

## GLOSSARY

### **DEATH**

means the irreversible permanent loss of all vital functions brain activity demonstrable by the loss of brain stem reflexes. This may be confirmed through a combination of criteria such as dilated pupil and absence of corneal reflex, cardiac activity and breathing.

### **DISTRESS**

means the state of an animal, that has been unable to adapt to stressors, and that manifests as abnormal physiological or behavioural responses. It can be acute or chronic and may result in pathological conditions.

### **EUTHANASIA**

means *killing of an animal* the act of inducing death using a method that causes a rapid and irreversible loss of consciousness with the most rapid, method and with the least painless and distress free suffering method possible minimum pain and distress to animal.

### **PAIN**

means an unpleasant sensory and emotional experience associated with actual or potential tissue damage. It may elicit protective actions, result in learned avoidance and distress and may modify species-specific traits of behaviour, including social behaviour.

### **SLAUGHTER**

means any *killing* procedure that causes the death of an animal by bleeding of an animal primarily for human consumption.

### **STUNNING**

means any mechanical, electrical, chemical or other procedure that causes rapid immediate loss of consciousness with minimal pain and other types of and suffering; when used before slaughter, the loss of consciousness lasts until death from the slaughter process; in the absence of slaughter, the procedure would allow the animal to recover consciousness.

### **SUFFERING**

means an unpleasant, undesired physical or mental state of being that is the outcome of the impact on an animal of noxious negative stimuli and/or the absence of important essential positive stimuli. It is the opposite of good welfare.



## 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 animal trypanosomes of African origin (*T. vivax*, *T. congolense*, *T. simiae* and *T. brucei*)
- Infection with Aujeszky's disease virus
- Infection with bluetongue virus
- Infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis*
- Infection with *Echinococcus granulosus*
- Infection with *Echinococcus multilocularis*
- Infection with epizootic hemorrhagic disease virus
- Infection with foot and mouth disease virus
- Infection with *Mycobacterium tuberculosis* complex
- Infection with rabies virus
- Infection with Rift Valley fever virus
- Infection with rinderpest virus
- Infection with *Trichinella* spp.
- Japanese encephalitis
- New World screwworm (*Cochliomyia hominivorax*)
- Old World screwworm (*Chrysomya bezziana*)
- Paratuberculosis
- Q fever
- Surra (*Trypanosoma evansi*)
- Tularemia
- West Nile fever.

## Article 1.3.2.

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

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

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

[...]

Article 1.3.9.

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

- Camelpox
  - = Infection of dromedary camels with Middle East Respiratory Syndrome Coronavirus
  - Leishmaniosis.
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## DRAFT CHAPTER 3.1.

# QUALITY OF VETERINARY SERVICES

### Article 3.1.1.

#### **General considerations**

The quality of *Veterinary Services* depends on ethical, organisational, legislative and technical factors.

Compliance with standards of quality is critical for *Veterinary Services* to meet their animal health, *animal welfare*, and veterinary public health objectives, and is important for the establishment and maintenance of trust in *international trade*.

*Veterinary Services* should conform to the fundamental operating principles in Article 3.1.2., regardless of the political, economic or social situation of their country.

The key components of a country's *Veterinary Services* are presented in Articles 3.1.3 to 3.1.12. Four components are focused on governance aspects: Policy and Management, Personnel and Resources, the Veterinary Profession, and Stakeholders; and six components are focused on technical aspects: Animal Health, Animal Production Food Safety, Veterinary Medicinal Products, Laboratories, Animal Welfare and International Trade.

This chapter should be read in conjunction with other chapters in the *Terrestrial Code*, relevant chapters of the *Terrestrial Manual* with regards to quality of *laboratories*, diagnosis and vaccines, as well as relevant Codex Alimentarius texts.

### Article 3.1.2.

#### **Fundamental operating principles**

*Veterinary Services* should comply with the following interrelating principles to ensure the quality of their activities:

1. Professional judgement

The personnel should have the relevant qualifications, expertise and experience to give them the competence to make sound professional judgements.

2. Independence and objectivity

Care should be taken to ensure that personnel are free from any undue commercial, financial, hierarchical, political or other pressures which might adversely affect their judgement or decisions. The *Veterinary Services* should, at all times, act in an objective manner.

3. Impartiality

*Veterinary Services* should be impartial. In particular, all the parties affected by their activities have a right to expect that their services are delivered reasonably and without discrimination.

4. Integrity

*Veterinary Services* should maintain a consistently high level of integrity. Any fraud, corruption or falsification should be identified and addressed.

Annex 18 (contd)5. Transparency

*Veterinary Services* should be as transparent as possible in all their governance and technical activities, including but not limited to, disease reporting, policy and programme decision-making, human resources and financial issues.

6. Scientific basis

*Veterinary Services* should develop and implement their activities on a scientific basis, incorporating relevant inputs from fields such as *risk analysis*, epidemiology, ~~and~~ economics ~~and social science~~.

Article 3.1.3.

**Policy and management**

*Veterinary Services* should have the leadership, organisational structure and management systems to develop, implement and update policies, legislation and programmes, incorporating *risk analysis* and sound epidemiological principles. *Veterinary Services*' decision making should be free from undue financial, political and other non-scientific influences.

The *Veterinary Authority* should coordinate with other *Competent Authorities* and should undertake active international engagement with OIE and other relevant regional and international organisations.

This component should comprise the following specific elements:

- 1) Comprehensive national *veterinary legislation* in accordance with Chapter 3.4, regularly updated with reference to changing international standards and ~~science~~ new scientific evidence.
- 2) Implementation of *veterinary legislation* through a programme of communications and awareness, as well as formal, documented inspection and compliance activities.
- 3) Capability to perform *risk analysis* and cost-benefit analysis to define and adapt policies and programmes.
- 4) Policies or programmes that are well documented, resourced and sustained, appropriately reviewed and updated to improve their effectiveness and efficiency, and addressing emerging issues.
- 5) Quality management systems with quality policies, procedures and documentation suited to the *Veterinary Services*' activities, including procedures for information sharing, complaints and appeals and for internal audits.
- 6) Information management systems for collecting data to monitor and evaluate *Veterinary Services*' policies and activities and to perform *risk analysis*.
- 7) Organisational structures with defined roles and responsibilities for effective internal coordination from central to field levels (chain of command) for activities, which are periodically reviewed and updated as necessary.
- 8) Formal external coordination mechanisms with clearly described procedures or agreements for activities between the *Veterinary Authority*, *Competent Authorities* and stakeholders, incorporating a One Health approach.
- 9) Appropriate levels of official representation at international multilateral fora, with ~~pre~~ consultation with stakeholders, active participation and sharing of information, and follow up on meeting outcomes.

Article 3.1.4.

**Personnel and resources**

*Veterinary Services* should be appropriately staffed, including *veterinarians*, *veterinary paraprofessionals* or other personnel, with appropriate competencies through initial and continuing education to allow for their functions to be undertaken effectively and efficiently.

Annex 18 (contd)

*Veterinary Services* should have functional and well-maintained physical resources, adequate operational resources for their ongoing and planned activities, and access to extraordinary resources to respond effectively to emergency situations or new emerging issues.

