

## GLOSSARY

### *EPIDEMIOLOGICAL UNIT*

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

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## CHAPTER 1.1.

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

## Article 1.1.1.

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

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

## Article 1.1.2.

- 1) Member Countries shall make available to other Member Countries, through the OIE, whatever information is necessary to minimise the spread of important animal diseases, and their pathogenic agents, and to assist in achieving better worldwide control of these diseases.
- 2) To achieve this, Member Countries shall comply with the *notification* requirements specified in Articles 1.1.3. and 1.1.4.
- 3) For the purposes of this chapter, an 'event' means a single *outbreak* or a group of epidemiologically related *outbreaks* of a given ~~disease~~, **disease**, *infection* or *infestation* that is the subject of a *notification*. An event is specific to a pathogenic agent and strain, when appropriate, and includes all related *outbreaks* reported from the time of the **immediate notification within 24 hours** through to the final report. Reports of an event include susceptible species, number and geographical distribution of affected animals and *epidemiological units*.
- 4) To assist in the clear and concise exchange of information, reports shall conform as closely as possible to the OIE disease reporting format.
- 5) The detection of the pathogenic agent of a *listed disease* in an *animal* should be reported, even in the absence of clinical signs. Recognising that scientific knowledge concerning the relationship between diseases and their pathogenic agents is constantly developing and that the presence of a pathogenic agent does not necessarily imply the presence of a disease, Member Countries shall ensure, through their reports, that they comply with the spirit and intention of point 1) above.
- 6) In addition to notifying new findings in accordance with Articles 1.1.3. and 1.1.4., Member Countries shall also provide information on the measures taken to prevent the spread of diseases, ~~infections and infestations~~. Information shall include biosecurity and quarantine sanitary measures and including restrictions applied to the movement of *animals*, animal products, biological products and other miscellaneous objects which could by their nature be responsible for the transmission of diseases, ~~infections or infestations~~. In the case of diseases transmitted by *vectors*, the measures taken against such *vectors* shall also be specified.

## Article 1.1.3.

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

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

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

## Article 1.1.4.

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

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

## Article 1.1.5.

- ~~1) The *Veterinary Authority* of a country in which an *infected zone* is located shall inform the *Headquarters* when this zone or the entire country becomes free from the *disease*, *infection* or *infestation*.~~
- ~~2) A country or zone may be considered to have regained freedom from a specific *disease*, *infection* or *infestation* when all relevant conditions given in the *Terrestrial Code* have been fulfilled.~~

Annex 15 (contd)

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

## Article 1.1.65.

- 1) Although Member Countries are only required to notify *listed diseases*, ~~*infections and infestations*~~ and *emerging diseases*, they are encouraged to provide the OIE with other important animal health information.
- 2) The *Headquarters* shall communicate by email or through the interface of WAHIS to *Veterinary Authorities* all *notifications* received as provided in Articles 1.1.2. to 1.1.54. and other relevant information.



## CHAPTER 1.6.

**PROCEDURES FOR PUBLICATION OF A SELF-  
DECLARATION OF DISEASE FREEDOM,  
RECOGNITION OF AN OFFICIAL DISEASE ANIMAL  
HEALTH STATUS AND FOR ENDORSEMENT OF AN  
OFFICIAL CONTROL PROGRAMME RECOGNITION  
BY THE OIE**

## Article 1.6.1.

**General principles Publication by the OIE of a self-declaration of disease freedom by a Member Country**

A Member Country may wish to make a self-declaration as to the freedom of a country, zone or compartment from an OIE listed disease or another animal disease. The Member Country may inform the OIE of its claimed status and the OIE may publish the claim. Publication does not imply endorsement of the claim, and request that the OIE publish the self-declaration for information of OIE Member Countries.

A Member Country requesting the publication of a self-declaration should follow the Standard Operating Procedure (available on the OIE website)<sup>4</sup> for submission of a self-declaration of disease freedom and provide documented information on its compliance with the relevant chapters of the *Terrestrial Code*, including:

- = evidence that the disease is a *notifiable disease* in the entire country;
- = history of absence or eradication of the disease in the country, zone or compartment;
- = surveillance and early warning system for all relevant species in the country, zone or compartment;
- = measures implemented to maintain freedom in the country, zone or compartment.

The self-declaration may be published only after all the information provided has been received and an administrative and technical screening has been performed by the OIE. Publication does not imply endorsement of the claim of freedom by the OIE and does not reflect the official opinion of the OIE. Responsibility for the accuracy of the information contained in a self-declaration lies entirely with the OIE Delegate of the Member Country concerned.

An outbreak in a Member Country, a zone or a compartment having a self-declared free status results in the loss of the self-declared free status. Member Countries wishing to reclaim a lost free status should submit a new self-declaration following the procedure described in this article.

The OIE does not publish self-declarations for of freedom for from bovine spongiform encephalopathy (BSE), foot and mouth disease (FMD), contagious bovine pleuropneumonia (CBPP), African horse sickness (AHS), peste des petits ruminants (PPR) and classical swine fever (CSF) listed diseases listed under point 1) of Article 1.6.21bis.

<sup>4</sup> <http://www.oie.int/en/animal-health-in-the-world/self-declared-disease-status/>

## Annex 16 (contd)

Article 1.6.24bis.Application for Official recognition of animal health status and endorsement of official control programme by the OIE

A Member Countries may request:

- 1) official recognition of animal health status by the OIE of as to:
    - a) freedom of a country or zone from African horse sickness (AHS);
    - b) risk status of a country or zone with regard to bovine spongiform encephalopathy (BSE);
    - c) freedom of a country or zone from classical swine fever (CSF);
    - d) freedom of a country or zone from contagious bovine pleuropneumonia (CBPP);
    - e) freedom of a country or zone from foot and mouth disease (FMD), with or without vaccination;
    - f) freedom of a country or zone from peste des petits ruminants (PPR);
  - 2) endorsement by the OIE of:
    - a) an official control programme for contagious bovine pleuropneumonia;
    - b) an official control programme for foot and mouth disease;
    - c) an official control programme for peste des petits ruminants;
    - d) an official control programme for dog-mediated rabies.
- 1) the risk status of a country or zone with regard to BSE;
  - 2) the freedom of a country or zone from FMD, with or without vaccination;
  - 3) the freedom of a country or zone from CBPP;
  - 4) the freedom of a country or zone from AHS;
  - 5) the freedom of a country or zone from PPR;
  - 6) the freedom of a country or zone from CSF.

The OIE does not grant official recognition of animal health status or endorsement of an official control programme for other diseases other than those listed under points 1) and 2) above.

~~In these cases,~~ Member Countries should present documentation setting out the compliance of their *Veterinary Services* with the applicant country or zone with the provisions of Chapters 1.1., 1.4., 3.1. and 3.2. and 4.3. of the *Terrestrial Code*, when relevant, and with the provisions of the relevant disease-specific chapters in the *Terrestrial Code* and the *Terrestrial Manual*.

When requesting official recognition of disease animal health status or endorsement by the OIE of an official control programme, the Member Country should follow the Standard Operating Procedures (available on the OIE website) and submit to the OIE ~~Status Department~~ a dossier providing the information requested in the following Chapters (as appropriate): 1.7. (for AHS), 1.8. (for BSE), 1.9. (for CSF), 1.10. (for CBPP), 1.11. (for FMD) or 1.12 (for PPR).

## Annex 16 (contd)

The OIE framework for the official recognition and maintenance of disease *animal health status*, the endorsement of *official control programmes*, and their maintenance is described in relevant Resolutions No. XV (administrative procedures) and Resolution No. XVI (financial obligations) adopted during the 83rd General Session in May 2015, as well as in the Standard Operating Procedures (available on the OIE website)<sup>2</sup> adopted by the World Assembly of OIE Delegates.

The country or the *zone*, or the country having its *official control programme endorsed* will be included in the relevant lists of official *animal health status* or endorsed *official control programmes* only after the evidence submitted, based on the provisions of Chapters 1.7. to 1.12., has been adopted by the World Assembly of OIE Delegates.

When a Member Country requests official recognition of *animal health status* for a *zone*, the boundaries of the proposed *zone* should be clearly defined describing the geographical boundaries of the *zone*. When applying for a free *zone* being adjacent to another *zone* of the same status, it should be stated if the new *zone* is being merged or kept separate. If the proposed *zone* remains separate, details should be provided on the control of the movement of susceptible animals and their products between the *zones* in accordance with Chapter 4.3.

The overall objective of the OIE endorsed *official control programmes* is for Member Countries to progressively improve their animal health situation and eventually attain official recognition of *animal health status*. The *official control programme* should be applicable to the entire country even if certain measures are directed towards defined *zones*.

#### Article 1.6.3.

#### Maintenance of official recognition of animal health status and endorsement of official control programme by the OIE

Retention on the list requires that the information in relevant chapters be re-submitted annually and that changes in the epidemiological situation or other significant events should be reported to the OIE in accordance with the requirements in Chapter 1.1.

Non-compliance with the requirements for the maintenance of an *animal health status* results in the suspension of that status. Member Countries may apply for the recovery of a previously recognised status, following the provisions of the relevant disease-specific chapter, within 24 months after suspension. When the status has not been recovered within 24 months of its suspension, it is withdrawn and Member Countries should reapply following the procedure for the application for official recognition of *animal health status*.

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

- ▬ non-compliance with the timelines or performance indicators of the programme; or
- ▬ significant problems with the quality of the *Veterinary Services* as described in Section 3 of the *Terrestrial Code*; or
- ▬ an increase in the *incidence* of the disease that cannot be addressed by the programme.

<sup>2</sup> <http://www.oie.int/en/animal-health-in-the-world/official-disease-status/official-recognition-policy-and-procedures/>



## CHAPTER 3.4.

# VETERINARY LEGISLATION

### Article 3.4.1.

#### Introduction and objective

Good governance is a recognised global public good and is of critical importance to Member Countries. Legislation is a key element in achieving good governance.

*Veterinary legislation* should, at a minimum, provide a basis for *Competent Authorities* to meet their obligations as defined in the *Terrestrial Code* and the relevant recommendations of the Codex Alimentarius Commission. It should also comply with the relevant requirements of international instruments dedicated related to the mitigation of biological threats. In addition, there is an obligation for World Trade Organization (WTO) Members under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) to notify the WTO of changes in *sanitary measures*, including changes in legislation that affect trade, and provide relevant information.

For the purposes of the *Terrestrial Code*, *veterinary legislation* comprises all legal instruments necessary for the governance of the veterinary domain.

The objective of this chapter is to provide advice and assistance to Member Countries when formulating or modernising *veterinary legislation* so as to comply with OIE standards and other relevant international standards and instruments, thus ensuring good governance of the entire veterinary domain.

### Article 3.4.2.

#### Definitions

For the purposes of this chapter the following definitions apply:

**Hierarchy of legislation:** means the ranking of the legal instruments as prescribed under the fundamental law (e.g. the constitution) of a country. Respect for the hierarchy means that each legal instrument must comply with higher order legal instruments.

**Legal instrument:** means the legally binding rule that is issued by a body with the required legal authority to issue the instrument.

**Primary legislation:** means the legal instruments issued by the legislative body of a Member Country.

**Secondary legislation:** means the legal instruments issued by the executive body of a Member Country under the authority of primary legislation.

**Stakeholder:** means a person, group, or organisation that can affect or be affected by the impacts of *veterinary legislation*.

**Veterinary domain:** means all the activities that are directly or indirectly related to *animals*, their products and by-products, which help to protect, maintain and improve the animal health, and animal welfare and veterinary public health of humans, including by means of the protection of animal health and animal welfare, and food safety consistent with a One Health approach.

Annex 17 (contd)

## Article 3.4.3.

**General principles**1. Respect for the hierarchy of legislation

*Veterinary legislation* should **scrupulously** respect the hierarchy between primary legislation and secondary legislation, **to ensure that the primary legislation provides the legal basis for the application and enforcement of the secondary legislation.**

2. Legal basis

*Competent Authorities* should have available the primary legislation and secondary legislation necessary to carry out their activities at all administrative ~~and geographic~~ levels within the whole territory.

When primary legislation requires that secondary legislation be made to implement the legislative scheme, or to provide details to the legislative scheme, the relevant secondary legislation should be developed and enacted as soon as possible.

*Veterinary legislation* should be consistent with national, regional and international law, as appropriate, including civil, penal and administrative laws.

3. Transparency

*Veterinary legislation* should be inventoried and be readily accessible and intelligible for use, updating and modification, as appropriate.

*Competent Authorities* should ensure communication of *veterinary legislation* and related documentation to stakeholders.

4. Consultation

The drafting of new and revised legislation relevant to the veterinary domain should be a consultative process involving *Competent Authorities* and legal experts to ensure that the resulting legislation has been evaluated through an impact analysis, as appropriate, and is scientifically, technically and legally sound.

