

CHAPTER 3.4.

VETERINARY LEGISLATION

Article 3.4.1.

Introduction and objective

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

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

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

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

Article 3.4.2.

Definitions

For the purposes of this chapter the following definitions apply:

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

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

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

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

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

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

Annex 18 (contd)

Article 3.4.3.

General principles1. Respect for the hierarchy of legislation

Veterinary legislation should scrupulously respect the hierarchy between primary legislation and secondary legislation.

2. Legal basis

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

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

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

3. Transparency

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

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

4. Consultation

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

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

5. Quality of legislation and legal certainty

Veterinary legislation should be clear, coherent, and stable and transparent and protect citizens against unintended adverse side effects of legal instruments. ~~4~~The legislation should be regularly updated to be technically relevant, acceptable to society, able to be effectively implemented and sustainable in technical, financial and administrative terms. A high quality of legislation is essential for achieving legal certainty.

Article 3.4.4.

The drafting of veterinary legislation

Veterinary legislation should:

- 1) be drafted in a manner that establishes clear authorities, rights, responsibilities and obligations (i.e. 'normative');
- 2) ~~be unambiguous, with clear and consistent syntax and vocabulary;~~
- 3) ~~be precise, accurate and consistent in the repeated use of the terminology;~~ be accurate, clear, precise and unambiguous, and use consistent terminology;

- 3) include only definitions that are sufficient, necessary and relevant to the country;
- 4) contain no definitions or provisions that create ~~any duplication or contradiction or ambiguity;~~
- 5) include a clear statement of scope and objectives;
- 6) provide for the application of penalties and sanctions, either criminal or administrative, as appropriate to the situation; and
- 7) make provision for the financing needed for the execution of all activities of *Competent Authorities*; or these activities ~~the financing should be ensured~~ should be supported by appropriate financing in accordance with the national funding system.

Article 3.4.5.

Competent Authorities

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

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

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

1. Necessary powers of the Competent Authority

The *veterinary legislation* should also ensure that:

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

Annex 18 (contd)

- ~~v)~~ = seizure of *animals*, products and food of animal origin;
- ~~vi)~~ = suspension of one or more activities of an inspected establishment;
- ~~vii)~~ = temporary, partial or complete closure of inspected establishments; ~~and~~
- ~~viii)~~ = suspension or withdrawal of authorisations or approvals; and
- = restrictions on movement of *commodities, vehicles/vessels* and, if required, *people*.

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

2. Delegation of powers by the Competent Authority

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

For this purpose, the *veterinary legislation* should:

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

Article 3.4.6.

Veterinarians and veterinary paraprofessionals4. Veterinary medicine/science

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

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

2. The control of veterinarians and veterinary paraprofessionals

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

Annex 18 (contd)

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

1. The regulation of veterinarians and veterinary paraprofessionals

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

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

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

Annex 18 (contd)

Article 3.4.7.

Laboratories in the veterinary domain1. Facilities

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

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

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

2. Reagents, diagnostic kits and biological agents and products

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

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

3. Laboratory containment and control of biological agents and products

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

Article 3.4.8.

Health provisions relating to animal production1. Identification and traceability

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

2. Animal markets and other gatherings

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

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

3. Animal reproduction

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

4. Animal feed

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

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

5. Animal by-products

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

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

6. Disinfection

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

Article 3.4.9.

Animal diseases

Veterinary legislation should provide a basis for the *Competent Authority* to manage diseases of importance to the country ~~and to list those diseases, guided by the recommendations in Chapters 1.1 and 1.2, as well as emerging diseases, using a risk-based approach.~~ The legislation should also provide for the listing of diseases of importance to the country.

1. Surveillance

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

2. Disease prevention and control

- a) *Veterinary legislation* should include general animal health measures applicable to all *diseases* and, if necessary, additional or specific measures such as *surveillance*, establishment of a regulatory programme or emergency response for particular *diseases* listed in the country.

Annex 18 (contd)

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

3. Emerging diseases

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

Article 3.4.10.

Animal welfare1. General provisions

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

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

2. Stray dogs and other free-roaming animals

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

Article 3.4.11.