This component should comprise the following specific elements:

- 1) A core of full-time civil service employees with qualified *veterinarians* and *veterinary paraprofessionals*.
- 2) Formal, consistent and merit-based recruitment and promotion procedures.
- 3) Job descriptions, formal performance assessment and management procedures for *veterinarians*, *veterinary paraprofessionals* and other personnel that are defined and being implemented.
- 4) Personnel remuneration, sufficient to minimise the risk of conflicts of interest and to preserve independence.
- 5) *Veterinarians'* and *veterinary paraprofessionals'* education, knowledge, skills and practices, standardised and sufficient to perform relevant activities of the *Veterinary Services*.
- 6) *Veterinary paraprofessionals* are adequately supervised by *veterinarians*.
- 7) All personnel have access to **professional development, including** continuing education programmes that are reviewed and updated as necessary.
- 8) Established procedures for *Veterinary Services* to access personnel and other resources, including in emergencies.
- 9) Access to suitable physical resources at all levels (national, state/provincial and local), including, but not limited to, functional buildings, furniture, equipment, communications, information technology, transport and cold chain, which are maintained or renewed as necessary.
- 10) Access to sufficient operational resources for planned and continued activities, as well as for new or expanded operations, including but not limited to, contracts, fuel, per diem, vaccines, diagnostic reagents, personal protective equipment and other consumables.

## Article 3.1.5.

**The veterinary profession**

*Veterinarians* and *veterinary paraprofessionals* are an essential component of *Veterinary Services*, whether as part of governmental authorities or as private service providers.

The *Veterinary Statutory Body* should regulate *veterinarians* and *veterinary paraprofessionals* to effectively and independently maintain educational and professional standards **relevant to their role**, including **for both** official tasks, **and** veterinary clinical services **and other veterinary tasks as appropriate**. Mechanisms for coordination between the *Veterinary Authority*, the *Veterinary Statutory Body* and veterinary educational establishments should be in place.

The OIE has produced guidelines on the expected competencies for *veterinarians* and *veterinary paraprofessionals* as well as guidelines on the curricula necessary to deliver those competencies.

This component should comprise the following specific elements:

- 1) An independent *Veterinary Statutory Body*, legally responsible and adequately resourced for:
  - a) licensing and registration of *veterinarians* and *veterinary paraprofessionals* to perform defined activities of veterinary science or animal health;
  - b) setting minimum standards of education required to be registered or licensed as *veterinarians* or *veterinary paraprofessionals*;

Annex 18 (contd)

- c) setting minimum standards of professional conduct and competence of registered *veterinarians* and *veterinary paraprofessionals* and ensuring that these standards are met and maintained;
  - d) investigating complaints and applying disciplinary measures.
- 2) Independence of the *Veterinary Statutory Body* is ensured through transparent governance and funding arrangements including an elected, representative council or equivalent, and financial arrangements for the collection and management of registration fees.
  - 3) Sufficient **quality** veterinary clinical services are available ~~of sufficient quality~~ to meet the needs of animal owners, including their access to essential animal disease and injury diagnosis and treatment.

## Article 3.1.6.

**Stakeholders**

A range of individuals or organisations have an interest or concern in the activities of the *Veterinary Services*, for example livestock farmers, processors, traders, feed manufacturers, private *veterinarians* and *veterinary paraprofessionals*, as well as relevant non-governmental organisations (NGOs) and the general public.

*Veterinary Services* should communicate with these stakeholders in an effective, transparent and timely manner on *Veterinary Services* activities and developments in animal health, *animal welfare* and veterinary public health. They should also consult effectively with relevant stakeholders on *Veterinary Services* policies and programmes, involving mechanisms that actively seek their views for consideration and response.

*Competent Authorities* should, where applicable, have the authority and capability to develop or engage in public private partnerships to deliver animal health, *animal welfare* or veterinary public health outcomes. That is:

- to accredit, authorise or delegate to the private sector;
- **the to development** or **participation** in collaborative joint programmes with producers or other stakeholders.

The OIE has produced guidelines for both public and private sectors to help advocate for, develop and implement public private partnerships in the veterinary domain.

This component should comprise the following specific elements:

- 1) Good governance relevant to all stakeholder engagement is in place to ensure compliance with Article 3.1.2, incorporating transparency and effective monitoring and evaluation.
- 2) Ongoing, targeted and effective communication with stakeholders in accordance with Chapter 3.3.
- 3) Consultation mechanisms, including written invitation, meetings or workshops with non-government stakeholder representatives, with consultation inputs documented and duly considered.
- 4) Public private partnerships, in the form of official delegation or joint programmes, have the legal authority, formal agreements, and documented procedures, in accordance with Chapter 3.4.

## Article 3.1.7.

**Animal health**

*Veterinary Services* should organise and implement programmes to prevent, control or eradicate animal diseases, and should be able to identify *animals* to trace and control their movements.

*Veterinary Services* should organise and implement an effective animal health surveillance system and be prepared to respond effectively to sanitary emergencies.

This component should comprise the following specific elements:

- 1) Effective surveillance for the early detection, monitoring and reporting of animal diseases via an appropriate field animal health network, using laboratory confirmation and epidemiological disease investigation with prompt and transparent reporting and data analysis technologies, in accordance with relevant chapters, including Chapters 1.1., 1.2., 1.3., 1.4. and 1.5.
- 2) An updated list of *notifiable diseases* that includes relevant *listed diseases*.
- 3) Use of the formal procedures for self-declaration and official recognition by the OIE for both disease freedom and disease control programmes, in accordance with Chapter 1.6.
- 4) Emergency management, including preparedness and response planning, a legal framework, and access to the human, physical and financial resources to respond rapidly to sanitary emergencies in a well-coordinated manner, including for disposal and *disinfection* in accordance with Chapters 4.13. and 4.14.
- 5) *Official control programmes* for priority diseases with scientific and risk-based evaluation of their efficacy and efficiency, in accordance with the relevant chapters of the *Terrestrial Code*.
- 6) A programme for managing the risks to animal health from germplasm, including the collection, processing and distribution of semen, oocytes or embryos, in accordance with the relevant chapters in Section 4.
- 7) A programme for the official health control of bee diseases, in accordance with Chapter 4.15.
- 8) A programme for managing the risks to animal and public health from animal *feed*, including feeding animal materials to susceptible livestock animals, in accordance with Chapter 6.4.
- 9) A system for *animal identification*, *animal traceability* and movement control for specific animal *populations* as required for traceability or disease control, in accordance with Chapters 4.1. and 4.2.

Article 3.1.8.

### Animal production food safety

*Veterinary Services* should contribute to assuring the safety of food of animal origin for domestic and export markets as part of a food safety system, with effective coordination of official controls between relevant *Competent Authorities*.

This component should comprise the following specific elements:

- 1) Regulation, inspection, authorisation, ~~and supervision~~ and auditing of establishments and processes for production and processing of food of animal origin (slaughter, rendering, dairy, egg, honey and other animal product processing establishments) for export, national and local markets, including the inspection, sampling and testing of products, in accordance with Chapters 6.1. and 6.2.
- 2) Implementation of procedures for ante-mortem and post-mortem inspection at slaughter facilities, incorporating *risk analysis* and principles of Hazard Analysis and Critical Control Point (HACCP), veterinary supervision, independent inspection, and the collection of information relevant to livestock animal diseases and zoonoses, in accordance with Chapters 6.2. and 6.3. and the relevant Codex Alimentarius texts.
- 3) Regulation and implementation of controls on animal *feed* safety covering processing, handling, storage, distribution and use of both commercial and on-farm produced animal *feed* and *feed ingredients*, including risks such as microbial, physical, chemical and toxin contamination.
- 4) A residue monitoring programme for veterinary medicines (e.g. antimicrobials and hormones), chemicals, pesticides, radionuclides, heavy metals, etc. and the capacity to respond appropriately to adverse findings.
- 5) Identification and traceability of products of animal origin for the purposes of food safety, animal health or trade, in accordance with Chapter 6.2.