To facilitate implementation of the *veterinary legislation*, *Competent Authorities* should establish relationships with stakeholders, including taking steps to ensure that they participate in the development of significant legislation and required follow-up.

5. Quality of legislation and legal certainty

*Veterinary legislation* should be clear, **and** coherent, **and stable** ~~and transparent~~ **provide legal certainty** and protect citizens against unintended adverse side effects of legal instruments. ~~‡~~The legislation should be stable but regularly evaluated and updated as appropriate to be technically relevant, acceptable to society, able to be effectively implemented and sustainable in technical, financial and administrative terms. A high quality of legislation is essential for achieving legal certainty.

## Article 3.4.4.

**The drafting of veterinary legislation**

*Veterinary legislation* should:

- 1) be drafted in a manner that establishes clear authorities, rights, responsibilities and obligations (i.e. 'normative');
- 2) ~~be unambiguous, with clear and consistent syntax and vocabulary;~~

## Annex 17 (contd)

- 32) ~~be precise, accurate and consistent in the repeated use of the terminology; be accurate, clear, precise and unambiguous, and use consistent terminology;~~
- 3) include only definitions that are sufficient, necessary and relevant to the country;
- 4) contain no definitions or provisions that create any duplication or contradiction or unnecessary duplication or ambiguity;
- 5) include a clear statement of scope and objectives;
- 6) provide for the application of penalties and sanctions, either criminal or administrative, as appropriate to the situation; and
- 7) make provision for the financing needed for the execution of all activities of *Competent Authorities*; or these activities the financing should be ensured should be supported by appropriate financing in accordance with the national funding system. and
- 8) indicate when the legislation comes into effect and its impact on similar pre-existing legislation, in particular regulations.

## Article 3.4.5.

**Competent Authorities**

*Competent Authorities* should be legally mandated, capacitated have the necessary technical, administrative and infrastructure capacity and be organised to ensure that all necessary actions are taken quickly timely and coherently to effectively address animal health, animal welfare and veterinary public health and animal welfare matters of concern emergencies effectively.

*Veterinary legislation* should provide for a chain of command that is as effective, as possible (i.e. as short as possible, and with all responsibilities clearly defined). For this purpose, the responsibilities and powers of *Competent Authorities*, from the central level to those responsible for the implementation of legislation in the field, should be clearly defined. Where more than one *Competent Authority* is involved such as in relation to environmental, food safety or other public health matters, including biological threats and natural disasters, a reliable system of coordination and cooperation should be in place.

*Competent Authorities* should appoint technically qualified officials to take any actions needed for implementation or verification of compliance with the *veterinary legislation*, respecting the principles of independence and impartiality prescribed in Article 3.1.2.

1. Necessary powers of the Competent Authority

The *veterinary legislation* should also ensure that:

- a) ~~officials have the legal authority to intervene in accordance with the legislation and the penal procedures in force; the Competent Authority has all the necessary legal authorities to achieve the purposes of the legislation, including the powers to enforce the legislation;~~
- b) while executing their legal mandate, officials are protected against legal action and physical harm for actions carried out in good faith and in accordance with professional standards;
- c) the powers and functions of officials are explicitly and thoroughly listed to protect the rights of stakeholders and the general public against any abuse of authority. This includes respecting confidentiality and transparency, as appropriate; and
- d) at least the following powers are available through the primary legislation:
- i) access to premises and vehicles for carrying out inspections;
  - ii) access to documents;
  - iii) ~~taking samples;~~ application of specific sanitary measures such as:
    - ≡ taking samples;
    - ≡ retention (setting aside) of animals and goods commodities, pending a decision on final disposition;

Annex 17 (contd)

- v) = seizure and destruction of animals, products and food of animal origin commodities and fomites;
- vi) = suspension of one or more activities of an inspected establishment facility;
- vii) = temporary, partial or complete closure of inspected establishments facilities; and
- viii) = suspension or withdrawal of authorisations or approvals; and
- = restrictions on the movement of commodities, vehicles/vessels and, if required, other fomites and people;
- = establishment of compensation mechanisms;
- = listing disease for mandatory reporting; and
- = ordering of disinfection.

These essential powers must should be clearly identified as they can result in actions that may conflict with individual rights ascribed in fundamental laws.

2. Delegation of powers by the Competent Authority

The *veterinary legislation* should provide the possibility for *Competent Authorities* to delegate specific tasks related to official activities. The specific tasks delegated, the competencies required, the bodies to which the tasks are delegated, and the conditions of supervision by the Competent Authority and the conditions of withdrawals of delegations should be defined.

For this purpose, ~~the veterinary legislation~~ should:

- a) ~~define the field of activities and the specific tasks covered by the delegation;~~
- b) ~~provide for the control, supervision and, when appropriate, financing of the delegation;~~
- c) ~~define the procedures for making delegation;~~
- d) ~~define the competencies to be held by persons receiving delegation; and~~
- e) ~~define the conditions of withdrawals of delegations.~~

Article 3.4.6.

**Veterinarians and veterinary paraprofessionals**4. Veterinary medicine/science

In order to ensure quality in the conduct of veterinary medicine/science, ~~the veterinary legislation~~ should:

- a) ~~define the prerogatives of veterinarians and of the various categories of veterinary paraprofessionals that are recognised by the Member Country;~~
- b) ~~define the minimum initial and continuous educational requirements and competencies for veterinarians and veterinary paraprofessionals;~~
- c) ~~prescribe the conditions for recognition of the qualifications for veterinarians and veterinary paraprofessionals;~~
- d) ~~define the conditions to perform the activities of veterinary medicine/science; and~~
- e) ~~identify the exceptional situations, such as epizootics, under which persons other than veterinarians can undertake activities that are normally carried out by veterinarians.~~

## 2- The control of veterinarians and veterinary paraprofessionals

~~Veterinary legislation should provide a basis for regulation of veterinarians and veterinary paraprofessionals in the public interest. To that end, the legislation should:~~

- ~~a) describe the general system of control in terms of the political, administrative and geographic configuration of the country;~~
- ~~b) describe the various categories of veterinary paraprofessionals recognised by the Member Country in accordance with its needs, notably in animal health and food safety, and for each category, prescribe its training, qualifications, tasks and extent of supervision;~~
- ~~c) prescribe the powers to deal with conduct and competence issues, including licensing requirements, that apply to veterinarians and veterinary paraprofessionals;~~
- ~~d) provide for the possibility of delegation of powers to a professional organisation such as a veterinary statutory body; and~~
- ~~e) where powers have been so delegated, describe the prerogatives, the functioning and responsibilities of the mandated professional organisation.~~

## 1. The regulation of veterinarians and veterinary paraprofessionals

Veterinary legislation should provide a basis for the regulation of veterinarians and veterinary paraprofessionals in the interests of the public. To this end, the legislation should:

- a) provide for the creation of a veterinary statutory body;
- b) describe the prerogatives, the functioning and responsibilities of the veterinary statutory body;
- c) describe the general structure and system of regulation of veterinarians and veterinary paraprofessionals by the veterinary statutory body; and
- d) give authority to the veterinary statutory body to make secondary legislation or otherwise deal with provide basic principles for or regulate the following matters:
  - i) describe the various categories specialisations of veterinarians and categories of veterinary paraprofessionals recognised in the country in accordance with its needs, notably in animal health, animal welfare and food safety;
  - ii) define the prerogatives of the various categories specialisations of veterinarians and categories of veterinary paraprofessionals that are recognised in the country;
  - iii) define the minimum initial and continuous educational requirements and competencies for the various categories specialisations of veterinarians and categories of veterinary paraprofessionals;
  - iv) prescribe the conditions for recognition of the qualifications for veterinarians and veterinary paraprofessionals;
  - v) define the conditions to perform the activities of veterinary medicine/science, including the extent of supervision for each category of veterinary paraprofessionals;
  - vi) prescribe the powers to deal with conduct and competence issues, including licensing requirements, that apply to veterinarians and veterinary paraprofessionals;
  - vii) identify the exceptional situations, such as epizootics, define the conditions (except those that are under the responsibilities of the Competent Authority) under which persons other than veterinarians can undertake activities that are normally carried out by veterinarians.

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2. If the veterinary legislation does not create a veterinary statutory body for the regulation of veterinarians and veterinary paraprofessionals, the legislation should at least address all the elements listed in paragraphs 1. d) (i) to (vii) to ensure quality in the conduct of veterinary medicine/science.

Article 3.4.7.

**Laboratories in the veterinary domain**1. Facilities

*Veterinary legislation* should define the role, responsibilities, obligations and quality requirements for:

- a) reference *laboratories*, which are responsible for controlling the veterinary diagnostic and analytical network, including the maintenance of reference methods;
- b) *laboratories* designated by the *Competent Authority* for carrying out the analysis of official samples; and
- c) *laboratories* recognised by the *Competent Authority* to conduct analyses **in-house testing** required under the legislation ~~e.g.~~ for the purposes of safety and quality control, e.g. bacteriological testing for pathogenic agents in milk at a dairy processing plant.

*Veterinary legislation* should define the conditions for the classification, approval, operations and supervision of each of these types of *laboratories*, including conditions for laboratory biosafety and biosecurity.

2. Reagents, diagnostic kits and biological agents and products

*Veterinary legislation* should provide a basis for actions to address the elements listed below:

- a) procedures for authorising the use and transfer of reagents, diagnostic kits and biological agents and products that are used to perform official analyses and other purposes approved by the *Competent Authority*;
- b) quality assurance by manufacturers and providers of reagents used in official analyses and other purposes approved by the *Competent Authority*; and
- c) **surveillance oversight** of marketing of reagents, diagnostic kits and biological agents and products where these can affect the quality of analyses required by the *veterinary legislation*.

3. Laboratory containment and control of biological agents and products

*Veterinary legislation* should make provisions for the effective containment and control of biological agents and products into, within and out of the laboratory, **including their disposal when applicable**, as described in Chapter 5.8. of the *Terrestrial Code* and Chapter 1.1.4. of the *Terrestrial Manual*.

Article 3.4.8.

**Health provisions relating to animal production**1. Identification and traceability

*Veterinary legislation* should provide a basis for actions to address all the elements in point 6) of Article 4.2.3.

2. Animal markets and other gatherings

*Veterinary legislation* should address, for animal markets and other commercially or epidemiologically significant animal gatherings, the following elements:

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- a) registration of animal markets and other animal gatherings;
- b) health measures to prevent *disease* transmission, including procedures for ~~cleaning and disinfection~~, and *animal welfare* measures; and
- c) provision for veterinary ~~checks~~ inspections.

3. Animal reproduction

*Veterinary legislation* should provide a basis for actions to address the health regulation of animal reproduction ~~as appropriate~~ in relation to the risk of disease transmission. Health regulations may be implemented at the level of *animals*, genetic material, establishments or operators.

4. Animal feed

*Veterinary legislation* should provide a basis for actions to address the elements listed below:

- a) standards for the production, composition and quality control of animal feed in relation to the risk of disease transmission;
- b) registration and, if necessary, approval of establishments and the provision of health requirements for relevant operations; and
- c) recall from the market of any product likely to present a hazard to human health or animal health.

5. Animal by-products

*Veterinary legislation* should provide a basis for actions to address the elements listed below:

- a) definition of the animal by-products subject to the legislation;
- b) rules for collection, transport, processing, use and disposal of animal by-products;
- c) registration and, if necessary, approval of establishments and the provision of health requirements for relevant operations; and
- d) rules to be followed by animal owners.

6. Disinfection

*Veterinary legislation* should provide a basis for actions to address the regulation and use of products and methods of *disinfection* relating to the prevention and control of animal *diseases*.

Article 3.4.9.

**Animal diseases**

*Veterinary legislation* should provide a basis for the *Competent Authorities* to manage diseases of importance to the country, present or not, and to list these diseases, guided by the recommendations in Chapters 1.1 and 1.2, as well as emerging diseases, using a risk-based approach. The legislation should also provide for the listing and mandatory reporting of diseases of importance to the country.

1. Surveillance

*Veterinary legislation* should provide a basis for the collection, transmission and utilisation of epidemiological data relevant to *diseases* listed by the *Competent Authority*.

Annex 17 (contd)2. Disease prevention and control

- a) *Veterinary legislation* should include general animal health measures applicable to all *diseases* and, if necessary, additional or specific measures such as *surveillance*, establishment of a regulatory programme or emergency response for particular *diseases* listed in the country.
- b) The legislation should also provide a basis for contingency plans to include the following for use in disease responses:
  - i) administrative and logistic organisation to activate, implement and coordinate activities;
  - ii) exceptional powers of the *Competent Authority*; and
  - iii) ~~special and temporary~~ measures to address all identified *risks* to human or animal health including accidental or deliberate introduction of biological agents or products.
- c) *Veterinary legislation* should provide for the financing of animal disease control measures, such as operational expenses and, as appropriate, owners' compensation in the event of *killing* or *slaughtering* of *animals* and seizure or destruction of carcasses, *meat*, animal feed or other things or the financing of these measures should be ensured in accordance with the national funding system.