Veterinary ~~medicines and biologicals~~ medicinal products

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

1. General measures

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

- a) definition of *veterinary ~~medicines and biologicals~~ medicinal products*, including any specific exclusions; and
- b) regulation of the importation, manufacture, distribution and usage of, and commerce in, *veterinary ~~medicines and biologicals~~ medicinal products*, including laboratory biosafety and biosecurity measures.

2. Raw materials for use in veterinary medicines and biologicals

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

Annex 18 (contd)

- a) quality standards for raw materials used in the manufacture or composition of *veterinary medicines and biologicals* medicinal products and arrangements for checking quality;
- b) establishment of the withdrawal periods and maximum residue limits for *veterinary medicines and biologicals*, as appropriate; and
- e) requirements for restrictions on substances in *veterinary medicines and biologicals* medicinal products that may, through their effects, interfere with the interpretation of veterinary diagnostic test results or the conduct of other veterinary checks.

3. Authorisation of veterinary medicinal products, medicines and biologicals

- a) *Veterinary legislation* should ensure that only authorised *veterinary medicines and biologicals* medicinal products may be placed on the market.
- b) Special provisions should be made for:
 - i) medicated feed;
 - ii) products prepared by authorised *veterinarians* or authorised pharmacists; and
 - iii) emergencies and temporary situations; and
 - iv) establishment of withdrawal periods for relevant *veterinary medicinal products* and maximum residue limits for the active substance contained in each such product.
- c) *Veterinary legislation* should address the technical, administrative and financial conditions associated with the granting, renewal, refusal and withdrawal of authorisations.
- d) In defining the procedures for seeking and granting authorisations, the legislation should:
 - i) describe the ~~role~~ responsibilities of the relevant *Competent Authorities*; and
 - ii) establish rules providing for the transparency in decision making.
- e) *Veterinary legislation* may provide for the possibility of recognition of the equivalence of authorisations made by other countries.

4. Quality of veterinary medicines and biologicals

~~*Veterinary legislation* should address the following elements:~~

- a) ~~the conduct of clinical and non-clinical trials to verify all claims made by the manufacturer;~~
- b) ~~conditions for the conduct of trials;~~
- e) ~~qualifications of experts involved in trials; and~~
- d) ~~surveillance for adverse effects arising from the use of *veterinary medicines and biologicals*.~~

54. Establishments producing, storing and wholesaling *veterinary medicines and biologicals* medicinal products

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

- a) registration or authorisation of all operators manufacturing importing, storing, processing, wholesaling or otherwise distributing *veterinary medicines and biologicals* medicinal products or raw materials for use in making *veterinary medicines and biologicals* medicinal products;
- b) definition of the responsibilities of operators;

Annex 18 (contd)

- c) good manufacturing practices appropriate;
- d) reporting on adverse effects to the *Competent Authority*; and
- e) mechanisms for traceability and recall.

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

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

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

Article 3.4.12.

Human food production chain

Veterinary legislation should provide a basis for actions to safeguard the human food production chain through controls at all critical steps, consistent with national food safety standards and taking into account the risk of accidental and deliberate contamination. The role of the *Veterinary Services* in food safety is described in Chapter 6.1.

1. General provisions

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

- a) the conduct of veterinary ante- and post-mortem inspections at *slaughterhouses/abattoirs*;
- ~~a)~~ controls over all stages of the production, processing and distribution of food of animal origin;
- ~~b)~~ recording all significant animal and public health events that occur during primary production including *slaughter*;
- ~~c)~~ giving operators of food production premises the primary responsibility for compliance with food safety requirements, including traceability established by the *Competent Authority*;
- ~~d)~~ inspection for compliance with food standards, where this is relevant to health or safety;
- ~~e)~~ inspection and audit of premises;
- ~~f)~~ prohibition of the marketing of products not fit for human consumption; and

Annex 18 (contd)

~~gh)~~ provisions for recall from the marketplace of all products likely to be hazardous for human or animal health.

2. Products of animal origin intended for human consumption

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

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

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

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

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

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

Article 3.4.13.

Import and export procedures and veterinary certification

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

Comments: African Union proposes the following editorial comment to reflect the right nomenclature for the OIE text being referred to: Section of the Code on Risk analysis and Trade measures, import/export procedures and veterinary certification.