Annex 18 (contd)

- 6) Procedures for corrective actions ~~or~~ and for proportional and dissuasive sanctions in response to regulatory non-compliance to mitigate risks to the safety of food of animal origin for export or domestic markets in accordance with Article 6.2.3.
- 7) Preparedness and response planning to manage food or *feed* safety incidents of animal origin.

Article 3.1.9.

**Veterinary medicinal products**

*Veterinary Services* should regulate all *veterinary medicinal products* such as veterinary medicines, biologicals and medicated *feed*, in order to ensure their quality and safety, as well as their responsible and prudent use, including *monitoring* antimicrobial use and antimicrobial resistance, and minimising the associated risks.

This article should be read in conjunction with the *Terrestrial Manual*, which set standards for the production and control of vaccines and other biological products.

This component should comprise the following specific elements:

- 1) Effective regulatory and administrative control, in accordance with Article 3.4.11., including communications and compliance programmes for:
  - a) the market authorisation of *veterinary medicinal products*, including registration, import, manufacture, quality control, and reducing the risk from illegal imports;
  - b) responsible and prudent use of *veterinary medicinal products*, including the labelling, distribution, sale, dispensing, prescription and administration of these products.
- 2) *Risk management* and *risk communication* for antimicrobial use and antimicrobial resistance, based on *risk assessment*. This includes *surveillance* and control of the use of antimicrobials and the development and spread of antimicrobial resistant pathogens in animal production and, animal origin food products, via a One Health approach, and in accordance with Chapter 3.4. and relevant chapters of Section 6.

Articles 3.1.10.

**Laboratories**

*Veterinary Services* should have access to quality *laboratory* diagnosis through a sustainable network of *laboratories*, capable of accurately identifying and reporting *infections* and *infestations* or other relevant *hazards*.

*Veterinary Services* require *laboratory* services for purposes such as early detection, measuring disease prevalence and progress with control, assessing ~~the veterinary medicinal products~~ quality and ~~protection effectiveness of veterinary medicinal products~~, antimicrobial resistance *surveillance*, assessing the safety of food or *feed*, or supporting *international trade* (e.g. demonstration of freedom animal health status). The *laboratory* services include official government *laboratories* and other *laboratories* authorised by the *Competent Authorities* to conduct official testing, including private *laboratories* or those overseas.

This article should be read in conjunction with the *Terrestrial Manual*, which sets *laboratory* diagnostic standards for all OIE *listed diseases* as well as several other diseases of global importance.

This component should comprise the following specific elements:

- 1) access to *laboratory* diagnosis that meets the needs of the *Veterinary Services*, which is efficient and sustainable with an appropriate throughput of samples, in accordance with the *Terrestrial Manual*;
- 2) access to approved *laboratories*, such as national, regional or international reference *laboratories*, to obtain or confirm a correct diagnosis for *notifiable diseases* and to investigate *emerging diseases* or *hazards*, in accordance with the *Terrestrial Manual*;

- 3) appropriate levels of laboratory biosafety and *biosecurity*;
- 4) formal *laboratory* Quality Management Systems and proficiency testing programmes, in accordance with the *Terrestrial Manual*.

Article 3.1.11.

### **Animal welfare**

*Veterinary Services* should implement policies, legislation and programmes in accordance with Section 7.

This component should comprise the following specific elements:

- 1) *animal welfare* programmes, supported by suitable legislation, with appropriate stakeholder and public awareness and compliance inspection activities;
- 2) communication, consultation and coordination with stakeholders.

Article 3.1.12.

### **International trade**

Through the implementation of OIE standards, *Veterinary Services* play a critical role in ensuring the safety of *international trade* of *commodities* and *veterinary medicinal products*, while avoiding unjustified barriers.

*Veterinary Services* should implement risk-based measures for import and export following relevant provisions in the *Terrestrial Code* and in accordance with Chapter 5.3. Quality of *Veterinary Services* is essential for these measures to be recognised and trusted.

This component should comprise the following specific elements:

- 1) *Sanitary measures* developed and implemented in accordance with Chapter 2.1. and other relevant chapters of the *Terrestrial Code*.
- 2) Effective implementation of *official veterinary controls* to prevent the entry of diseases and other *hazards* through effective border inspection and quarantine operations, in accordance with Chapter 5.6.
- 3) Effective application of relevant animal health measures at or before departure for exports, during transit through the country, and on arrival for imports, in accordance with Chapters 5.4., 5.5. and 5.7.
- 4) Effective development and implementation of international veterinary certification for *animals*, animal products, services and processes for export under their mandate, in accordance with *importing country* requirements and relevant chapters in Section 5.
- 5) Effective development, implementation and maintenance of equivalence and other types of sanitary agreements with trading partners, where applicable, in collaboration with national stakeholders, and in accordance with Chapter 5.3.
- 6) Regular and timely official notification to the OIE, WTO, trading partners and other relevant organisations of changes in animal disease status, regulations and *sanitary measures* and systems, in accordance with the procedures established by these organisations, including Chapters 1.1. and 1.3.
- 7) Where applicable, effective implementation and maintenance of disease-free *zones*, *compartments* or other high health status *subpopulations* for the purposes of trade, in collaboration with producers and other stakeholders, and in accordance with relevant chapters in Sections 4 and 5.
- 8) Active participation in the OIE and Codex Alimentarius standard setting processes.



## DRAFT CHAPTER 3.2.

# EVALUATION OF VETERINARY SERVICES

### Article 3.2.1.

#### **General considerations**

This chapter covers the evaluation of a country's *Veterinary Services*, including the various objectives and types of evaluation that may be considered.

Member Countries may develop their own mechanisms and methods for the evaluation of their *Veterinary Services*. The evaluation of the quality of *Veterinary Services* should be in accordance with Chapter 3.1.

The OIE Tool for the Evaluation of Performance of Veterinary Services (OIE PVS Tool) provides a thorough, benchmarked methodology for the consistent, comprehensive evaluation of *Veterinary Services*. The OIE PVS Tool is aligned with the OIE standards, in particular, with the quality standards for *Veterinary Services* defined in Chapter 3.1. Based on the OIE PVS Tool, the OIE has developed a capacity building platform, the PVS Pathway, for the sustainable improvement of a country's *Veterinary Services*' compliance with OIE standards.

### Article 3.2.2.

#### **Objectives of the Evaluation of Veterinary Services**

The evaluation of *Veterinary Services* has the following objectives:

- 1) to provide an independent, objective perspective on the performance of *Veterinary Services*;
- 2) to verify performance, provide confidence, enhance reputation and avoid complacency, and as part of a process of continuous improvement;
- 3) to demonstrate compliance of the *Veterinary Services* with Chapter 3.1.;
- 4) to better advocate for, allocate and prioritise resources;
- 5) to generate trust between trading partners in the quality and integrity of *Veterinary Services*.

The evaluation of *Veterinary Services* can be performed by the country itself (self-evaluation), by another country or countries, or by OIE experts under the auspices of the OIE as part of the PVS Pathway.

### Article 3.2.3.

#### **Self-evaluation of the Veterinary Services of a Member Country**

- 1) Member Countries should undertake a self-evaluation of their *Veterinary Services* periodically as part of their quality management system.
- 2) Self-evaluation may be undertaken by *Competent Authorities* for the whole or part of the *Veterinary Services*.
- 3) Self-evaluation at the sub-national level such as of individual **regions**, provinces or states can usefully supplement national level evaluation.
- 4) The use of the OIE PVS Tool is encouraged.