3. Emerging diseases

*Veterinary legislation* should provide for measures to investigate and respond to *emerging diseases* including those due to natural, accidental or deliberate introduction of biological agents, using a risk-based approach.

Article 3.4.10.

**Animal welfare**1. General provisions

*Veterinary legislation* should provide a basis for actions to address the *animal welfare* related requirements in Section 7.

To this end, the legislation should contain, as a minimum, a legal definition of cruelty as an offence, and provisions for direct intervention of the *Competent Authority* in the case of neglect by animal keepers.

2. Stray dogs and other free-roaming animals

*Veterinary legislation* should provide a basis for actions to address the requirements in Chapter 7.7. and, as appropriate, prohibition of the abandonment of *animals*, and management of abandoned *animals*, including transfer of ownership, veterinary interventions and *euthanasia*.

Article 3.4.11.

**Veterinary medicines and biologicals medicinal products**

*Veterinary legislation* should provide a basis for assuring the quality of *veterinary medicines and biologicals medicinal products* and minimising the *risk* to human, animal and environmental health associated with their use, including the development of antimicrobial resistance.

1. General measures

*Veterinary legislation* should provide a basis for actions to address the elements listed below:

- a) definition of *veterinary medicines and biologicals medicinal products*, including any specific exclusions; and

## Annex 17 (contd)

- b) regulation of the importation, manufacture, safety, efficacy, distribution and usage of, and commerce in, ~~veterinary medicines and biologicals~~ medicinal products, including laboratory biosafety and biosecurity measures.
2. Raw materials for use in veterinary ~~medicines and biologicals~~ medicinal products
- Veterinary legislation* should provide a basis for actions to address the elements listed below:
- a) quality standards for raw materials used in the manufacture or composition of ~~veterinary medicines and biologicals~~ medicinal products and arrangements for checking quality;
- b) ~~establishment of the withdrawal periods and maximum residue limits for veterinary medicines and biologicals, as appropriate; and~~
- ~~eb)~~ requirements for restrictions on substances in ~~veterinary medicines and biologicals~~ medicinal products that may, through their effects, interfere with the interpretation of veterinary diagnostic test results or the conduct of other veterinary checks.
3. Authorisation of veterinary ~~medicinal products, medicines and biologicals~~
- a) *Veterinary legislation* should ensure that only authorised ~~veterinary medicines and biologicals~~ medicinal products may be placed on the market.
- b) Special provisions should be made for:
- i) veterinary medicinal products incorporated into medicated feed;
- ii) products prepared by authorised ~~veterinarians~~ or authorised pharmacists; ~~and~~
- iii) emergencies and temporary situations; and
- iv) establishment of withdrawal periods for relevant veterinary medicinal products and maximum residue limits for the active substance contained in each such product.
- c) *Veterinary legislation* should address the technical, administrative and financial conditions associated with the granting, renewal, refusal and withdrawal of authorisations.
- d) In defining the procedures for seeking and granting authorisations, the legislation should:
- i) describe the ~~role~~ responsibilities of the relevant *Competent Authorities*; and
- ii) establish rules providing for the transparency in decision making.
- e) *Veterinary legislation* may provide for the possibility of recognition of the equivalence of authorisations made by other countries.
4. Quality of veterinary ~~medicines and biologicals~~
- ~~*Veterinary legislation* should address the following elements:~~
- ~~a)- the conduct of clinical and non-clinical trials to verify all claims made by the manufacturer;~~
- ~~b)- conditions for the conduct of trials;~~
- ~~c)- qualifications of experts involved in trials; and~~
- ~~d)- surveillance for adverse effects arising from the use of veterinary medicines and biologicals.~~

Annex 17 (contd)54. Establishments producing, storing and wholesaling veterinary medicines and biologicals medicinal products

*Veterinary legislation* should provide a basis for actions to address the following elements:

- a) registration or authorisation of all operators manufacturing importing, storing, processing, wholesaling or otherwise distributing ~~veterinary medicines and biologicals~~ medicinal products or raw materials for use in making ~~veterinary medicines and biologicals~~ medicinal products;
- b) definition of the responsibilities of operators;
- c) good manufacturing practices appropriate;
- d) reporting on adverse effects to the *Competent Authority*; and
- e) mechanisms for traceability and recall.

65. Retailing, use and traceability of veterinary medicines and biologicals medicinal products

*Veterinary legislation* should provide a basis for actions to address the following elements:

- a) control over the distribution of ~~veterinary medicines and biologicals~~ medicinal products and arrangements for traceability, recall and conditions of use;
- b) establishment of rules for the prescription and provision of ~~veterinary medicines and biologicals~~ medicinal products to end users;
- c) restriction to veterinarians or other authorised professionals and, as appropriate, authorised ~~veterinary paraprofessionals~~ of commerce in veterinary medicines and biologicals medicinal products that are subject to prescription;
- d) obligation of veterinarians, other authorised professionals or authorised veterinary paraprofessionals to inform end users of the withdrawal periods of relevant veterinary medicinal products and the obligation of end users to observe those withdrawal periods when using those products;
- ~~e)~~ the supervision by an authorised professional of organisations approved for holding and use of ~~veterinary medicines and biologicals~~ medicinal products;
- ~~ef)~~ the regulation of advertising claims and other marketing and promotional activities; and
- ~~fg)~~ reporting on adverse effects to the *Competent Authority*.

Article 3.4.12.

**Human food production chain**

*Veterinary legislation* should provide a basis for actions to safeguard the human food production chain through controls at all critical steps, consistent with national food safety standards and taking into account the risk of accidental and deliberate contamination. The role of the *Veterinary Services* in food safety is described in Chapter 6.2.

**1. General provisions**

*Veterinary legislation* should provide a basis for actions to address the following elements:

- a) the conduct of veterinary ante- and post-mortem inspections at slaughterhouses/abattoirs in accordance with Chapter 6.3;
- ~~ab)~~ controls over all stages of the production, processing and distribution of food of animal origin;

Annex 17 (contd)

- ~~bc)~~ recording all significant animal and public health events that occur during primary production including slaughter;
  - ~~ed)~~ giving operators of food production premises the primary responsibility for compliance with food safety requirements, including traceability established by the *Competent Authority*;
  - ~~de)~~ inspection for compliance with food standards, where this is relevant to health or safety;
  - ~~ef)~~ inspection and audit of premises;
  - ~~fg)~~ prohibition of the marketing of products not fit for human consumption; and
  - ~~gh)~~ provisions for recall from the marketplace of all products likely to be hazardous for human or animal health.
2. Products of animal origin intended for human consumption

*Veterinary legislation* should provide a basis for actions to address the following elements:

- ~~a)~~ ~~arrangements for inspection and audit~~;
- ~~b)~~ ~~the conduct of inspection and audit~~;
- ~~ea)~~ health standards including measures to control diseases, and monitoring and enforcement of maximum residue levels (MRL); ~~and~~
- ~~eb)~~ the application use of health identification marks that are visible to the intermediary or and final user visible marks that indicate the product has been inspected.

The *Competent Authority* should have the necessary powers and means to rapidly withdraw any products deemed to be hazardous from the food chain or to prescribe uses or treatments that ensure the safety of such products for human or animal health.

3. Operators responsible for premises and establishments pertaining to the food chain

*Veterinary legislation* should provide a basis for actions to address the following elements as appropriate:

- a) registration of premises and establishments by the *Competent Authority*;
- b) the use of *risk*-based management procedures; and
- c) prior authorisation of operations that are likely to constitute a significant *risk* to human or animal health.

Article 3.4.13.

**Import and export procedures and veterinary certification**

*Veterinary legislation* should provide a basis for actions to address the elements ~~relating to import and export procedures and veterinary certification~~ referred to in Sections 2 Risk Analysis and Section 5 Trade measures, import/export procedures and veterinary certification.



## CHAPTER 4.Y.

# OFFICIAL CONTROL PROGRAMMES MANAGEMENT OF OUTBREAKS OF FOR LISTED AND EMERGING AND LISTED DISEASES

## Article 4.Y.1.

## Introduction

When a *listed disease or emerging disease, including a zoonosis*, occurs in a Member Country, the *Veterinary Services Authority* should implement *a response control measures* proportionate to the likely impact of the disease and as a result of a *risk analysis*, in order to minimise its spread and consequences and, if possible, eradicate it. These measures can vary from rapid response (e.g. *the first occurrence to of a new hazard disease*) and management of *outbreaks*, to long-term control (e.g. of an endemic disease) *infection or infestation*.

The purposes of this chapter is to provide recommendations to prepare, develop and implement *official control programmes* for plans in response to *outbreaks occurrence outbreaks of listed and emerging or listed diseases*, including zoonoses. It is not aimed at giving ready-made fit-for-all solutions, but rather at outlining principles to follow when combating *transmissible* animal diseases *through organised control programmes* plans. Although this chapter focuses primarily on *listed and emerging diseases*, the recommendations may also be used by the *Veterinary Authorities* for any *notifiable diseases* or diseases against which they have established *official control programmes*.

The *Veterinary Authority* should determine which diseases to establish *official control programmes* against and at which regulatory level, according to an evaluation of the actual or likely impact of the disease. *Disease Official control programmes* plans should be prepared in advance by the *Veterinary Authority* and *Veterinary Services* in close collaboration with the relevant stakeholders and other authorities, as appropriate *disposing of the necessary regulatory, technical and financial tools*.

Control plans *They Official control programmes* should be justified by rationales developed *through based on risk analyses* and considering *taking into account* animal health, public health, and socio-economic, *animal welfare* and environmental aspects. *They should preferably be supported by relevant cost-benefit analysis when possible and should include the necessary regulatory, technical and financial tools*.

*Official control programmes* Control plans should be developed with the aim of achieving defined measurable objectives, in response to a situation in which *purely private action alone* is not sufficient. Depending on the prevailing epidemiological, environmental and socio-economic situation, the goal may vary from the reduction of impact to the eradication of a given disease *infection or infestation*.

The general components of an *official control programme* should include:

- 1) *a plan of the programme to control or eradicate the relevant disease in the country or zone;*
- 2) *regular and prompt animal disease reporting appropriate veterinary legislation;*
- 3) *emergency preparedness plans and emergency response plans;*
- 4) *surveillance of the relevant disease in accordance with Chapter 1.4.;*
- 45) *regular and prompt animal disease reporting;*
- 6) *rapid detection and management of, and response to, cases of the relevant disease, to reduce the incidence and the prevalence to by eliminating transmission;*

## Annex 18 (contd)

57) measures implemented to prevent introduction or spread of the relevant disease, including biosecurity and sanitary measures including movement control;

68) a vaccination programme, as relevant appropriate;

79) preparedness and contingency plans measures to protect public health, as appropriate;

810) communication and collaboration with other among all relevant Competent Authorities.

In any case, the critical components of official control programmes plans for management of outbreaks for diseases that are not present in the Member Country country or zone are measures to prevent the introduction of the disease, an an early detection warning system (including a warning procedure), and and a plan for rapid response and quick and effective action, possibly followed by long-term measures. Such Plans programmes should always include an exit strategy options.

Learning from past outbreaks, and reviewing the response sequence and revising the methods are critical for adaptation to evolving epidemiological situations circumstances and for better future performance in future situations. Experiences of the Veterinary Services of other Member Countries may also provide useful lessons. Plans should be tested regularly to ensure that they are fit-for-purpose, practical, feasible and well-understood and that field staff are trained and other stakeholders are fully aware of their respective roles and responsibilities in implementing the response. This is especially important for diseases that are not present in the Member Country.

