Annex 18

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 Article3.1.2., regardless of the political, economic or social situation of their country.

The key components of a country’s *Veterinary Services* are presented in Articles3.1.3 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* arean 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 develop~~ment~~ or participate~~ion~~ 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 andbe prepared to respond effectively to sanitary emergencies.

Annex 18 (contd)

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*;

Annex 18 (contd)

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.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_