Annex 19 (contd)

## Article 3.2.4.

**Evaluation of the Veterinary Services of a Member Country by another Member Country**

- 1) Every Member Country should recognise the right of another Member Country to request, in a non-discriminatory manner, an evaluation of its *Veterinary Services* to facilitate decision-making on trade.
- 2) The evaluation should be in accordance with Chapter 3.1.
- 3) The evaluation process may be desktop or field based, and cover whole or part of the *Veterinary Services*, depending on its objective.
- 4) A Member Country which intends to conduct an evaluation of another Member Country's *Veterinary Services* should give them notice in writing. This should define the purpose and scope of the evaluation and detail the information required.
- 5) Prior to the evaluation, the parties should agree on the objective, scope and approach of the evaluation, including any financing and confidentiality requirements of confidentiality.
- 6) The evaluation should be conducted in accordance with the Fundamental Operating Principles set-out for *Veterinary Services* in Article 3.2.2 in a timely and efficient manner, ensuring the level of evaluation activity is undertaken only to the extent necessary.
- 7) The evaluation should start with a review of available information including existing PVS Pathway or other reports, analysis of publicly available or previously provided information, or historical performance such as relating to safe trade or transparency.
- 8) The outcome of the evaluation conducted by another Member Country should be provided in writing to the evaluated country as soon as possible. The evaluation report should detail any findings which affect trade prospects. The Member Country which conducts the evaluation should clarify any points of the evaluation on request, and provide the opportunity for the evaluated country to clarify or respond to the findings before the production of the final evaluation report.
- 9) The use of the OIE PVS Tool is encouraged.

## Article 3.2.5.

**Evaluation of the Veterinary Services of a Member Country by OIE experts, under the auspices of the OIE**

- 1) The OIE has established procedures for the evaluation of the *Veterinary Services* of a Member Country using the OIE PVS Tool, following a voluntary request from the Member Country.
- 2) The report of such an evaluation belongs to the *Veterinary Authority* of the Member Country. The OIE encourages Member Countries to make their reports publicly available.
- 3) Member Countries are encouraged to use these reports in a transparent way to achieve some or all of the objectives listed in Article 3.2.2.
- 4) Support for further use of the evaluation report in national planning and targeted capacity building is available from the OIE as part of its PVS Pathway.

## DRAFT CHAPTER 3.X.

**INTRODUCTION TO RECOMMENDATIONS  
ON VETERINARY SERVICES**

## Article 3.X.1.

*Veterinary Services* are critical to global and national health security, food security and food safety, agricultural and rural development, poverty alleviation, safe *international trade*, *wildlife* and environmental protection; as such they are considered a global public good. To achieve these goals, *Veterinary Services* require good governance, including effective policy and management, personnel and resources, veterinary professionals and interaction with stakeholders.

Member Countries have the sovereign right to structure and manage the delivery of animal health, *animal welfare* and veterinary public health in the veterinary domain in their countries as they see fit. The veterinary domain covers a broad scope of possible activities. Section 3 focuses on aspects of the *Veterinary Services* that enable the OIE standards to be met even when under the responsibility of one or more *Competent Authorities*.

Member Countries should implement the OIE standards across their whole territory and should meet their obligations at the international level through representation by their respective OIE Delegate. The *Veterinary Authority*, including the OIE Delegate, should coordinate with other *Competent Authorities* to ensure international standards and responsibilities are met.

*Veterinary Services* have responsibility for implementing the activities necessary for the Member Country to comply with OIE standards. These activities can be delivered by a combination of individuals or organisations, public or private that are responsible to one or more *Competent Authorities*. *Veterinary Services* also include the personnel of the *Competent Authorities* themselves. The term *Veterinary Services* refers to the combination of a number of separate actors, with different organisational affiliations.

Section 3 provides standards to assist the *Veterinary Services* of Member Countries in meeting their objectives of improving terrestrial animal health and *animal welfare* and veterinary public health, as well as to establish and maintain confidence in their *international veterinary certificates*.

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## CHAPTER 4.4.

## ZONING AND COMPARTMENTALISATION

[...]

Article 4.4.6.

**Protection zone**

A *protection zone* may be established to preserve the *animal health status* of an *animal population* in a free country or a *free zone* by preventing the introduction of a pathogenic agent of a specific *infection* or *infestation* from neighbouring countries or *zones* of different *animal health status* ~~to that animal population~~

A *protection zone* can be established as a temporary measure in response to an increased risk of disease. The *protection zone* can be established within or outside a *free zone* or within a free country. Based on the results of a risk assessment, more than one *protection zone* may be established.

*Biosecurity* and *sanitary measures* should be implemented in the *protection zone* based on the animal management systems, the epidemiology of the disease under consideration and the epidemiological situation prevailing in the neighbouring infected countries or *zones*.

Increased *surveillance*, in accordance with Chapter 1.4. and the relevant disease-specific chapter, should be implemented in the *protection zone* and the rest of the country or *zone*, including *surveillance* of *wildlife* and *vectors* as relevant.

In addition to the general considerations in Article 4.4.2. and the principles in Article 4.4.3., ~~These~~ measures should include intensified movement control, ~~and *surveillance* and specific *animal identification* and *animal traceability* to ensure that *animals* in the *protection zone* are clearly distinguishable from other populations.~~ *Vaccination* of susceptible *animals* in accordance with Chapter 4.18. may also be applied.

- 1) ~~*vaccination* of all or at risk susceptible *animals*;~~
- 2) ~~testing or *vaccination* of *animals* moved;~~
- 3) ~~specific procedures for sample handling, dispatching and testing;~~
- 4) ~~enhanced *biosecurity* including *disinfection* and *disinsection* procedures for *vehicles/vessels* and *vehicles* used for transportation of animal products, *feed* or *fodder*, and possible compulsory routes for their movements within, to or from the *zone*;~~
- 5) ~~specific *surveillance* of susceptible *wildlife* and relevant *vectors*;~~
- 6) ~~awareness campaigns aimed at the public or targeted at breeders, traders, hunters or *veterinarians*.~~

~~Anytime the status of the *protection zone* changes, the status of the country or *zone* in which it was established should be redetermined in accordance with the relevant *listed disease*-specific chapters.~~

Unless otherwise specified in the relevant disease-specific chapters of the *Terrestrial Code*, if the *animal health status* of an established *protection zone* changes due to the occurrence of a case or implementation of *vaccination*, the *animal health status* of the rest of the country or *zone* is not affected.

Regarding diseases for which the OIE grants official recognition of *animal health status*, a *protection zone* is considered as effectively established when the conditions described in this article and in the relevant disease-specific chapters have been applied and documented evidence is submitted to the OIE. A *protection zone* established on a temporary basis should be limited to less than 24 months from the date of its approval by the OIE. If a Member wishes to make the *protection zone* permanent, the process for official recognition by the OIE should be followed.