## Article 4.Y.2.

**Legal framework and regulatory environment**

- 1) In order to be able to effectively control listed diseases and emerging diseases and listed diseases, the Veterinary Authority should ensure that:
  - the Veterinary Services comply with the principles of Chapter 3.1., especially the services dealing with the prevention and control of contagious infectious transmissible animal diseases, including zoonoses;
  - the veterinary legislation complies with the principles of Chapter 3.4.
- 2) In particular, in order for the Veterinary Services to be the most effective when combatting animal disease outbreaks, the following should be addressed in the veterinary legislation or other relevant legal framework:
  - legal powers and structure of command and responsibilities, including responsible officials with defined powers authority; especially a right of entry to establishments or other related enterprises such as live animal markets, slaughterhouses/abattoirs and animal products processing plants, for regulated purposes of surveillance and disease control actions, with the possibility of obliging owners to assist;
  - ≡ sources of financing for dedicated staff and additional supporting staff when needed;
  - sources of financing for epidemiological enquiries, laboratory diagnostic, disinfectants, insecticides, vaccines and other critical supplies;
  - ≡ sources of financing for communication and awareness campaigns;
  - sources of financing and compensation policy for livestock commodities and property that may be lost or destroyed as part of disease control programmes, or for direct losses incurred due to movement restrictions imposed by the control programme;
  - coordination with other authorities, especially law enforcement and public health authorities.
- 3) Furthermore, the specific regulations, policies, or guidance on disease control activities policies should include the following:
  - risk analysis to identify assess and prioritise potential disease risks, including a regularly updated list of notifiable diseases;

## Annex 18 (contd)

- definitions and procedures for the reporting and management of a suspected case, or confirmed case, of an listed disease or an emerging disease or a listed disease;
- procedures for the management of infected establishments, directly or indirectly affected by the disease infected establishment, contact establishment;
- = procedures for epidemiological investigations of outbreaks including forward and backward tracing of animals and animal products, commodities and fomites;
- definitions and procedures for the declaration and management of *infected zones* and other zones, such as *free zones*, *protection zones*, *containment zones*, or less specific ones such as *zones of intensified surveillance*;
- procedures for the collection, transport and testing of animal samples;
- procedures for animal identification and the management of animal identification systems ~~the identification of animals~~;
- procedures for the restrictions of movements, including possible standstill or compulsory veterinary certification, of relevant animals, and animal products, commodities and fomites within, to, or from given *zones* or *establishments* or other related enterprises;
- procedures for the destruction or *slaughter* and safe disposal or processing of infected or potentially infected *animals*, including relevant *wildlife*; ~~and~~
- = procedures for the destruction and collection, treatment or safe disposal or processing of contaminated or potentially contaminated animal products of animal origin and other materials;
- = procedures for collection, treatment or safe disposal of contaminated or potentially contaminated fodder and effluents such as fodder, bedding, and litter, manure and waste water;
- = procedures for cleaning, disinfection and disinsection of establishments and related premises, vehicles/vessels or equipment;
- procedures for compensation for the owners of animals or animal products, commodities, including defined standards and means of implementing such a compensation;
- ~~procedures for cleaning, disinfection and disinsection of establishments and related premises, vehicles or equipment~~;
- procedures for the ~~compulsory emergency~~ implementation of vaccination programmes or treatment of *animals*, as relevant, and for any other necessary disease control actions; ~~;~~
- = procedures for post-control surveillance and possible gaining or recovery of status, as relevant.

## Article 4.Y.3.

**Emergency Preparedness**

In case of occurrence of an emerging disease or a listed disease that was not present in the country or zone, or of sudden increase of incidence of a listed disease that is present, Rapid and effective response to a new occurrence or emergence of contagious infectious diseases is dependent on the level of preparedness. The Veterinary Authority should define emergencies and integrate emergency preparedness planning, and practice equipping, training and exercising within the official control programmes against these diseases as one of its core functions. Rapid, effective response to a new occurrence or emergence of contagious diseases is dependent on the level of preparedness.

Emergency Preparedness should be justified supported by risk analysis, should be planned in advance, and should include training, capacity building and simulation exercises.

## Annex 18 (contd)

## 1. Risk analysis

*Risk analysis*, including import *risk analysis*, in accordance with Chapter 2.1., should be used to determine ~~which a list of *notifiable diseases* that~~ require preparedness planning and to what extent.

A *risk analysis* identifies the pathogenic agents that present the greatest *risk* and for which preparedness is most important and therefore helps to prioritise the range of disease threats and categorise the consequent actions. It also helps to define the best strategies and control options.

The *risk analysis* should be ~~reviewed~~ ~~updated~~ regularly to detect changes (e.g. new pathogenic agents, or changes in distribution and virulence of pathogenic agents previously identified as presenting the major *risk* and changes in possible pathways) and be updated accordingly, taking into account the latest scientific findings.

## 2. Planning

~~Four kinds of plans,~~ Emergency planning consists of describing the following in advance:

- what ~~governmental or national and~~ local authorities and all relevant stakeholders should do; ~~comprise any comprehensive preparedness and response system~~
- how they should be trained, equipped and exercised to be ready to do it;
- how their actions should be activated and coordinated.

This implies the development of:

- a) a preparedness plan, which outlines what should be done before an *outbreak* of a notifiable listed disease or an emerging disease or a notifiable disease occurs;
- b) a response or contingency plan, which details what should be done in the event of an occurrence of a notifiable listed disease or an emerging disease or notifiable disease, beginning from the point when a suspected case is reported;
- c) a comprehensive set of instructions for ~~field~~ staff and other stakeholders on how to undertake specific tasks required by the response or contingency plan;
- d) a recovery plan for the safe restoration of normal activities, including food supply, possibly including procedures and practices modified in light of the experience gained during the management of the *outbreak* notifiable listed disease or the emerging disease.

## 3. Simulation exercises

The *Veterinary Services* and all stakeholders should be made aware of the sequence of measures to be taken in the framework of a contingency plan through the organisation of simulation exercises, mobilising a sufficient number of staff and stakeholders to evaluate the level of preparedness and fill possible gaps in the plan or in staff capacity. Simulation exercises may be organised between the *Veterinary Services* of neighbouring countries and other relevant agencies.

Article 4.Y.4.

**Surveillance and early warning detection systems**

- 4) Depending on the priorities identified by the *Veterinary Authority*, *Veterinary Services* should implement adequate *surveillance* for *listed diseases* in accordance with Chapter 1.4. ~~or and *listed disease*-specific chapters, in order to detect suspected cases and either rule them out or confirm them. The *surveillance* should be adapted to the epidemiological and environmental situation. Early warning systems are an integral component of emergency preparedness management. They should be in place for diseases *infections or infestations* for which a rapid response is desired, and should comply with the relevant articles of Chapter 1.4. When used, *vector surveillance* should be conducted in accordance with Chapter 1.5.~~

~~All suspected case investigations should provide a result, either positive or negative. Criteria should be established in advance for a case definition. Confirmation can be made on clinical and post mortem grounds, epidemiological information, laboratory test results or a combination of these, in accordance with relevant articles of the *Terrestrial Code* or *Terrestrial Manual*. Strong suspicion of a listed disease or an emerging disease based on supportive, but not definitive, findings should lead to at least the implementation of local pre-emptive control measures as a precaution. When Once a case is confirmed, full sanitary measures should be implemented as planned.~~

## Annex 18 (contd)

- 2) ~~In order to implement adequate surveillance, the Veterinary Authority should have access to good diagnostic capacity. This means that the veterinarians and other relevant personnel of the Veterinary Services have adequate knowledge of the disease, its clinical and pathological manifestation and its epidemiology, and that laboratories approved for the testing of animal samples for the relevant diseases are available.~~
- 3) ~~Suspected cases of notifiable diseases should be reported without delay to the Veterinary Authority, ideally with the following information:~~
- ~~– the disease or pathogenic agent suspected, with brief descriptions of clinical signs or lesions observed, or laboratory test results as relevant;~~
  - ~~– the date when the signs were first noticed at the initial site and any subsequent sites;~~
  - ~~– the names and addresses or geographical locations of suspected infected establishments or premises;~~
  - ~~– the animal species affected, including possible human cases, and the approximate numbers of sick and dead animals;~~
  - ~~– initial actions taken, including biosecurity and precautionary movement restrictions of animals, products, staff, vehicles and equipment;~~
- 4) ~~Immediately following the report of a suspected case, investigation should be conducted by the Veterinary Services, taking into account the following:~~
- ~~– biosecurity to be observed when entering and leaving the establishment, premises or locality;~~
  - ~~– clinical examinations to be undertaken (number and types of animals);~~
  - ~~– samples to be taken from animals showing signs or not (number and types of animals), with specified sampling and sample handling equipment and sample handling procedures, including for the safety of the investigator and animal owners;~~
  - ~~– procedure for submitting samples for testing;~~
  - ~~– size of the affected establishment, premises or locality and possible entry pathways;~~
  - ~~– investigation of the approximate numbers of similar or possibly susceptible animals in the establishment and its surroundings;~~
  - ~~– details of any recent movements of possibly susceptible animals or vehicles or people to or from the affected establishments, premises or locality;~~
  - ~~– any other relevant epidemiological information, such as presence of the suspected disease in wildlife or abnormal vector activity;~~

~~A procedure should be in place for reporting findings to the Veterinary Authority and for record keeping.~~

- 5) ~~All suspected case investigations should provide a result, either positive or negative. Criteria should be established in advance for a case definition. Confirmation can be made on clinical and post-mortem grounds, epidemiological information, laboratory test results or a combination of these, in accordance with relevant articles of the Terrestrial Code or Terrestrial Manual. Strong suspicion based on supportive, but not definitive, findings should lead to the implementation of local control measures as a precaution. When a case is confirmed, full sanitary measures should be implemented as planned.~~
- 6) ~~When a case of a listed disease is detected, notification shall be made to the OIE in accordance with Chapter 1.1.~~

## Annex 18 (contd)

## Article 4.Y.5.

**General considerations when managing an outbreak management**

Upon confirmation of ~~Once~~ an outbreak of a notifiable listed disease or an emerging disease or a notifiable disease that is subject to an official control programme is confirmed effective risk management should be applied. It depends on the application of a combination of measures that are operating at the same time or consecutively, aimed at:

- 1) epidemiological investigation to tracing back and forward and backward animals in contact and potentially infected or contaminated products commodities or fomites through epidemiological investigation;
- 2) eliminating the source of pathogenic agent, through:
  - the *killing* or *slaughter* of *animals* infected or suspected of being infected, as appropriate, and safe disposal of dead *animals* and other potentially contaminated products commodities;
  - the cleaning, *disinfection* and, if relevant, *disinsection* of premises and equipment;
- 3) stopping the spread of *infection*, through:
  - movement restrictions on animals commodities and fomites, vehicles, and equipment and people, as appropriate;
  - *biosecurity*;
  - *vaccination*, treatment or culling of *animals* at risk;
  - control of vectors;
  - communication and public awareness.

Different strategies may be chosen depending on the expected outcome of the official control programme (i.e. eradication, containment or partial control) and the epidemiological, environmental, economic and social situation. The *Veterinary Authority* should assess the situation beforehand and at the time of the *outbreak* detection. For example, the wider the spread of the disease and the more locations affected at the beginning of the implementation of the measures, the less likely it will be that culling as a main eradication tool will be effective, and the more likely it will be that other control tools such as *vaccination* or treatment, either in conjunction with culling or alone, will be needed. The involvement of *vectors* or *wildlife* will also have a major influence on the control strategy and different options chosen. The strategies chosen will, in turn, influence the final objective of the control programme.

In any case, the management plan response measures should consider the costs of the measures in relation to the benefits expected, and should at least integrate the compensation of owners for losses incurred by the measures, as described in regulations, policies or guidance.

In case of highly contagious transmissible or high impact disease events, the management plan response measures should be closely coordinated through an inter-sectoral mechanism such as an incident command system.

## Article 4.Y.6.

**Culling of animals and disposal of dead animals and animal products other potentially contaminated commodities**

Living infected *animals* ~~can be~~ are the greatest source of pathogenic agents. These *animals* may directly transmit the pathogenic agent to other *animals*, They may and also cause lead to indirect ~~infection~~ transmission of pathogenic agents through live organisms (vectors, people) or through the contamination of fomites, including breeding and handling equipment, bedding, feed, vehicles, and people's clothing and footwear, or the contamination of the environment. Although carcasses may remain contaminated for a period after death, active shedding of the pathogenic agent ~~effectively~~ ceases when the *animal* is killed or slaughtered. Thus, culling of *animals* is often a the preferred strategy for the control of contagious transmissible diseases.

Veterinary Services should adapt any strategy for culling of ~~animals, killing or disposal of dead animals and their products~~ other **potentially contaminated commodities** strategy to the transmission pathways of the pathogenic agent. ~~A stamping-out policy is should be~~ the preferred strategy for highly **contagious transmissible** diseases and for situations where the country or zone was ~~formerly previously~~ free or freedom was impending, while other strategies, such as test and cull, are better suited to less **contagious transmissible** diseases and situations where the disease is endemic.

For control measures, including destruction of *animals* or products, to be most effective, *animal identification* and *animal traceability* should be in place, in accordance with Chapters 4.1. and 4.2.

The *slaughter* or *killing* of *animals* should be performed in accordance with Chapter 7.5. or Chapter 7.6., respectively.

The disposal of dead *animals* and ~~their~~ other **related** potentially contaminated **products** **commodities** should be performed in accordance with Chapter 4.12.

