value of clinical examination alone somewhat inefficient as a *surveillance* tool. These factors, along with the compounding effects of concurrent *infections* and *diseases* caused by ruminant pestiviruses, dictate the need for *laboratory* testing in order to clarify the status of CSF suspects detected by clinical monitoring.

Nevertheless, clinical presentation should not be ignored as a tool for early detection; in particular, any cases where clinical signs or lesions consistent with CSF are accompanied by high morbidity and/or mortality should be investigated without delay. In CSFV infections involving low virulence strains, high mortality may only be seen in young animals. Otherwise close physical examination of susceptible animals is useful as a selection criteria for CSF *surveillance*, particularly in diagnostic *laboratories* or *slaughter* establishments or when applied to high risk populations such as swill feeding operations.

The difficulties in detecting chronic *disease* manifested by non-specific clinical signs and delayed seroconversion and seronegativity, in persistently infected piglets, both of which may be clinically normal, makes virological investigation essential. As part of a *herd* investigation, such animals are likely to be in a minority and would not confound a diagnosis based on serology. Individually or as part of recently mixed batches, such animals may, however, escape detection by this method. A holistic approach to investigation, taking note of *herd* history, pig, personnel and *vehicle* movements and disease status in neighbouring *zones* or countries, can also assist in targeting *surveillance* in order to increase efficiency and enhance the likelihood of early detection.

The labour-intensive nature of clinical, pathological and virological investigations, along with the smaller 'window of opportunity' inherent in virus, rather than antibody detection, has, in the past, resulted in greater emphasis being placed on mass serological screening as the best method for *surveillance*. However, *surveillance* based on clinical and pathological inspection and virological testing should not be underrated. If targeted at high risk groups in particular, it provides an opportunity for early detection that can considerably reduce the subsequent spread of *disease*. *Herds* predominated by adult animals, such as nucleus *herds* and artificial insemination studs, are particularly useful groups to monitor, since *infection* by low virulence viruses in such groups may be clinically inapparent, yet the degree of spread may be high.

Clinical and virological monitoring may also provide a high level of confidence of rapid detection of *disease* if a sufficiently large number of clinically susceptible animals is examined. In particular, molecular detection methods are increasingly able to offer the possibility of such large-scale screening for the presence of virus, at reasonable cost.

Wild pigs and, in particular, those with a wholly free-living existence, rarely present the opportunity for clinical observation, but should form part of any *surveillance* scheme and should, ideally, be monitored for virus as well as antibody.

Vaccine design and diagnostic methodologies, and in particular methods of virus detection, are increasingly reliant on up-to-date knowledge of the molecular, antigenic and other biological characteristics of viruses currently circulating and causing *disease*. Furthermore, epidemiological understanding of the pathways of spread of CSFV can be greatly enhanced by molecular analyses of viruses in endemic areas and those involved in *outbreaks* in disease free areas. It is therefore essential that CSFV isolates are sent regularly to the regional OIE Reference Laboratory for genetic and antigenic characterisation.

3. Serological surveillance

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

- a) natural *infection* with CSFV;
- b) legal or illegal vaccination against CSF;
- c) maternal antibodies derived from an immune sow (maternal antibodies) are usually found only up to 4.5 months of age, but, in some individuals, maternal antibodies can be detected for considerably longer periods;
- d) cross-reactions with other pestiviruses;
- e) non-specific reactors.

The *infection* of pigs with other pestiviruses may complicate a *surveillance* strategy based on serology. Antibodies to bovine viral diarrhoea virus (BVDV) and Border disease virus (BDV) can give positive results in serological tests for CSF, due to common antigens. Such samples will require differential tests to confirm their identity. Although persistently infected immunotolerant pigs are themselves seronegative, they continuously shed virus, so the prevalence of antibodies at the *herd* level will be high. Chronically infected pigs may have undetectable or fluctuating antibody levels.

It may be possible to use sera collected for other survey purposes for CSF *surveillance*. However, the principles of survey design described in this chapter and the requirement for statistical validity should not be compromised.

The discovery of clustering of seropositive reactions should be foreseen. It may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of *infection* by field strains or other pestiviruses. Because clustering may signal field strain *infection*, the investigation of all instances **must should** be incorporated in the survey design. Clustering of positive animals is always epidemiologically significant and therefore should be investigated.

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In countries or *zones* that are moving towards freedom, serosurveillance can provide valuable information on the disease status and efficacy of any control programme. Targeted serosurveillance of young stock will indicate whether newly circulating virus is present, although the presence of maternal antibody will also need to be considered. If conventional attenuated vaccine is currently being used or has been used in the recent past, serology aimed at detecting the presence of field virus will likewise need to be targeted at unvaccinated animals and after the disappearance of maternal antibody. General usage in such situations may also be used to assess levels of vaccine coverage.

Vaccines also exist which, when used in conjunction with dedicated serological tests, may allow discrimination between vaccinal antibody and that induced by field *infection*. Such tools, described in the *Terrestrial Manual*, will need to be fully validated. They do not confer the same degree of protection as that provided by conventional vaccines, particularly with respect to preventing transplacental *infections*. Furthermore, serosurveillance using such differentiation requires cautious interpretation on a *herd* basis.

The results of random or targeted serological surveys are important in providing reliable evidence that no CSFV infection is present in a country or *zone*. It is therefore essential that the survey be thoroughly documented.