Annex 21 (contd)

## Article 4.4.7.

**Containment zone**

- 1) In the event of *outbreaks* in a country or *zone* previously free from a disease, a *containment zone*, which includes all epidemiologically linked *outbreaks* may be established to minimise the impact on the rest of the country or *zone*.
- 2) A *containment zone* is an *infected zone* that should be managed in such a way that *commodities* for *international trade* can be shown to have originated either from inside or outside the *containment zone*.
- 3) Establishment of a *containment zone* should be based on a rapid response, prepared in a contingency plan, and that includes:
  - appropriate control of movement of *animals* and other *commodities* upon declaration of suspicion of the specified disease;
  - epidemiological investigation (trace-back, trace-forward) after confirmation of *infection* or *infestation*, demonstrating that the *outbreaks* are epidemiologically related and all contained within the defined boundaries of the *containment zone*;
  - a *stamping-out policy* or another effective emergency control strategy aimed at eradicating the disease;
  - *animal identification* of the susceptible population within the *containment zone* enabling its recognition as belonging to the *containment zone*;
  - increased passive and targeted *surveillance* in accordance with Chapter 1.4. in the rest of the country or *zone* demonstrating no occurrence of *infection* or *infestation*;
  - *biosecurity* and *sanitary measures*, including ongoing *surveillance* and control of the movement of *animals*, other *commodities* and fomites within and from the *containment zone*, consistent with the *listed disease-specific* chapter, when there is one, to prevent spread of the *infection* or *infestation* from the *containment zone* to the rest of the country or *zone*.
- 4) A *containment zone* is considered as effectively established when the following is demonstrated:
 

EITHER

  - a) there have been no new *cases* in the *containment zone* within a minimum of two *incubation periods* from the disposal of the last detected case;

OR

  - b) ~~the containment zone it comprises an infected~~ a *zone* where *cases* may continue to occur and a *protection* another zone where no *outbreaks* have occurred for at least two *incubation periods* after the control measures above are in place and which that separates the zone where cases may continue to occur the infected zone from the rest of the country or *zone*.
- 5) The free status of the areas outside the *containment zone* is suspended pending the effective establishment of the *containment zone*. Once the *containment zone* has been established, the areas outside the *containment zone* regain free status.
- 6) The free status of the *containment zone* should be regained in accordance with the relevant *listed disease-specific* chapters or, if there are none, with Article 1.4.6.
- 7) In the event of an occurrence of a *case* of the *infection* or *infestation* for which the *containment zone* was established, either in the *containment zone* defined in point a) or in the *protection zone* where no outbreaks had occurred as defined in point b), the rest of the country or *zone* is considered infected.

## CHAPTER 8.Y.

# INFECTION WITH ANIMAL TRYPANOSOMES OF AFRICAN ORIGIN

### Article 8.Y.1.

#### General provisions

- 1) Animal trypanosomes of African origin is a disease complex caused by several protozoan parasites of the genus *Trypanosoma*, transmitted mainly cyclically by the genus *Glossina* (tsetse flies), but also mechanically by several biting flies (e.g. tabanids, *Stomoxys* spp). The disease can be caused by many different trypanosomes and can affect various mammals such as horses, donkeys, camels, goats, sheep, pigs, dogs, cats and non-human primates. ~~From the socio-economic point of view. The disease is has a particularly significant socio-economic impact deleterious in on~~ cattle production. Some trypanosomes of African origin (i.e. *T. brucei gambiense*, *T. brucei rhodesiense*) also affect humans and are responsible for a disease ~~known as sleeping sickness or human African trypanosomosis, which is~~ almost always fatal if untreated ~~(sleeping sickness also known as human African trypanosomosis).~~
- 2) Infection with several trypanosome species in the same animal could exist although ~~they this~~ may not always ~~be detected~~ ~~be evidenced~~ ~~using routine testing methods.~~
- 3) For the purposes of this chapter, 'susceptible animals' means domestic and *wild animals* from the following families: bovidae, suidae, equidae, camelidae, canidae, felidae and non-human primates.
- 4) For the purposes of the *Terrestrial Code*, infection with animal trypanosomes of African origin is defined as an infection of susceptible animals with one or more Salivarian trypanosomes of the subgenus *Duttonella* (only *T. vivax*), *Nannomonas* (only *T. congolense* and *T. simiae*) and *Trypanozoon* (*T. brucei* *sspp* excluding *T. evansi* and *T. equiperdum*), hereafter referred to as 'pathogenic agent'.
- 5) Infection of susceptible animals with *T. evansi* or *T. equiperdum* is covered by Chapter 8.X. and Chapter 12.3., respectively.
- 6) Other trypanosomes including *T. uniforme*, *T. godfreyi* and *T. suis*, which are rarely reported, ~~and~~ of limited distribution and impact, do not play a significant role in the epidemiology of the disease; however, they should be considered in the *surveillance* system due to their interference (hidden *infection*) with the diagnosis of ~~infection with~~ animal trypanosomes of African origin.
- 7) The following defines the occurrence of *infection* with animal trypanosomes of African origin:
  - a) the pathogenic agent has been observed in a sample from a susceptible animal; or
  - b) ~~presence of~~ genetic material specific to the pathogenic agent has been detected in a sample from a susceptible animal showing clinical signs consistent with *infection* with animal trypanosomes of African origin or which has an epidemiological link to a confirmed case; or
  - c) antibodies have been detected in a sample from a susceptible animal showing clinical signs consistent with *infection* with animal trypanosomes of African origin or which has an epidemiological link to a confirmed case ~~in any susceptible animal species.~~
- 8) For the purposes of the *Terrestrial Code*, the *incubation period* of *infection* with animal trypanosomes of African origin ~~in susceptible animals~~ shall be 90 days.
- 9) Standards for diagnostic tests are described in the *Terrestrial Manual*.

Annex 22 (contd)

## Article 8.Y.2.

**Safe commodities**

When authorising the import or transit of the following *commodities* from susceptible animals, Veterinary Authorities should not require conditions related to animal trypanosomes of African origin regardless of the status of the exporting country or zone:

- 1) pasteurised milk and pasteurised milk products;
- 2) hair, wool and fibre;
- 3) gelatine;
- 4) horns, hooves and claws;
- 5) meat from animals that have been slaughtered in a slaughterhouse/abattoir and have been subjected to ante- and post-mortem inspections with favourable results;
- 6) meat products;
- 7) hides and skins (except raw);
- 8) semen collected and processed in accordance with Chapter 4.6.;
- 9) embryos.

## Article 8.Y.3.

**Country or zone free from infection with animal trypanosomes of African origin**

A *country or zone* may be considered free from *infection* with animal trypanosomes of African origin when:

- 1) the *infection* is notifiable in the entire country;
- 2) measures to prevent the introduction of the *infection* have been in place: in particular, the importations or movements of susceptible animals and other *commodities* into the country or *zone* have been carried out in accordance with this chapter and other relevant chapters of the *Terrestrial Code*;
- 3) and either:
  - a) the relevant provisions in point 2 of Article 1.4.6. have been complied with; or
  - b) for at least the past two years:
    - i) *surveillance* in accordance with Articles 8.Y.13. to 8.Y.16. has been in place in the entire country;
    - ii) there has been no *case* of *infection* with animal trypanosomes of African origin in the country, or zone or compartment.

A country or *zone* free from *infection* with animal trypanosomes of African origin neighbouring to an infected country or *zone* should include a *zone* in which *surveillance* is conducted in accordance with Articles 8.Y.13. to 8.Y.16.

## Article 8.Y.4.

**Compartment free from infection with animal trypanosomes of African origin**

The establishment and bilateral recognition of a *compartment* free from *infection* with animal trypanosomes of African origin should follow the provisions laid down in this chapter and in Chapters 4.4. and 4.5.

Annex 22 (contd)

Susceptible animals in the free *compartment* should be protected against the *vectors* by the application of an effective *biosecurity* management system.

Article 8.Y.5.