#### 1. Stamping-out policy

A stamping-out policy consists primarily ~~in~~ of the *killing* of all the *animals* ~~affected~~ **infected** or suspected of being ~~affected~~ **infected**, including those ~~which~~ that have been directly or indirectly exposed to the causal pathogenic agent. This strategy is used for the most **contagious transmissible** diseases.

A stamping-out policy can be limited to the affected *establishments* and, where appropriate, other *establishments* found to be epidemiologically linked with an affected *establishment*, or be broadened to ~~include all establishments of~~ a defined zone, when pre-emptive depopulation can be used to stop the transmission of a fast spreading pathogenic agent.

A stamping-out policy can be applied to all the animal species present on an affected *establishment*, or to all susceptible species, or only to the same species as the infected *animals*, based on the assessment of associated risks.

Depopulation and carcass disposal can be applied to *wildlife* within a defined zone, based on the assessment of associated risks.

*Killing* should preferably be performed on site, and the carcasses either disposed of on site or transported directly and safely to a rendering plant or other dedicated site for destruction. If to be killed outside of the *establishment* or slaughtered, the *animals* should be transported directly to a dedicated *approved* rendering plant or *slaughterhouse/abattoir* respectively, without any possible direct or indirect contacts with other *animals*. Slaughtered *animals* and their products should be processed separately from others.

~~Stamping-out can be applied to all the animal species present on affected premises, or to all susceptible species, or only to the same species as the affected animals.~~

Products originating from killed or slaughtered *animals*, (ranging from carcasses, *meat*, *milk*, *eggs* or genetic material to hair, wool, feathers or manure, slurry) should be destroyed or processed in a way that inactivates the pathogenic agent. The inactivating process should be carried out in accordance with the relevant articles of the listed disease-specific chapters.

Stamping-out policy procedures systematically include the cleaning and *disinfection* of *establishments* and *vehicles/vessels* used for the transport of *animals*, carcasses or products, as well as of any equipment and material that has been in direct or indirect contact with the *animals*. The procedures may include *disinsection* or *disinfestation* in the case of *vector-borne* disease or parasitic *infestation*. These procedures should be conducted in accordance with the relevant articles of Chapter 4.13.

#### 2. Test and cull

This strategy consists primarily of finding the ~~proven~~ infected *animals* in order to remove them from the population and either *slaughter* or kill and dispose of them. This strategy is ~~it should be~~ **used more suitable** for less **contagious transmissible** or slow-spreading diseases. Veterinary Services may apply different test and cull strategies based on the epidemiology of the infection or infestation or on the characteristics of available diagnostic tests. In particular, the design of test and cull strategy will depend on the sensitivity and specificity of the tests. Veterinary Services may adjust test and cull strategies to the changes of the prevalence.

Annex 18 (contd)

Apart from the selection of *animals* to be culled, the same principles apply as for *stamping-out policy* in terms of processing, treatment and disposal of dead or slaughtered *animals* and their products.

## Article 4.Y.7.

**Movement control**

Disease spread due to the movement of live *animals*, *animal products* and contaminated *material commodities and fomites* should be controlled by movement restrictions that are adequately enforced.

These restrictions can be applied to one or more animal species and their associated products commodities, and to different types of fomites (e.g. people, clothing, vehicles/vessels and equipment). They may vary from pre-movement certification to total standstill, and be limited to one or more establishment only or multiple establishments, or cover specific *zones*, or the entire country. The restrictions can include the complete isolation of individual *animals* or group of *animals*, and specific rules applied to movements, such as protection from *vectors*.

Specific rules covering movement controls should apply to each of any defined *zones*. Physical barriers ~~should~~ may be installed as needed, to ensure the effective application of movement restrictions.

Movement controls should be in place until the end of other disease control operations, e.g. such as a stamping-out policy, and after surveillance and a revised risk assessment ~~has~~ have demonstrated they are no longer needed.

*Veterinary Services* should coordinate their movement control actions with other relevant authorities such as local authorities, and law enforcement agencies, and with communication media, as well as with the Veterinary Services of neighbouring countries in the case of transboundary *animal* diseases.

Article 4.Y.8.**Zoning**

The Veterinary Authority should use the tool of zoning in official control programmes, in accordance with Chapter 4.3.

The use of zoning for disease control and eradication is inherently linked with measures of killing or slaughter, movement control, vaccination and surveillance, which apply differently according to the zones. In particular, efforts should be concentrated on those parts of a territory affected by the disease, to prevent the spread of the pathogenic agent and to preserve the status of the parts of the territory not affected by the disease.

Zones established in response to outbreaks of listed diseases or emerging diseases are usually infected zones, containment zones and protection zones. However, other types of zones, such as zones where specific surveillance, vaccination or other activities are conducted, can also be used.

Article 4.Y.~~89~~.**Biosecurity**

In order to avoid the spread of the pathogenic agent outside of the affected *establishments* or *infected zones*, and in addition to the management measures described in Articles 4.Y.5. to 4.Y.7., *biosecurity* should be applied, in particular measures to avoid the contamination of people's clothes and shoes, of equipment, of vehicles/vessels, ~~and~~ of the environment or anything capable of acting as a fomite.

Disinfection and disinsection should be applied in accordance with Chapter 4.13. When disinfection is applied, specific disinfectant solutions should be used for footbaths or disinfectant baths for vehicles' wheels. Single use material and clothes or material and clothes that can be effectively cleaned and disinfected should be used for the handling of animals and animal products. Protection of premises from wildlife and other unwanted animals should be ensured. Wastes, waste-water and other effluents should be collected and treated appropriately.

## Article 4.Y.910.

**Vaccination and treatment and treatment**

Vaccination as part of an official control programme in response to a contagious disease outbreak should be conducted in accordance with Chapter 4.17.

Vaccination programmes, especially in response to an outbreak, require previous planning to identify potential sources of vaccine, including vaccine or antigen banks, and to plan the possible strategies for application, such as emergency barrier, blanket, vaccination or ring or targeted vaccination.

The properties of the vaccines should be well understood, especially the level of protection against *infection* or disease and the possibility to differentiate the immune response produced by the vaccine from that produced induced by *infection* with the pathogenic agent or to differentiate live vaccine strains from field strains.

Although *vaccination* may hide ongoing *infection* or agent transmission, it can be used to decrease the shedding of the pathogenic agent, hence reduce the reproductive rate of the *infection*. In particular, when stamping-out is not feasible, *vaccination* can be used to reduce the circulation prevalence of the *infection* until its levels are is low enough for the implementation of another strategies such as a test and cull strategy.

Vaccination can also be used to minimise the impact of an infection by reducing clinical signs or economic losses.

Whenever *vaccination* is to be used as a tool to control *outbreaks* or spread of disease, the official control programme plan should include consider a cost/benefit analysis with regard to trade and public health and an exit strategy, i.e. when and how to stop the *vaccination* or whether *vaccination* should become systematic routine.

Treatment can also be used as part of an official control programme. It would require planning to identify potential sources of veterinary medicinal products, and to plan the possible strategies for application and an exit strategy.

## Article 4.Y.10.

**Zoning**

The Veterinary Authority should use the tool of zoning in official control programmes, in accordance with Chapter 4.3.

The use of zoning for disease control and eradication is inherently linked with measures of killing or slaughter, movement control, vaccination and surveillance, which apply differently according to the zones. In particular, efforts should be concentrated on those parts of a territory affected by the disease, to prevent the spread of the pathogenic agent and to preserve the status of the parts of the territory not affected by the disease.

Zones established defined in response to outbreaks of notifiable diseases or emerging diseases or listed diseases may be are usually infected zones, containment zones and protection zones, and containment zones. However, or other types of zones, e.g. such as zones of intensified surveillance, or zones of intensified vaccination can also be used.

## Article 4.Y.11.

**Communication in outbreak management**

For the best implementation of disease control measures, *Veterinary Services* should ensure good communication with all concerned stakeholders, including the general public. This should be part of the official control programme and be carried out, among others, through awareness campaigns targeted at breeders, *veterinarians*, veterinary paraprofessionals, local authorities, the media, consumers and general public.

*Veterinary Services* should communicate before, during and after *outbreaks*, in accordance with Chapter 3.3.

Annex 18 (contd)

## Article 4.Y.12.

**Specific post-control surveillance**

Specific *surveillance* should be applied in order to monitor the effectiveness of the official control programme plan, and assess the status of the ~~remaining~~ *animal populations* in the different *zones* established by the *Veterinary Services*.

The results of this *surveillance* should be used to reassess the measures applied, including reshaping of the *zones* and re-evaluation of the culling or *vaccination* strategies, and for the eventual recovery of free status, if possible.

This *surveillance* should be conducted in accordance with Chapter 1.4. and with the relevant articles of the listed disease-specific chapters.

## Article 4.Y.13.

**Further outbreak investigation, monitoring, evaluation and review**

In order to gather information required for any management information system, *Veterinary Services* should conduct an in-depth epidemiological investigation of each *outbreak* to build up a detailed first-hand, field-based knowledge of how the disease is transmitted, and inform further disease control plans. This requires staff who have been trained in the way to conduct it and the use of the standardised data collection forms.

Information gathered and experience gained should be used to monitor, evaluate and review ~~disease~~ official control programmes plans.

## USER'S GUIDE

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[...]

### B. *Terrestrial Code* content

[...]

- 3) The standards in the chapters of Section 1 are designed for the implementation of measures for the diagnosis, surveillance and notification of ~~pathogenic agents~~ diseases, infections and infestations. The standards include procedures for notification to the OIE, tests for international trade, and procedures for the assessment of the health status of a country, zone or compartment.

[...]

### C. Specific issues

[...]

#### 5. Trade requirements

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

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

The OIE aims to include an article listing the commodities that are considered safe for trade without the need for risk mitigation measures specifically directed against a particular listed disease, infection or infestation, regardless of the status of the country or zone of origin for the agent in question, at the beginning of each listed disease-specific chapter in Sections 8 to 15. This is work in progress and some chapters do not yet contain articles listing safe commodities. When a list of safe commodities is present in a chapter, importing countries should not apply trade restrictions to such commodities with respect to the agent in question. Chapter 2.2. describes the criteria used to assess the safety of commodities.

[...]



## CHAPTER 8.11.

**INFECTION WITH *MYCOBACTERIUM*  
*TUBERCULOSIS* COMPLEX *BOVIS* AND *M. CAPRAE***

## Article 8.11.1.

**General provisions**

The recommendations in this chapter are intended to manage the human and animal health risks associated with infection of animals with ~~a member of the *Mycobacterium bovis* and *M. caprae* tuberculosis (*M. tuberculosis*) complex.~~

~~For the purposes of the Terrestrial Code, *M. tuberculosis* complex comprises *M. bovis*, *M. caprae* and *M. tuberculosis*, but excludes vaccine strains.~~

Many different domestic and *wild animal* species belonging to diverse mammalian taxa are known to be susceptible to infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae*. Their epidemiological significance depends on the degree of susceptibility, the husbandry system, the density, spatial distribution and ecology of populations as well as the pathogenesis and transmission pathways. In some geographical regions, certain *wild animal* species can act as reservoirs.

For the purposes of this chapter, 'animals' means domestic and *captive wild animal* populations of the following categories:

- 1) bovids: this term means bovines (*Bos taurus*, *B. indicus*, *B. frontalis*, *B. javanicus* and *B. grunniens*), water buffaloes (*Bubalus bubalis*), and bison (*Bison bison* and *B. bonasus*);
- 2) cervids: this term means red deer (*Cervus elaphus elaphus*), wapiti/elk (*C. elaphus canadensis*), sika (*C. nippon*), samba (*C. unicolorunicolor*), rusa (*C. timorensis*), roe deer (*Capreolus capreolus*), fallow deer (*Dama dama*), white-tailed, black-tailed and mule deer (*Odocoileus* spp.) and reindeer/caribou (*Rangifer tarandus*);
- 3) goats (*Capra hircus*);
- 4) New World camelids: this term means alpacas (*Lama guanicoe pacos*) and llamas (*Lama guanicoe glama*).

The chapter deals not only with the occurrence of clinical signs caused by infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae*, but also with the presence of infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in the absence of clinical signs.

For the purposes of the *Terrestrial Code*, the following defines the occurrence of infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae*:

- ~~a member of *M. tuberculosis* complex~~ *M. bovis* or *M. caprae*, excluding vaccine strains, has been identified in a sample from an animal or a product derived from that animal;

OR

- positive results to a diagnostic test have been obtained and there is an epidemiological link to a case of infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae*, excluding vaccine strains, or there is other reason to suspect infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae*.

When authorising import or transit of *commodities* listed in this 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 *M. bovis* and *M. caprae* ~~*M. tuberculosis* complex~~ infection status of the animal population of the country, zone or herd of origin.