The free status should be reviewed whenever evidence emerges to indicate that changes which may alter the underlying assumption of continuing historical freedom, has occurred. Such changes include but are not limited to:

- f) an emergence or an increase in the prevalence of CSF in countries or *zones* from which live pigs or products are imported;
- g) an increase in the volume of imports or a change in their country or *zone* of origin;
- h) an increase in the prevalence of CSF in the domestic or wild pigs of adjacent countries or *zones*;
- i) an increased entry from, or exposure to, infected wild pig populations of adjacent countries or *zones*.

Article 15.3.26.

Countries, zones or compartments declaring freedom from CSF: additional surveillance procedures

1. Country or zone free of CSF

In addition to the general conditions described above, a Member seeking recognition of CSF freedom for the country or a *zone*, whether or not vaccination had been practised, should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances in and around the country or *zone* and will be planned and implemented according to the general conditions and methods described in this chapter, to demonstrate the absence of CSFV infection in domestic and wild pig populations. This requires the support of a national or other *laboratory* able to undertake identification of CSFV infection through virus detection and serological tests described in the *Terrestrial Manual*.

2. Compartment free of CSF

The objective of *surveillance* is to demonstrate the absence of CSFV infection in the *compartment*. The provisions of Chapter 4.3. should be followed. The effective separation of the two subpopulations should be demonstrated. To this end, a *biosecurity plan* that includes but is not limited to the following provisions should be implemented:

- a) proper containment of domestic pigs;
- b) control of movement of *vehicles* with cleaning and *disinfection* as appropriate;
- c) control of personnel entering into the *establishments* and awareness of risk of fomite spread;
- d) prohibition of introduction to the *establishments* of wild caught animals and their products;
- e) record of animal movements into and out of *establishments*;
- f) information and training programmes for farmers, processors, *veterinarians*, etc.

The *biosecurity plan* implemented also requires internal and external monitoring by the *Veterinary Authority*. This monitoring should include:

- g) periodic clinical and serological monitoring of *herds* in the country or *zone*, and adjacent wild pig populations following these recommendations;
- h) *herd* registration;
- i) official accreditation of *biosecurity plans*;
- j) periodic monitoring and review.

Monitoring the CSF status of wild and domestic pig populations outside the *compartment* will be of value in assessing the degree of risk they pose to the CSF free *compartment*. The design of a monitoring system is dependent on several factors such as the size and distribution of the population, the organisation of the *Veterinary Services* and resources available. The occurrence of CSF in wild and domestic pigs may vary considerably among countries. *Surveillance* design should be epidemiologically based, and the Member should justify its choice of design prevalence and level of confidence based on Chapter 1.4.

The geographic distribution and approximate size of wild pig populations need to be assessed as a prerequisite for designing a monitoring system. Sources of information may include government wildlife authorities, wildlife conservation organisations, hunter associations and other available sources. The objective of a *surveillance* programme when the *disease* is already known to exist should be to determine the geographic distribution and the extent of the *infection*.

Article 15.3.27.

Recovery of free status: additional surveillance procedures

In addition to the general conditions described in the above-mentioned articles, a Member seeking reestablishment of country or *zone* freedom from CSF should show evidence of an active *surveillance* programme to demonstrate absence of CSFV infection.

Annex XXXVI (contd)

Populations under this *surveillance* programme should include:

- a) *establishments* in the proximity of the *outbreak*;
- b) *establishments* epidemiologically linked to the *outbreak*;
- c) animals used to re-populate affected *establishments* and any *establishments* where contiguous culling is carried out;
- d) wild pig populations in the area of the *outbreak*.

In all circumstances, a Member seeking reestablishment of country or *zone* freedom from CSF with vaccination or without vaccination should report the results of an active and a passive *surveillance* programme in which the pig population undergoes regular clinical, pathological, virological, and/or serological examination, planned and implemented according to the general conditions and methods described in these recommendations. The *surveillance* should be based on a statistically representative sample of the populations at risk.

Article 15.3.28.

Surveillance for CSF in wild pigs

While the same principles apply, *surveillance* in wild pigs presents challenges beyond those encountered in domestic populations in each of the following areas:

- a) determination of the distribution, size and movement patterns associated with the wild pig population;
- b) assessment of the possible presence of CSF within the population;
- c) determination of the practicability of establishing a *zone*.

The design of a monitoring system for wild pigs is dependent on several factors such as the organisation of the *Veterinary Services* and resources available. The geographic distribution and approximate size of wild pig populations need to be assessed as a prerequisite for designing a monitoring system. Sources of information may include wildlife conservation organisations, hunter associations and other available sources. The objective of a *surveillance* programme is to determine if a given *disease* is present, and if so, at what prevalence.

Estimates of wild pig populations can be made using advanced methods (e.g. radio tracking, linear transect method, capture/recapture) or traditional methods based on the number of animals that can be hunted to allow for natural restocking (hunting bags).

For implementation of the monitoring programme, it will be necessary to define the limits of the territory over which wild pigs range in order to delineate the *epidemiological units* within the monitoring programme. It is often difficult to define *epidemiological units* for wild animals. The most practical approach is based on natural and artificial barriers.

The monitoring programme should also include animals found dead, road kills, animals showing abnormal behaviour or exhibiting gross lesions during dressing.

There may be situations where a more targeted *surveillance* programme can provide additional assurance. The criteria to define high risk areas for targeted *surveillance* include:

- a) areas with past history of CSF;
- b) sub-regions with large populations of wild pigs;
- c) border regions with CSF affected countries or *zones*;
- d) interface between wild and domestic pig populations;
- e) picnic and camping areas;
- f) farms with free-ranging pigs;
- g) garbage dumps;
- h) other risk areas determined by the *Veterinary Authority*.

— text deleted