**Recovery of free status**

Should a *case of infection* with animal trypanosomes of African origin occur in a previously free country or *zone*, its status may be recovered after the following:

- 1) infected *animals* have been isolated and then immediately treated, slaughtered, or killed and appropriately disposed of;
- 2) *animals* in contact with infected *animals* have been put immediately under *vector*-protection and tested;

**AND**

- 3) **and** for six consecutive months, either:
  - a) after the last *case* was slaughtered or killed, the *animals* in contact have undergone monthly repeated serological and agent detection tests with negative results in both tests; or
  - b) when treatment is applied to the infected *animals*, both treated and in contact *animals* have undergone monthly repeated serological and agent detection tests with negative results in both tests;

**AND**

- 4) *surveillance* in accordance with Articles 8.Y.13. to 8.Y.16. has been carried out with negative results;
- 5) appropriate *biosecurity* is in place, that may include *vector* control or *vector* protection in the affected area.

Otherwise, Article 8.Y.3. applies.

Article 8.Y.6.

**Recommendations for importation of susceptible animals from countries, zones or compartments free from infection with animal trypanosomes of African origin**

**For susceptible animals**

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

- 1) showed no clinical signs of *infection* with animal trypanosomes of African origin on the day of shipment;
- 2) were kept since birth in a free country, *zone* or *compartment* or were imported from a free country, *zone* or *compartment*;
- 3) did not transit through an *infected zone* during transportation to the *place of shipment* or were protected from any source of animal trypanosomes of African origin during transportation to the *place of shipment*.

**Article 8.Y.7.**

~~**Recommendations for importation from countries, zones or compartments free from infection with animal trypanosomes of African origin**~~

Annex 22 (contd)For semen

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

- ~~1) the donor males:
 
  - ~~a) were kept since birth in a free country, zone or compartment or were imported from a free country, zone or compartment;~~
  - ~~b) showed no clinical signs of *infection* with animal trypanosomes of African origin on the day of collection;~~~~
- ~~2) the semen was collected, processed and stored in accordance with Chapters 4.6. and 4.7.~~

Article 8.Y.8.~~Recommendations for importation from countries or zones infected with animal trypanosomes of African origin~~For semen

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

- ~~1) the donor males:
 
  - ~~a) were kept in isolation in a *vector-protected artificial insemination centre* for at least 90 days prior to semen collection;~~
  - ~~b) were subjected, with negative results, to an agent identification test and an ELISA test for antibody detection adapted to the epidemiological situation on samples collected at entrance of the *vector-protected artificial insemination centre* and at least 90 days after the first test;~~
  - ~~c) showed no clinical signs of *infection* with animal trypanosomes of African origin during the isolation period and on the day of collection;~~~~
- ~~2) the semen was collected, processed and stored in accordance with Chapters 4.6. and 4.7.~~

Article 8.Y.9.~~Recommendations for importation from countries, zones or compartments free from infection with animal trypanosomes of African origin~~For *in vivo* derived embryos and for *in vitro* produced embryos

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

- ~~1) the donor females:
 
  - ~~a) were kept since birth in a free country, zone or compartment or were imported from a free country, zone or compartment;~~
  - ~~b) showed no clinical signs of *infection* with animal trypanosomes of African origin on the day of collection;~~~~
- ~~2) the semen used for the production of embryos complied with the provisions of Article 8.Y.7. or Article 8.Y.8.;~~
- ~~3) the embryos were collected, processed and stored in accordance with Chapters 4.8., 4.9. and 4.10., as relevant.~~

Article 8.Y.10.~~Recommendations for importation from countries or zones infected with animal trypanosomes of African origin~~

For *in vivo* derived embryos and for *in vitro* produced embryos

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

- 1) the donor females:
  - a) were kept in isolation in a vector protected *collection centre* for at least 90 days prior to the collection;
  - b) were subjected, with negative results, to an agent identification test and an ELISA test for antibody detection adapted to the epidemiological situation on samples collected at entrance to the vector protected *collection centre* and at least 90 days after the first test;
  - c) showed no clinical signs of *infection* with animal trypanosomes of African origin on the day of collection;
- 2) the semen used for the production of embryos complied with the provisions of Article 8.Y.7. or Article 8.Y.8.;
- 3) the embryos were collected, processed and stored in accordance with Chapters 4.8., 4.9. and 4.10., as relevant.

## Article 8.Y.11.

Recommendations for importation from countries, zones or compartments free from infection with animal trypanosomes of African originFor meat

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

- 1) were kept since birth in a free country, *zone* or *compartment* or were imported from a free country, *zone* or *compartment*;
- 2) have been slaughtered in a *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections with favourable results.

## Article 8.Y.12.

Recommendations for importation from countries or zones infected with animal trypanosomes of African originFor meat

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

- 1) comes from *animals* which have been slaughtered in a *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections with favourable results; and
- 2) either:
  - a) has been kept at a temperature lower than + 4°C for a minimum period of five days; or
  - b) has been subjected to any procedure of equivalent efficacy recognised by the *Veterinary Authority*.

Annex 22 (contd)

## Article 8.Y.137.

**Introduction to surveillance**

Articles 8.Y.13. to 8.Y.16. define the principles and provide guidance on *surveillance* for *infection* with animal trypanosomes of African origin, complementary to Chapter 1.4. and to Chapter 1.5.

The purposes of *surveillance* could be the demonstration of the absence of *infection*, the early detection of cases, or the measurement and monitoring of the *prevalence* and distribution of the *infection* in a country, *zone* or *compartment*.

*Vectors* are an essential component of the epidemiology of animal trypanosomes of African origin. Therefore, the *surveillance* system should include a *vector surveillance* component to detect the presence and ~~the~~ estimate the abundance of tsetse flies. When appropriate, it should also allow the estimation of the *vector infection* rate with animal trypanosomes of African origin. *Vector surveillance* may also ~~aim assist with~~ the estimation of ~~the abundance of mechanical vectors abundance~~.

The impact and epidemiology of animal trypanosomes of African origin widely differs between different regions of the world and therefore, it is not appropriate to provide specific recommendations for all situations. Member Countries should provide scientific data explaining the epidemiology of the disease in the concerned country or *zone* and adapt the *surveillance* strategies for defining their status to the local conditions. There is considerable latitude available to Member Countries to justify their status at an acceptable level of confidence.

*Wildlife* should be considered in the *surveillance* system because they can serve as reservoirs of *infection* and as indicators of *risk* to humans and domestic *animals*. *Surveillance* in *wildlife* presents challenges that may differ significantly from those in domestic *animals*.

## Article 8.Y.148.

**General conditions and methods for surveillance**

- 1) A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. In particular, it should include:
  - a) a formal and ongoing system for detecting and investigating *outbreaks* of disease;
  - b) a procedure for the rapid diagnosis in the field or for the collection and transport of samples from suspected *cases* to a *laboratory* for diagnosis;
  - c) a system for recording, managing and analysing diagnostic and *surveillance* data.
- 2) The *surveillance* programme for animal trypanosomes of African origin should, at least:
  - a) in a free country ~~or~~, ~~zone~~ ~~or compartment~~, have an *early warning system* which obliges farmers and workers, who have regular contact with susceptible animals as well as diagnosticians, to report promptly any suspicion of animal trypanosomes of African origin to the *Veterinary Authority*.

An effective *surveillance* system will periodically identify suspected *cases* that require follow-up and investigation to confirm or exclude whether the cause of the condition is animal trypanosomes of African origin. The rate at which such suspected *cases* are likely to occur will differ between epidemiological situations and cannot therefore be ~~reliably~~ predicted ~~reliably~~. All suspected *cases* should be investigated immediately, and samples should be taken and submitted to a *laboratory*;

- b) include the conduct ~~of~~ random or targeted serological or parasitological ~~surveys surveillance~~ appropriate to the status of the country or *zone*.