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

Annex 20 (contd)

## Article 8.11.2.

**Safe commodities**

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any ~~*M. tuberculosis* complex-related conditions~~ related with *M. bovis* and *M. caprae*, regardless of the ~~*M. tuberculosis* complex infection~~ *M. bovis* and *M. caprae* status of the animal populations of the country, zone or herd of origin:

- 1) *fresh meat* and *meat products* originating from animals that have been subjected to ante- and post-mortem inspections as described in Chapter 6.2.;
- 2) cured hides, skins and trophies;
- 3) gelatine, collagen, tallow and *meat-and-bone meal*.

## Article 8.11.3.

**Country or zone historically free from infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in specified animal categories**

A country or zone may be considered historically free from *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in specified animal categories when the requirements of point 1 a) of Article 1.4.6. have been met for the relevant animal categories.

## Article 8.11.4.

**Country or zone free from infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in bovids**

- 1) To qualify as free from *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in bovids, a country or zone should satisfy the following requirements:
  - a) *infection* in animals is a *notifiable disease* in the entire country;
  - b) a *surveillance* programme based on regular testing of all *herds* has been in place for at least three years and for the past three years this testing has demonstrated that *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* was not present in at least 99.8% of the *herds* representing at least 99.9% of the bovids in the country or zone;
  - c) a *surveillance* programme in accordance with Chapter 1.4. is in place to detect *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in the country or zone through ante- and post-mortem inspections of bovids as described in Chapter 6.3.;
  - d) regulatory measures have been implemented for the early detection of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in bovids;
  - e) bovids and their germplasm introduced into the country or zone comply with the recommendations in Articles 8.11.7., 8.11.10. and 8.11.12.
- 2) To maintain the status as free from *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in bovids, a country or zone should satisfy the following requirements:
  - a) the requirements in points 1 a), 1 c), 1 d) and 1 e) above are met;
  - b) a *surveillance* programme based on regular testing of bovids is in place in the country or zone to detect *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in accordance with Article 1.4.4.;
  - c) once the *surveillance* programme described in point b) has demonstrated that *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* has not been present in at least 99.8% of the *herds* representing 99.9% of the bovids in the country or zone for two consecutive years, *surveillance* may be maintained through ante- and post-mortem inspections as described in Chapter 6.3.
- 3) The country or zone status of free from *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in bovids is not affected by the occurrence of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in other animal categories or *feral* or *wild animals* provided that measures intended to prevent transmission of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* to bovids have been implemented and are periodically reassessed.

## Article 8.11.5.

**Country or zone free from infection with ~~M. tuberculosis complex~~ M. bovis and M. caprae in cervids**

- 1) To qualify as free from *infection* with ~~M. tuberculosis complex~~ M. bovis and M. caprae in cervids, a country or zone should satisfy the following requirements:
  - a) *infection* with ~~M. tuberculosis complex~~ M. bovis and M. caprae in animals is a *notifiable disease* in the entire country;
  - b) regular testing of all cervid *herds* has been in place for at least three years and for the past three years this testing has demonstrated that *infection* with ~~M. tuberculosis complex~~ M. bovis and M. caprae was not present in at least 99.8% of the *herds* representing at least 99.9% of the cervids in the country or zone;
  - c) a *surveillance* programme is in place to detect *infection* with ~~M. tuberculosis complex~~ M. bovis and M. caprae in the country or zone through ante- and post-mortem inspections as described in Chapter 6.3.;
  - d) regulatory measures have been implemented for the early detection of *infection* with ~~M. tuberculosis complex~~ M. bovis and M. caprae in cervids;
  - e) cervids and their germplasm introduced into the country or zone comply with the recommendations in Articles 8.11.7., 8.11.11. and 8.11.12.
- 2) To maintain the status as free from *infection* with ~~M. tuberculosis complex~~ M. bovis and M. caprae in cervids, a country or zone should satisfy the following requirements:
  - a) the requirements in points 1 a), 1 c), 1 d) and 1 e) above are met;
  - b) a *surveillance* programme based on regular testing of cervids is in place in the country or zone to detect *infection* with ~~M. tuberculosis complex~~ M. bovis and M. caprae in accordance with Article 1.4.4.;
  - c) once the *surveillance* programme described in point b) has demonstrated that *infection* with ~~M. tuberculosis complex~~ M. bovis and M. caprae has not been present in at least 99.8% of the *herds* representing 99.9% of the cervids in the country or zone for two consecutive years, *surveillance* may be maintained through ante- and post-mortem inspections as described in Chapter 6.3.
- 3) The country or zone status free from *infection* with ~~M. tuberculosis complex~~ M. bovis and M. caprae in cervids is not affected by the occurrence of *infection* with ~~M. tuberculosis complex~~ M. bovis and M. caprae in other animal categories or *feral* or *wild animals* provided that measures intended to prevent transmission of *infection* with ~~M. tuberculosis complex~~ M. bovis and M. caprae to cervids have been implemented and are periodically reassessed.

## Article 8.11.6.

**Herd free from infection with ~~M. tuberculosis complex~~ M. bovis and M. caprae in bovids or cervids**

- 1) To qualify as free from *infection* with ~~M. tuberculosis complex~~ M. bovis and M. caprae, a *herd* of bovids or cervids should satisfy the following requirements:
  - a) the *herd* is in a country or zone free from *infection* with ~~M. tuberculosis complex~~ M. bovis and M. caprae in bovids or in cervids and is certified free by the *Veterinary Authority*;

OR

  - b) the *herd* satisfies the following requirements:
    - i) *infection* with ~~M. tuberculosis complex~~ M. bovis and M. caprae in animals is a *notifiable disease* in the entire country;

Annex 20 (contd)

- ii) no occurrence of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* has been detected in the *herd* for at least the past 12 months;
  - iii) bovids or cervids in the *herd* have shown no clinical signs of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* or lesions at ante- or post-mortem inspections for at least the past 12 months;
  - iv) two tests have been performed with negative results at a minimum interval of six months on all bovids or cervids over six weeks of age present in the *herd* at the time of testing. The first test was performed at least six months after the removal of the last case;
  - v) bovids or cervids and their germplasm introduced into the *herd* comply with Articles 8.11.7., 8.11.10., 8.11.11. and 8.11.12.;
  - vi) for at least the past 12 months, there has been no occurrence of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in other *herds* of the same *establishments* or measures have been implemented to prevent any transmission of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* from these other *herds*.
- 2) To maintain the free status, either:
- a) the requirements in point 1 a) are met;
- OR
- b) the requirements in points 1 b) i) to iii), v) and vi) are met and bovids or cervids in the *herd*:
    - i) showed a negative result to an annual test to ensure the continuing absence of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae*; OR
    - ii) showed a negative result to a test every two years to ensure the continuing absence of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* if it has been confirmed that the annual percentage of *herds* infected with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* is not more than 1% of all *herds* in the country or *zone* during the past two years; OR
    - iii) showed a negative result to a test every three years to ensure the continuing absence of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* if it has been confirmed that the annual percentage of *herds* infected with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* is not more than 0.2% of all *herds* in the country or *zone* during the past four years; OR
    - iv) showed a negative result to a test every four years to ensure the continuing absence of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* if it has been confirmed that the annual percentage of *herds* infected with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* is not more than 0.1% of all *herds* in the country or *zone* during the past six years;
- OR
- c) the requirements in points 1 b) i) to iii), v) and vi) are met; and
    - i) the risk of transmission of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* from known *wildlife* reservoirs has been assessed through active *surveillance*;
    - ii) all *herds* identified as being at risk are subjected to a testing programme commensurate with the assessed epidemiological risk of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae*. In identifying *herds* at risk, the following should be considered:
      - a location associated with suspected or confirmed *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in *wildlife*; or
      - a history of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* within last five years; or
      - an epidemiological link with *herds* in either of the two points above.

## Article 8.11.7.

**Recommendations for the importation of bovids or cervids for breeding or rearing**

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

- 1) showed no clinical signs of infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* on the day of shipment;
- 2)
  - a) originate from a herd free from infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* that is in a country or zone free from infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae*; or
  - b) originate from a herd free from infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* and have been tested for infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* with negative results within 30 days prior to shipment; or
  - c) have been isolated for at least six months prior to shipment including protection from contact with any reservoir of ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* and all isolated animals showed negative results to at least two consecutive tests carried out at a six-month interval, with the second test performed within 30 days prior to shipment.

## Article 8.11.8.

**Recommendations for the importation of goats for breeding or rearing**

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

- 1) infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in animals is a *notifiable disease* in the entire country;
- 2) the goats showed no clinical signs of infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* on the day of shipment;
- 3) either:
  - a) the goats have been kept since birth in herds in which no case of infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* has been detected for the past three years; or
  - b) have been isolated for at least six months prior to shipment including protection from contact with any reservoir of ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* and all isolated animals showed negative results to at least two consecutive tests carried out at a six-month interval, with the second test performed within 30 days prior to shipment.

## Article 8.11.9.

**Recommendations for the importation of bovids or cervids for slaughter**

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

- 1) showed no clinical signs of infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* on the day of shipment;

Annex 20 (contd)

- 2) either:
- a) originate from a country, zone or herd free from infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae*; or
  - b) are not being culled as part of an eradication programme against infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* and were tested for infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* with negative results within 30 days prior to shipment.

Article 8.11.10.

**Recommendations for the importation of semen of bovids**

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

- 1) the donor males showed no clinical signs of infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* on the day of collection of the semen;
- 2) the donor males:
  - a) were kept in an *artificial insemination centre* complying with the provisions of Chapter 4.5. and complied with Article 4.6.2.; or
  - b) were kept in a herd free from infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* that is in a country or zone free from infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae*; or
  - c) were kept in a herd free from infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* and showed negative results to a test performed within 30 days prior to collection of the semen, which was collected, processed and stored in accordance with Articles 4.5.4., 4.5.5., and 4.6.5. to 4.6.7.

Article 8.11.11.

**Recommendations for the importation of semen of cervids**

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

- 1) the donor males showed no clinical signs of infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* on the day of collection of the semen;
- 2) the donor males either:
  - a) were kept in a herd free from infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in a country or zone free from infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae*; or
  - b) were kept in a herd free from infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* and showed negative results to a test performed within 30 days prior to collection of the semen, which was collected, processed and stored in accordance with Articles 4.5.4., 4.5.5., and 4.6.5. to 4.6.7.

Article 8.11.12.

**Recommendations for the importation of embryos of bovids or cervids**

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

Annex 20 (contd)

- 1) the donor females either:
  - a) originated from a *herd* free from *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in a country or *zone* free from *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae*; or
  - b) were kept in a *herd* free from *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae*, and were subjected to a test for *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* with negative results during an isolation period of 30 days in the *establishment* of origin prior to collection;
- 2) the semen used for embryo production complied with Article 8.11.10. or Article 8.11.11.;
- 3) the embryos were collected, processed and stored in accordance with the relevant provisions of Chapters 4.7. to 4.9.

Article 8.11.13.

**Recommendations for the importation of milk and milk products of bovids**

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

- 1) have been derived from bovids in a *herd* free from *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae*; or
  - 2) were subjected to pasteurisation or any combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.
-



## CHAPTER 1.3.

## DISEASES, INFECTIONS AND INFESTATIONS LISTED BY THE OIE

[...]

### Article 1.3.1.

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

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

[...]



## CHAPTER 8.15.

## INFECTION WITH RIFT VALLEY FEVER VIRUS

## Article 8.15.1.

**General provisions**

- 1) The aim of this chapter is to mitigate the animal and public health risks posed by Rift Valley fever (RVF) and to prevent its international spread.
- 2) Humans and many animal species are susceptible to *infection*. For the purposes of the *Terrestrial Code*, RVF is defined as an *infection* of ruminants with Rift Valley fever virus (RVFV).
- 3) The following defines the occurrence of *infection* with RVFV:
  - a) RVFV, excluding vaccine strains, has been isolated and identified as such from a sample from a ruminant; or
  - b) antigen or ribonucleic acid specific to RVFV, excluding vaccine strains, has been identified in a sample from a ruminant epidemiologically linked to a confirmed or suspected case of RVF, or giving cause for suspicion of association or contact with RVFV; or
  - c) antibodies to RVFV antigens which are not the consequence of *vaccination*, have been identified in a sample from a ruminant with either epidemiological links to a confirmed or suspected case of RVF, or giving cause for suspicion of association or contact with RVFV.
- 4) For the purposes of the *Terrestrial Code*, the *infective period* for RVF shall be 14 days.
- 5) In areas where RVFV is present, epizootics of RVF may occur following favourable climatic, environmental conditions and availability of susceptible host and competent *vector* populations. Epizootics are separated by inter-epizootic periods. The transition from an inter-epizootic period to an epizootic complies with point 1 d) of Article 1.1.3. in terms of notification.
- 6) For the purposes of this chapter:
  - a) 'area' means a part of a country that experiences epizootics and inter-epizootic periods, but which does not correspond to the definition of *zone*;
  - b) 'epizootic of RVF' means the occurrence of *outbreaks* at an incidence ~~substantially~~ exceeding that during an inter-epizootic period or the occurrence of indigenous human cases;
  - c) 'inter-epizootic period' means the period of variable duration, often long, with intermittent low level of *vector* activity and low rate of virus transmission, which is often not detected;
  - d) ruminants include dromedary camels.
- 7) The historical distribution of RVF has been parts of the African continent, Madagascar, some other Indian Ocean Islands and the south western Arabian Peninsula. However, *vectors*, environmental and climatic factors, land-use dynamics, and animal movements may modify the temporal and spatial distribution of the *infection*.