Article 8.Y.159.

### Surveillance strategies

The target population should include domestic and *wild* susceptible animals of epidemiological significance within the country or *zone*. Active and passive *surveillance* for animal trypanosomes of African origin should be ongoing as epidemiologically appropriate. *Surveillance* should be composed of random or targeted approaches using parasitological, serological, clinical and entomological methods appropriate for the status of the country or *zone*.

In a free country or *zone*, it is appropriate to focus *surveillance* in an area neighbouring to a border of an infected country or *zone*, considering relevant ecological or geographical features likely to interrupt the transmission of animal trypanosomes of African origin.

A Member Country should justify the *surveillance* strategy chosen as being adequate to detect the presence of *infection* with animal trypanosomes of African origin in accordance with Chapter 1.4. and Chapter 1.5., and with the prevailing epidemiological situation.

If a Member Country wishes to declare freedom from *infection* with animal trypanosomes of African origin in a specific *zone*, the design of the *surveillance* strategy should be targeted to the susceptible population within the *zone*.

For random surveys, the sample size selected for testing should be large enough to detect evidence of *infection* if it was to occur at a predetermined minimum rate. The sample size and expected *prevalence* determine the level of confidence in the results of the survey. The Member Country should justify the choice of the minimum expected *prevalence* and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Irrespective of the survey approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the *infection* history and the different species in the target population.

Irrespective of the testing system employed, *surveillance* system design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There should be an effective procedure for following up positive reactions to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as those which may be epidemiologically linked to it.

The principles involved in *surveillance* are technically well defined. The design of *surveillance* programmes to prove the absence of *infection* of animal trypanosomes of African origin should be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by international trading partners, or excessively costly and logistically complicated.

The results of random or targeted surveys are important in providing reliable evidence that no *infection* with animal trypanosomes of African origin is present in a country or *zone*. It is, therefore, essential that the survey is thoroughly documented. It is critical to interpret the results considering the movement history of the *animals* being sampled.

An active programme of *surveillance* of susceptible populations to detect evidence of *infection* with animal trypanosomes of African origin is essential to establish the *animal health status* of a country or *zone*.

#### 1. Clinical surveillance

Clinical *surveillance* aims to detect clinical signs of *infection* with animal trypanosomes of African origin in susceptible animals, particularly during a newly introduced *infection*. However, neither clinical nor post-mortem signs of *infection* with animal trypanosomes of African origin are pathognomonic. Therefore, diagnosis must rely on direct or indirect laboratory tests that confirm the presence of trypanosomes.

#### 2. Parasitological surveillance

Suspected cases of animal trypanosomes of African origin detected by clinical *surveillance* should always be confirmed by *laboratory* testing.

Annex 22 (contd)

Parasitological *surveillance* can be conducted to:

- a) confirm clinically suspected cases;
- b) identify parasite at the subgenus level;
- c) confirm active *infection* after positive serological results.

3. Molecular techniques

Molecular techniques increase the sensitivity of the detection of active *infections*. They can also be applied to identify the parasite and to better characterise the genotype of circulating parasites in a country or zone.

Molecular techniques can be used to:

- a) detect an active *infection*;
- b) characterise the parasite at the species, subspecies, group and population level.

4. Serological surveillance

- a) Serological testing of susceptible animals is one of the most effective methods for detecting the exposure to animal trypanosomes of African origin. The host species tested should reflect the epidemiology of the disease. Management variables that may influence likelihood of *infection*, such as the use of insecticides or animal treatment, should be considered.
- b) Due to cross reactions with *T. evansi*, *T. equiperdum*, *T. cruzi* and *Leishmania* spp, the presence of these pathogenic agents should be considered when interpreting the results of the serological *surveillance* system.
- c) Serological *surveillance* can be used to:
  - i) demonstrate individual or population freedom;
  - ii) evidence subclinical or latent *infection* by animal trypanosomes of African origin;
  - iii) determine by seroprevalence the magnitude of *infection* by animal trypanosomes of African origin in the host population.
- d) Positive test results can have four different possible causes:
  - i) active *infection*;
  - ii) antibodies from previous *infection* (after effective treatment or self-cure);
  - iii) maternal antibodies;
  - iv) cross reactions with *T. evansi*, *T. equiperdum*, *T. cruzi* and *Leishmania* spp.

5. Sentinel animals

Sentinel *surveillance* may provide evidence of freedom from *infection* or provide data on *prevalence* and *incidence* as well as the distribution of disease or *infection*. Sentinel *surveillance* may consist of:

- a) the identification and regular testing of one or more of sentinel animal units of known health or immune status in a specified geographical location to detect the occurrence of *infection* with animal trypanosomes of African origin;
- b) the investigation of clinical suspect cases targeting highly susceptible animals such as dogs, donkeys or horses.

6. Vector surveillance

This point should be read in conjunction with Chapter 1.5.

For the purposes of this chapter, *vector surveillance* aims at determining different levels of *risk* by identifying the ~~various vector species~~ presence and abundance of various vector species in an area or by demonstrating the absence of *vectors*.

Demonstration of absence of tsetse flies may support the claim of freedom from *infection* with animal trypanosomes of African origin that are cyclically transmitted.

The most effective way of gathering *vector surveillance* data should consider the biology and behavioural characteristics of the local *vector* species and include traps, fly rounds, sticky targets or other collection tools. Vector surveillance should be based on scientific sampling techniques. The choice of the number and type of collecting tools to be used and the frequency of their use should consider the size and ecological characteristics of the area to be surveyed.

When sentinel *animals* are used, *vector surveillance* should be conducted at the same locations.

Article 8.Y. 1610.

**Additional surveillance procedures for recovery of free status**

In addition to the general conditions described in this chapter, a Member Country seeking recovery of country or zone free status, including a *containment zone* established in accordance with Article 4.4.7., should show evidence of an active *surveillance* programme to demonstrate absence of *infection* with animal trypanosomes of African origin.

Populations under this *surveillance* programme should include:

- 1) *establishments* in the proximity of the *outbreak*;
  - 2) *establishments* epidemiologically linked to the *outbreak*;
  - 3) *animals* moved from or used to re-populate affected *establishments*.
-



## 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) For the purposes of this chapter:
  - a) 'epizootic area' means a part of a country or zone in which an epizootic of RVF is occurring, and which does not correspond to the definition of zone;
  - b) 'epizootic of RVF' means a sudden and unexpected change in the distribution or increase in incidence of, or morbidity or mortality of RVF;
  - c) 'inter-epizootic period' means a period with low levels of vector activity and low rates of RVF virus (RVFV) transmission;
  - d) 'susceptible animals' means ruminants and dromedary camels.
- 3) Humans and many animal species are susceptible to *infection*. For the purposes of the *Terrestrial Code*, RVF is defined as an *infection* of ruminants susceptible animals with Rift Valley fever virus (RVFV).
- 4) 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 susceptible animal; or
  - b) antigen or ribonucleic acid specific to RVFV, excluding vaccine strains, has been identified in a sample from a ruminant susceptible animal epidemiologically linked to a confirmed or suspected case of RVF, including in a human, 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 susceptible animal with either epidemiological links to a confirmed or suspected case of RVF, including in a human, or giving cause for suspicion of association or contact with RVFV.
- 5) For the purposes of the *Terrestrial Code*, the *infective period* for RVF shall be 14 days and the incubation period shall be 7 days.
- 6) For the purposes of the *Terrestrial Code*, the incubation period for RVF shall be 7 days.
- 7) In areas where RVFV is present, epizootics of RVF may occur following favourable climatic, and other 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.