Annex 22 (contd)

- 8) When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 8.15.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the RVF status of the ruminant population of the *exporting country*.
- 9) Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 8.15.2.

**Safe commodities**

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

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

Article 8.15.3.

**Country or zone free from RVF**

A country or a *zone* may be considered free from RVF when *infection* with RVFV is notifiable in the entire country and either:

- 1) it meets the requirements for historical freedom in point 1 a) of Article 1.4.6.; or
- 2) met the following conditions:
  - a) an on-going pathogen-specific *surveillance* programme in accordance with Chapter 1.4. has demonstrated no evidence of *infection* with RVFV in ruminants in the country or *zone* for a minimum of ten years; and
  - b) during that period no indigenous human cases have occurred in the country or *zone*.

A country or *zone* free from RVF will not lose its free status through the importation of ruminants that are seropositive, so long as they are either permanently identified as such or destined for immediate *slaughter*.

Article 8.15.4.

**Country or zone infected with RVFV during the inter-epizootic period**

A country or *zone* infected with RVFV, during the inter-epizootic period, is one in which virus activity is present at a low level but the factors predisposing to an epizootic are absent.

Article 8.15.5.

**Country or zone infected with RVFV during an epizootic**

A country or *zone* infected with RVFV, during an epizootic, is one in which *outbreaks* of RVF are occurring at an incidence substantially exceeding that of the inter-epizootic period; or one in which indigenous human cases of RVF are occurring even in the absence of detection of animal cases.

## Article 8.15.6.

**Strategies to protect from vector attacks during transport**

Strategies to protect animals from *vector* attacks during transport should take into account the local ecology of the *vectors* and potential *risk management* measures include:

- 1) treating animals with insect repellents prior to and during transportation;
- 2) *loading*, transporting and *unloading* animals at times of low *vector* activity;
- 3) ensuring *vehicles* do not stop en route during dawn or dusk, or overnight, unless the animals are held behind insect-proof netting;
- 4) using historical and current information to identify low risk ports and transport routes.

## Article 8.15.7.

**Recommendations for importation from countries or zones free from RVF**For ruminants

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

- 1) were kept in a country or *zone* free from RVF since birth or for at least 14 days prior to shipment;

AND

- 2) either:
  - a) were vaccinated at least 14 days prior to leaving the free country or *zone*; or
  - b) did not transit through an area experiencing an epizootic during transportation to the *place of shipment*, or
  - c) were protected from *vector* attacks when transiting through an area experiencing an epizootic.

## Article 8.15.8.

**Recommendations for importation from countries or zones infected with RVFV during the inter-epizootic period**For ruminants

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

- 1) showed no sign of RVF on the day of shipment;
- 2) met one of the following conditions:
  - a) were vaccinated against RVF at least 14 days prior to shipment with a modified live virus vaccine; or
  - b) were held for at least 14 days prior to shipment in a *vector*-protected *quarantine station*, which is located in an area of demonstrated low *vector* activity. During this period the animals showed no clinical sign of RVF;

AND

- 3) either:
  - a) did not transit through an area experiencing an epizootic during transportation to the *place of shipment*, or
  - b) were protected from *vector* attacks when transiting through an area experiencing an epizootic.

Annex 22 (contd)

## Article 8.15.9.

**Recommendations for importation from countries or zones infected with RVFV during an epizootic**For ruminants

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the 1

- 1) showed no sign of RVF on the day of shipment;
- 2) did not originate in the area of the epizootic;
- 3) were vaccinated against RVF at least 14 days prior to shipment;
- 4) were held for at least 14 days prior to shipment in a *vector-protected quarantine station*, which is located in an area of demonstrated low *vector* activity outside the area of the epizootic. During this period the animals showed no sign of RVF;
- 5) either:
  - a) did not transit through an area experiencing an epizootic during transportation to the *place of shipment*;  
or
  - b) were protected from *vector* attacks when transiting through an area experiencing an epizootic.

## Article 8.15.10.

**Recommendations for importation from countries or zones not free from RVF**For semen and *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 sign of RVF within the period from 14 days prior to and 14 days following collection of the semen or embryos;

AND

- 2) either:
  - a) were vaccinated against RVF at least 14 days prior to collection; or
  - b) were demonstrated to be seropositive on the day of collection; or
  - c) testing of paired samples has demonstrated that seroconversion did not occur between semen or embryo collection and 14 days after.

## Article 8.15.11.

**Recommendations for importation of fresh meat and meat products from ruminants from countries or zones not free from RVF**

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

Annex 22 (contd)

- 1) ruminants which showed no clinical sign of RVF within 24 hours before *slaughter*;
- 2) ruminants which were slaughtered in an approved *slaughterhouse/abattoir* and were subjected to ante- and post-mortem inspections with favourable results;
- 3) carcasses which were submitted to maturation at a temperature above 2°C for a minimum period of 24 hours following *slaughter*.

Article 8.15.12.

### **Recommendations for importation from countries or zones not free from RVF**

#### For milk and milk products

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

- 1) was subjected to pasteurisation; 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.

Article 8.15.13.

### **Surveillance**

*Surveillance* should be carried out in accordance with Chapter 1.4.

- 1) During an epizootic, *surveillance* should be conducted to define the extent of the affected area.
- 2) During the inter-epizootic period, *surveillance* and monitoring of climatic factors predisposing an epizootic should be carried out in countries or *zones* infected with RVFV.
- 3) Countries or *zones* adjacent to a country or *zone* in which epizootics have been reported should determine their RVF status through an on-going *surveillance* programme.

To determine areas of low *vector* activity (see Articles 8.15.8. and 8.15.9.) *surveillance* for arthropod *vectors* should be carried out in accordance with Chapter 1.5.

Examination of *vectors* for the presence of RVFV is an insensitive *surveillance* method and is therefore not recommended.



## CHAPTER 12.6.

## INFECTION WITH EQUINE INFLUENZA VIRUS

[...]

Article 12.6.6.

**Recommendations for the importation of domestic equids for unrestricted movement**

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

- 1) came from an EI free country, *zone* or *compartment* in which they had been resident for at least 21 days; in the case of a vaccinated domestic equid, information on its *vaccination* status should be included in the veterinary certificate;

OR

- 2) came from a country, *zone* or *compartment* not known to be free from EI, were subjected to pre-export isolation for 21 days and showed no clinical sign of EI during isolation nor on the day of shipment; and
- 3) were ~~immunised~~ vaccinated in accordance with the recommendations of the manufacturer with a vaccine complying with the standards described in the *Terrestrial Manual*, ~~between 21 and 90 days before shipment either with a primary course or a booster; information on their vaccination status should be included in the veterinary certificate or the passport in accordance with Chapter 5.12. in accordance with one of the following procedures:~~
  - a) between 14 and 90 days before shipment either with a primary course or a booster; or
  - b) between 14 and 180 days before shipment, if they are older than four years of age, previously having received at least four doses of the same vaccine at intervals not greater than 180 days.

Information on the vaccination status should be included in the *international veterinary certificate* or the passport in accordance with Chapter 5.12 as relevant.

For additional security, countries that are free of EI or undertaking an eradication programme may also request that the domestic equids were tested negative for EIV by an agent identification test for EI described in the *Terrestrial Manual* conducted on samples collected on two occasions at 7 to 14 days and less than 5 days before shipment.

[...]



CHAPTER 14.7.  
INFECTION WITH  
PESTE DES PETITS RUMINANTS VIRUS

[...]

Article 14.7.3.

**PPR-free Country or zone free from PPR**

A country or zone may be considered free from PPR when the relevant provisions of point 2) of Article 1.4.6. and Chapter 1.6. have been complied with, and when within the proposed free country or zone for at least the past 24 months:

- 1) there has been no case of infection with PPRV;
  - 2) the Veterinary Authority has current knowledge of, and authority over, all domestic sheep and goats in the country or zone;
  - 3) appropriate surveillance has been implemented in accordance with:
    - a) Chapter 1.4. where historical freedom can be demonstrated; or
    - b) Articles 14.7.27. to 14.7.33. where historical freedom cannot be demonstrated;
  - 4) no vaccination against PPR has been carried out;
  - 5) no animals vaccinated against PPR have been introduced since the cessation of vaccination.
- ~~1) The PPR status of a country or zone should be determined on the basis of the following criteria, as applicable:~~
- ~~a) PPR is notifiable in the whole territory, and all clinical signs suggestive of PPR should be subjected to appropriate field or laboratory investigations;~~
  - ~~b) an ongoing awareness programme is in place to encourage reporting of all cases suggestive of PPR;~~
  - ~~c) systematic vaccination against PPR is prohibited;~~
  - ~~d) importation of domestic ruminants and their semen, oocytes or embryos is carried out in accordance with this chapter;~~
  - ~~e) the Veterinary Authority has current knowledge of, and authority over, all domestic sheep and goats in the country or zone;~~
  - ~~f) appropriate surveillance, capable of detecting the presence of infection even in the absence of clinical signs, is in place; this may be achieved through a surveillance programme in accordance with Articles 14.7.27. to 14.7.33.~~

Annex 24 (contd)

- 2) To qualify for inclusion in the list of PPR free countries or zones, a Member Country should either:
- a) apply for recognition of historical freedom as described in point 1) of Article 1.4.6.; or
  - b) apply for recognition of freedom and submit to the OIE:
    - i) a record of regular and prompt animal disease reporting;
    - ii) a declaration stating that:
      - there has been no *outbreak* of PPR during the past 24 months;
      - no evidence of PPRV *infection* has been found during the past 24 months;
      - no *vaccination* against PPR has been carried out during the past 24 months;
      - importation of domestic ruminants and their semen, oocytes or embryos is carried out in accordance with this chapter;
    - iii) supply documented evidence that *surveillance* in accordance with Chapter 1.4. is in operation and that regulatory measures for the prevention and control of PPR have been implemented;
    - iv) evidence that no animals vaccinated against PPR have been imported since the cessation of *vaccination*.

The Member Country will be included in the list only after the application and submitted evidence has been accepted by the OIE. Changes in the epidemiological situation or other significant events should be reported to the OIE in accordance with the requirements in Chapter 1.1.

Retention on the list requires ~~annual reconfirmation of point 2) above~~ that information in point 4 d) of Article 1.4.6. and points 1) to 3) above be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 4 a) to 4 c) of Article 1.4.6. and points 4) and 5) above be reported to the OIE.

[...]

Article 14.7.34.

### OIE endorsed official control programme for PPR

The objective of an OIE endorsed *official control programme* for PPR is for Member Countries to progressively improve the situation in their territories and eventually attain free status for PPR.

Member Countries may, on a voluntary basis, apply for endorsement of their *official control programme* for PPR in accordance with Chapter 1.6., when they have implemented measures in accordance with this article.