Annex 23 (contd)

- 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*.
- 78) 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 susceptible animal population of the *exporting country*.
- 89) 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 susceptible animal 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) meets 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 susceptible animals 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*.

## Annex 23 (contd)

A country or zone free from RVF will not lose its free status through the importation of ruminants susceptible animals 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 that does not comply with meet the requirements of Article 8.15.3. 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 and potential insecticide resistance of the vectors, and potential rRisk management measures include:

- 1) treating animals and vehicles/vessels with insect repellents and insecticides prior to and during transportation;
- 2) *loading*, transporting and *unloading* animals at times of low vector activity;
- 3) ensuring vehicles/vessels 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 of susceptible animals from countries or zones free from RVF

##### For ruminants susceptible animals

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 epizootic area experiencing an epizootic during transportation to the place of shipment; or
  - c) were protected from vector attacks when transiting through an epizootic area experiencing an epizootic.

Article 8.15.8.

#### Recommendations for importation of susceptible animals from countries or zones infected with RVFV during the inter-epizootic period

Annex 23 (contd)For ruminants susceptible animals

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

- 1) showed no clinical signs 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 area during transportation to the place of shipment~~; or
  - b) were protected from *vector* attacks when transiting through an ~~area experiencing an epizootic area~~.

Article 8.15.98.

**Recommendations for importation of susceptible animals from countries or zones infected with RVFV during an epizootic**

For ruminants susceptible animals

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the susceptible animals 4

- 1) showed no clinical signs of RVF on the day of shipment;
- 2) did not originate ~~from an in the epizootic 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 of an epizootic area of the epizootic~~. During this period the animals showed no clinical signs of RVF;

**AND**

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

## Article 8.15.109.

**Recommendations for importation of semen and *in vivo* derived embryos of susceptible animals from countries or zones not free from infected with RVFV****For semen and *in vivo* derived embryos of ruminants susceptible animals**

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

- 1) showed no clinical signs 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 subjected to a serological test demonstrated to be seropositive on the day of collection, with positive result; or
  - c) were subjected to a serological test on two occasions with negative results on the day of collection and 14 days after collection testing of paired samples has demonstrated that seroconversion did not occur within 14 days of between semen or embryo collection and 14 days after.

## Article 8.15.110.

**Recommendations for importation of fresh meat and meat products from ruminants susceptible animals from countries or zones not free from infected with RVFV**

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

- 1) the entire consignment of *meat* comes from:
  - ~~1a)~~ ruminants which susceptible animals that showed no clinical signs of RVF within 24 hours before *slaughter*;
  - ~~2b)~~ ruminants which susceptible animals that were slaughtered in an approved *slaughterhouse/abattoir* and were subjected to ante- and post-mortem inspections with favourable results;
  - ~~3c)~~ carcasses which that were submitted to maturation at a temperature above 2°C for a minimum period of 24 hours following *slaughter*;
- 2) the necessary precautions were taken to avoid contact of the products meat with any potential source of RVFV.

## Article 8.15.10bis.

**Recommendations for importation of meat products from susceptible animals from countries or zones infected with RVFV**

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat products* comes from *meat* that complies with Article 8.15.10.

Annex 23 (contd)Article 8.15.4211.

Recommendations for importation **of milk and milk products of susceptible animals** from countries or zones ~~not free from infected with RVFV~~

**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 8.15.4312.**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 **to** 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 8.15.87 and 8.15.98.) *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 9.4.

**INFESTATION WITH *AETHINA TUMIDA*  
(SMALL HIVE BEETLE)**

[...]

Article 9.4.5.

**Recommendations for the importation of individual consignments containing a single live queen bee, accompanied by a small number of associated attendants (a maximum of 20 attendants per queen)**

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

1) the bees come from *apiaries* situated in a country or *zone* free from *A. tumida*;

OR

2) the bees come from hives or colonies which were inspected ~~immediately prior to dispatch~~ on the day of packing and show no evidence of the presence of *A. tumida* based on a visual inspection and the use of one of the methods described in the relevant chapter of the *Terrestrial Manual*; and

3) the bees come from an area of at least ~~400~~ 50 km radius where no *apiary* has been subject to any restrictions associated with the occurrence of *A. tumida* for the previous six months; and

4) the bees and accompanying packaging presented for export have been thoroughly and individually inspected and do not contain *A. tumida*; and

5) the packaging material, containers, accompanying products and food are new; and

6) all precautions have been taken to prevent *infestation* or contamination with *A. tumida*, in particular, measures that prevent *infestation* of queen cages such as no long term storage of queens prior to shipment and covering the consignment of bees with fine mesh through which a live beetle cannot enter.

2) all precautions have been taken to prevent contamination with *A. tumida*.

[...]



## CHAPTER 10.5.

## AVIAN MYCOPLASMOSIS (*MYCOPLASMA GALLISEPTICUM*)

## Article 10.5.1.

**General provisions**

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

## Article 10.5.2.

**Establishment free from avian mycoplasmosis**

To qualify as free from avian mycoplasmosis, an *establishment* should satisfy the following requirements:

- 1) it is under *official veterinary control*;
- 2) it contains no bird which has been vaccinated against avian mycoplasmosis;
- 3) 5% of the birds, with a maximum of 100 birds of different age groups present in the *establishment*, are subjected to ~~the serum agglutination test with negative results at the age of 10, 18 and 26 weeks, and thereafter at 4-week intervals (the results of at least the last two tests carried out on adult birds should be negative);~~
  - a) an agent identification test at the age of 10, 18 and 26 weeks with negative results, and thereafter at 4-week intervals with negative results on at least the last two tests; or
  - b) a serological test at the age of 10, 18 and 26 weeks with negative results, and thereafter at 4-week intervals with negative results on at least the last two tests;
- 4) all birds introduced into the *flocks* come from an *establishment* free from avian mycoplasmosis.

## Article 10.5.3.

**Recommendations for the importation of chickens and turkeys**

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

- 1) showed no clinical sign of avian mycoplasmosis on the day of shipment; and
- 2) come from an *establishment* free from avian mycoplasmosis; ~~and/or~~
- 3) were kept in a *quarantine station* for the 28 days prior to shipment and were subjected to ~~a diagnostic~~ an agent identification test for avian mycoplasmosis with negative results, on two occasions, at the beginning and at the end of the 28-day period.

## Article 10.5.4.

**Recommendations for the importation of day-old birds**

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

Annex 25 (contd)

- 1) come from *establishments* free from avian mycoplasmosis and from hatcheries which comply with the standards referred to in Chapter 6.5.;
- 2) were shipped in clean and unused packages.

Article 10.5.5.

**Recommendations for the importation of hatching eggs of chickens and turkeys**

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

- 1) have been disinfected in accordance with the standards referred to in Chapter 6.5.;
  - 2) come from *establishments* free from avian mycoplasmosis and from hatcheries which comply with the standards referred to in Chapter 6.5.;
  - 3) were shipped in clean and unused packages.
-

## 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* and considered effective against the epidemiologically relevant virus strains, 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 up to the date of this pre-shipment vaccination, 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, e~~Countries that are free of from EI or undertaking an eradication programme may also request that the domestic equids were ~~tested negative for EIV by~~ subjected to an agent identification test for EI described in the *Terrestrial Manual* with negative results, conducted on samples collected on two occasions, ~~at 7 to 14 days~~ four to six days after commencement of pre-export isolation and less than 5 ~~prior to~~ within four days ~~before~~ of shipment.

[...]