For a Member Country's *official control programme* for PPR to be endorsed by the OIE, the Member Country should provide a detailed *official control programme* for the control and eventual eradication of PPR in the country or zone. This document should address and provide documentary evidence on the following:

1. epidemiology:
  - a) the detailed epidemiological situation of PPR in the country, highlighting the current knowledge and gaps;
  - b) the main livestock production systems and movement patterns of sheep and goats and their products within and into the country and, where applicable, the specific zone;

2. surveillance and diagnostic capabilities:
    - a) PPR surveillance in place, in accordance with Chapter 1.4. and Articles 14.7.27. to 14.7.33.;
    - b) diagnostic capability and procedures, including regular submission of samples to a laboratory that carries out diagnosis and further characterisation of strains;
    - c) serosurveillance conducted in susceptible species, including wildlife, to serve as sentinels for PPRV circulation in the country;
  3. strategies to reach the objectives:
    - a) where vaccination is practised as a part of the official control programme for PPR, documentary evidence (such as copies of national legislation, regulations and Veterinary Authority directives) that vaccination of selected populations is compulsory, and detailed information on vaccination campaigns, in particular on:
      - i) the strategy that is adopted for the vaccination campaign;
      - ii) target populations for vaccination;
      - iii) target geographical area for vaccination;
      - iv) monitoring of vaccination coverage, including serological monitoring of population immunity;
      - v) technical specification of the vaccines used and description of the vaccine licensing procedures in place;
      - vi) if relevant, proposed timeline for the transition to the use of vaccines fully compliant with the standards and methods described in the Terrestrial Manual;
      - vii) the proposed strategy and work plan including timeline for the transition to the cessation of the use of vaccination;
    - b) the measures implemented to prevent the introduction of the pathogenic agent, and to ensure the rapid detection of, and response to, all PPR outbreaks in order to reduce outbreaks and to eliminate PPRV circulation in domestic sheep and goats in at least one zone in the country;
  4. the defined work plan and timelines of the official control programme;
  5. performance indicators for assessing the effectiveness of the control measures to be implemented;
  6. assessment of the evolution and implementation of the official control programme to demonstrate the effectiveness of the strategies;
  7. existence of an emergency preparedness plan and of an emergency response plan to be implemented in case of PPR outbreaks.
- 1) submit documented evidence on the capacity of its Veterinary Services to control PPR; this evidence can be provided by countries following the OIE PVS Pathway;
  - 2) submit documentation indicating that the official control programme for PPR is applicable to the entire territory (even if it is on a zonal basis);
  - 3) have a record of regular and prompt animal disease reporting in accordance with the requirements in Chapter 1.1.;

Annex 24 (contd)

- 4) ~~submit a dossier on the status of PPR in the country describing the following:~~
  - a) ~~the general epidemiology of PPR in the country highlighting the current knowledge and gaps;~~
  - b) ~~the measures implemented to prevent introduction of *infection*, the rapid detection of, and response to, all PPR *outbreaks* in order to reduce the incidence of *outbreaks* and to eliminate virus circulation in domestic sheep and goats in at least one *zone* in the country;~~
  - c) ~~the main livestock production systems and movement patterns of sheep and goats and their products within and into the country and, where applicable, the specific *zone(s)*;~~
- 5) ~~submit a detailed plan of the programme to control and eventually eradicate PPR in the country or *zone* including:~~
  - a) ~~the timeline for the programme;~~
  - b) ~~the performance indicators that will be used to assess the efficacy of the control measures;~~
- 6) ~~submit evidence that PPR *surveillance* is in place, taking into account the provisions in Chapter 1.4. and the provisions on *surveillance* in this chapter;~~
- 7) ~~have diagnostic capability and procedures in place, including regular submission of samples to a *laboratory*;~~
- 8) ~~where *vaccination* is practised as a part of the *official control programme* for PPR, provide evidence (such as copies of legislation) that *vaccination* of sheep and goats in the country or *zone* is compulsory;~~
- 9) ~~if applicable, provide detailed information on *vaccination* campaigns, in particular on:~~
  - a) ~~the strategy that is adopted for the *vaccination* campaign;~~
  - b) ~~monitoring of *vaccination* coverage, including serological monitoring of population immunity;~~
  - c) ~~serosurveillance in other susceptible species, including *wildlife* to serve as sentinels for PPRV circulation in the country;~~
  - d) ~~disease *surveillance* in sheep and goat populations;~~
  - e) ~~the proposed timeline for the transition to the cessation of the use of *vaccination* in order to enable demonstration of absence of virus circulation;~~
- 10) ~~provide an emergency preparedness and contingency response plan to be implemented in case of PPR *outbreak(s)*.~~

The Member Country's *official control programme* for PPR will be included in the list of programmes endorsed by the OIE only after the submitted evidence has been accepted by the OIE.

Retention on the list of endorsed official control programmes for PPR requires an annual update on the progress of the *official control programme* and information on significant changes concerning the points above.

Changes in the epidemiological situation and other significant events should be reported to the OIE in accordance with the requirements in Chapter 1.1.

Annex 24 (contd)

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

- non-compliance with the timelines or performance indicators of the programme; or
  - significant problems with the performance of the *Veterinary Services*; or
  - an increase in the incidence of PPR that cannot be addressed by the programme.
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**WORK PROGRAMME FOR  
THE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION**

Subject	Issue by priority order	Status and Action (Onset of process / # of rounds for comments now)
<b>Horizontal chapters</b>		
<b>Restructuring of the Code</b>	1) Work with AAHSC towards harmonisation, as appropriate, of the horizontal parts of the <i>Codes</i> , notably Glossary, User's Guide, Section 4 on Disease prevention and control and Section 5 on Trade measures, import/export procedures and veterinary certification	Ongoing
	2) Work with BSC for accurate disease description and diagnostic in the <i>Manual</i> and case definitions in the <i>Code</i> and names of diseases and country and zone disease status	Ongoing
	3) Revision and formatting of chapters (articles numbering, tables and figures)	Ongoing
	4) Revision of the Users' guide	Ongoing
<b>Glossary</b>	1) 'early warning system' and 'sanitary measures'	Revised definitions proposed for adoption (Sep 2017/4th and Feb 2018/3rd, respectively)
	2) 'epidemiological unit'	Revised definitions sent for comments (Sep 2018/2nd)
	3) 'Competent Authority', 'Veterinary Authority', 'Veterinary Services' and 'captive wild [animal]'	'CA', 'VA' and 'VA': the comments sent to AHG (Sep 2018/1st) 'captive wild [animal]': the comments sent to wildlife WG (Sep 2018/1st)
	4) New definitions for 'animal product', 'product of animal origin' and 'animal by-product'	Preliminary discussion
	5) Review the terms 'notify', 'notifiable disease', 'report' and 'reportable disease'	Preliminary discussion
<b>Horizontal issues not yet in the Code</b>		
<b>Section 4. Disease control</b>	1) New CH on official control programmes for listed and emerging diseases	Revised new CH proposed for adoption (Feb 2017/5th)
	2) New introductory CH in Section 4	Revised new CH proposed for adoption (Sep 2017/4th)
	3) New CH on biosecurity (Discussion with AAHSC)	Preliminary discussion

Subject	Issue by priority order	Status and Action (Onset of process / # of rounds for comments now)
	4) New CH on application of zoning	Preliminary discussion
<b>Section 6. Veterinary public health</b>	1) Control of Shiga toxin-producing <i>E. coli</i> (STEC) in food-producing animals	Preliminary discussion pending FAO/WHO expert consultation
<b>Section 7. Animal welfare</b>	1) New CH on slaughter and killing methods of farmed reptiles	Revised new CH proposed for adoption (Sep 2017/4th)
	2) New CH on AW and laying hen production systems	The comments sent to AHG (Sep 2017/2nd)
<b>Horizontal chapters in need of revision</b>		
<b>Section 1. Animal disease diagnosis, surveillance and notification</b>	1) CH 1.4. on animal health surveillance (MCs comments and implications for status recognition)	Revised CH proposed for adoption (Feb 2016/5th)
	2) CH 1.6. on procedures for publication of a self-declaration of disease freedom, recognition of an official animal health status and endorsement of an official control programme by the OIE	Revised CH sent for comments (Feb 2018/3rd)
	3) CH 1.1. on notification of diseases	Revised CH sent for comments (Sep 2018/2nd)
	4) CH 1.3. on listed diseases: assess CWD, WNF, PED, <i>Theileria</i> spp., <i>M. paratuberculosis</i> , <i>Trypanosoma</i> spp., MERS-Cov, against the listing criteria	Pending expert advice
<b>Section 3. Veterinary Services</b>	1) CHs 3.4. on veterinary legislation (the return of experience of the PVS Pathway)	Revised CH sent for comments (Sep 2018/2nd)
	2) CHs 3.1. and 3.2. on Veterinary Services (the return of experience of the PVS Pathway)	Pending proposal from AHG
<b>Section 4. Disease control</b>	1) CH 4.13. on disinfection	Preliminary discussion
	2) CH 4.6. on collection and processing of semen	Pending expert advice
	3) CH 4.5. on general hygiene in semen collection and processing centres	Pending expert advice
	4) CH 4.8. on collection and processing of oocytes and <i>in vitro</i> produced embryos from livestock and horses	Preliminary discussion
	5) CH 4.7. on collection and processing of <i>in vivo</i> derived embryos	Pending expert advice
<b>Section 5. Trade measures</b>	1) CHs 5.4. to 5.7. on measures applicable at departure and on arrival	Preliminary discussion and pending decision on AHG
	2) CH 5.12. on model certificates for competition horses	Preliminary discussion and pending revision of CHs on horse diseases

Subject	Issue by priority order	Status and Action (Onset of process / # of rounds for comments now)
<b>Section 6. Veterinary public health</b>	1) CH 6.3. on meat inspection	Preliminary discussion pending AHG
	2) CH 6.10. on responsible and prudent use of antimicrobial agents in veterinary medicine	Pending expert advice
<b>Section 7. Animal welfare</b>	1) CH 7.5. on slaughter and CH 7.6. on killing of animals	Pending further work of AHG
	2) CH 7.7. on stray dog population control	Preliminary work of AHG
<b>Diseases not yet in the Code</b>		
<b>Disease-specific chapters</b>	1) New CH on surra and revision of CH on Dourine	Pending expert advice
	2) New CH on animal trypanosomoses of African origin	Pending further work of AHG
	3) New CH on Crimean Congo hemorrhagic fever (MCs comments, listed disease without chapter)	Preliminary discussion
<b>Listed disease chapters/articles in need of revision</b>		
<b>Sections 8 to 15</b>	1) CH 10.4. on avian influenza	Some of the comments sent to AHG (Sep 2018/1st)
	2) CH 8.14. on rabies	Revised CH proposed for adoption (Feb 2018/3rd)
	3) CH 11.4. on BSE	Pending work of AHGs (Feb 2015/1st)
	4) CH 15.2. on CSF	The comments to be addressed (Feb 2017/2nd)
	5) Revision of Articles 8.15.1., 8.15.4. and 8.15.5. (Infection with Rift Valley fever virus)	Revised CH sent for comments (Feb 2019/1st)
	6) CH 8.16. on rinderpest	Pending work of HQs and JAC
	7) Harmonisation of articles regarding official status recognition by the OIE	Pending work of HQs
	8) Revision of safe commodities list to add lactose	Pending expert advice
	9) CH 12.2. on Contagious equine metritis and CH12.7. on Equine piroplasmiasis	Pending work of HQs
	10) CH 11.12. on Theileriosis and new CH 14.X. on infection with <i>Theileria</i> in small ruminants	Revised/new CHs sent for expert advice on listing pathogenic agents (Sep 2017/1st)
	11) CH 8.8. on FMD	Pending outcome of discussion on zoning (Sep 2015/2nd)

Subject	Issue by priority order	Status and Action (Onset of process / # of rounds for comments now)
	12) Revision of Article 15.3.9. on import of semen from countries not free from PRRS	Pending expert advice
	13) CH 14.8. on scrapie	Pending expert opinion
	14) CH 10.5. on avian mycoplasmosis	Pending expert opinion
	15) Pet food ( for certification or safe commodities)	Pending expert advice

Subject	Issue by priority order	Status and Action (Onset of process / # of rounds for comments now)
<b>Follow-up revision of chapters recently adopted</b>		
<b>Recently adopted chapters</b>	1) Articles 15.1.1.-bis, 15.1.2., 15.1.3., 15.1.16., 15.1.22. and 15.1.31 on ASF	Revised CH proposed for adoption (Sep 2017/4th)
	2) CH 4.3. on zoning and compartmentalisation	Pending discussion on temporary protection zone
	3) CH 6.2. on the role of Veterinary Services in food safety systems	Revised CH proposed for adoption (Sep 2018/2nd)
	4) Article 7.1.4. on the guiding principles for the use of measures to assess animal welfare	Revised article proposed for adoption (Sep 2018/2nd)
	5) CH 7.13. on animal welfare and pig production systems	Revised article proposed for adoption (Sep 2018/2nd)

List of abbreviations	
AAHSC	Aquatic Animal Health Standards Commission
AHG	<i>ad hoc</i> Group
AMR	Antimicrobial resistance
ASF	African swine fever
AW	Animal Welfare
BSC	Biological Standards Commission
BSE	Bovine Spongiform Encephalopathy
CH	Chapters
CSF	Classical swine fever
CWD	Chronic wasting disease
FMD	Foot and mouth disease
HQs	Headquarters
JAC	FAO-OIE Rinderpest Joint Advisory Committee
LSD	Lumpy skin disease
MERS-CoV	Middle East Respiratory Syndrome Coronavirus
NGO	Non-Governmental Organisation
PVS	Performance of Veterinary Service
TAHSC	Terrestrial Animal Health Standards Commission
WNF	West Nile fever



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