TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION
SEPTEMBER 2011 REPORT

CHAPTER 3.4.

VETERINARY LEGISLATION

Article 3.4.1.

Introduction and objective

Good governance is a recognized global public good and is of critical importance to OIE Members. 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.

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 OIE Members when formulating or modernising veterinary legislation so as to comply with OIE standards, thus ensuring good governance of the entire veterinary domain.

Article 3.4.2

Definitions

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 certainty: means the situation in which citizens are protected against any adverse side effects of legal instruments. The situation of legal uncertainty could arise when legislative instruments are not coherent, are overly complex or change frequently.

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

Legislative quality: means the technical relevance, acceptability to society, sustainability in technical, financial and administrative terms and effective implementation of laws.

Primary legislation: legal instruments issued by the legislature.

Secondary legislation: means the legal instruments issued by the executive and relating to the regulated domain. The equivalent term, subsidiary legislation, is used in some countries.

Stakeholder: means a person, group, or organization 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 health and welfare of humans, including by means of the protection of animal health and welfare, and food safety.

Veterinary legislation: means the collection of specific legal instruments (primary and secondary legislation) required for the governance of the veterinary domain.

Article 3.4.3

General principles

1. Respect for the hierarchy of legislation

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

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.

   Veterinary legislation should be consistent with national 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 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. Legislative quality and legal certainty

   Veterinary legislation should achieve a high level of legislative quality so as to ensure legal certainty.

Article 3.4.4.

The drafting of veterinary legislation

Veterinary legislation should:

a) be drafted in a manner that establishes clear rights, responsibilities and obligations (i.e. 'normative');

b) be unambiguous, with clear and consistent syntax and vocabulary;

c) be precise and accurate even if this results in repetition and a cumbersome style;

d) contain no definitions that create any conflict or ambiguity;

e) include a clear statement of scope and objectives;

f) provide for the application of sanctions, either criminal or administrative, as appropriate to the situation; and

g) make provision for the financing needed for the execution of all activities of *Competent Authorities*.

Article 3.4.5.

Matters relating to the Competent Authority

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, a reliable system of coordination and cooperation should be in place.

Competent Authorities should be organised to ensure that all necessary actions are taken quickly and coherently to effectively address animal health and public health emergencies.

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;

   b) officials are protected against legal action and physical harm;

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;

iv) retention (setting aside) of *animals* and goods, pending a decision on final disposition;

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.

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 body(ies) to which the tasks are delegated and the conditions of supervision by the *Competent Authority* 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.

Veterinary professionals and veterinary para-professionals

1. Veterinary medicine

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

a) provide an official definition of veterinary medicine;

b) define the prerogatives of the professionals involved in the conduct of veterinary medicine;

c) define the minimum initial and continuous educational requirements and competencies for *veterinarians* and *veterinary para-professionals*;

d) prescribe the conditions for recognition of professional qualifications for *veterinarians* and *veterinary para-professionals*;

e) define the conditions to perform the activities of veterinary medicine; and

f) identify the exceptional situations, such as epizootics, under which persons other than qualified *veterinarians* can undertake activities that are normally carried out by *veterinarians*.

2. The control of veterinary professionals and veterinary para-professionals

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

a) describe the general system of control in terms of the political, administrative and geographic configuration of the country;

b) provide for the possibility of the delegation of powers to a professional organisation such as a *veterinary statutory body*;

c) where powers have been so delegated, describe the prerogatives, the functioning and responsibilities of the mandated professional organisation; and

d) prescribe the powers to deal with conduct and competence issues, including licensing requirements, that apply to veterinary professionals and *veterinary para-professionals*.

Article 3.4.7.

Laboratories in the veterinary domain

1. Facilities

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

a) reference *laboratories*, which are responsible for controlling the veterinary diagnostic and analytical network, including the maintenance of reference methods;

b) *laboratories* designated by the *Competent Authority* for carrying out the analysis of official samples; and

c) *laboratories* recognised by the *Competent Authority* to conduct analyses required under the legislation e.g. for the purposes of quality control.

The veterinary legislation should define the conditions for the classification, approval, operations and supervision of *laboratories* at each level.

2. Laboratory reagents

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

a) procedures for authorising the reagents that are used to perform official analyses;

b) quality assurance by manufacturers of the reagents used in official analyses; and

c) surveillance of marketing of reagents, where these can affect the quality of analyses required by the veterinary legislation.

Article 3.4.8.

Health provisions relating to animal production

1. Identification and traceability

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

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.

3. Animal reproduction

Veterinary legislation should provide a basis for actions to address the health regulation of animal reproduction as appropriate. 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;

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, processing methods and authorised uses 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, as appropriate, concerning owners' use and disposition of animal by-products.

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.

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.

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.

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.

3. Emerging diseases

Veterinary legislation should provide for measures to investigate and respond to *emerging diseases*.

Article 3.4.10.

Animal welfare

1. General provisions

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

To this end, the legislation should contain as a minimum, a legal definition of cruelty as an offence subject to penal action, 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

Veterinary legislation should provide a basis for assuring the quality of veterinary medicines and biologicals and minimizing the *risk* to human, animal and environmental health associated with their use.

1. General measures

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

a) definition of veterinary medicines and biologicals, including any specific exclusions; and

b) regulation of the importation, manufacture, distribution and usage of, and commerce in, veterinary medicines and biologicals.

2. Raw materials for use in veterinary medicines and biologicals

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

a) quality standards for raw materials used in the manufacture or composition of veterinary medicines and biologicals and arrangements for checking quality;

b) establishment of the withdrawal periods and maximum residue limits for veterinary medicines and biologicals, as appropriate; and

c) requirements for substances in veterinary medicines and biological that may, through their effects, interfere with the conduct of veterinary checks.

3. Authorisation of veterinary medicines and biologicals

a) Veterinary legislation should ensure that only authorised veterinary medicines and biologicals 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.

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 of the relevant *Competent Authority*; and

ii) establish rules providing for the transparency in decision making.

e) Veterinary legislation may provide for the possibility of recognition of the equivalence of authorisations made by other countries.

4. Quality of veterinary medicines and biologicals

Veterinary legislation should address the following elements:

a) the conduct of clinical and non clinical trials to verify all claims made by the manufacturer;

b) conditions for the conduct of trials;

c) qualifications of experts involved in trials; and

d) surveillance for adverse effects arising from the use of veterinary medicines and biologicals.

5. Establishments producing, storing and wholesaling veterinary medicines and biologicals

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 or raw materials for use in making veterinary medicines and biologicals;

b) definition of the responsibilities of operators;

c) good manufacturing practices as appropriate;

d) reporting on adverse effects to the *Competent Authority*; and

e) mechanisms for traceability and recall.

6. Retailing, use and traceability of veterinary medicines and biologicals

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

a) control over the distribution of veterinary medicines and biologicals and arrangements for traceability, recall and conditions of use;

b) establishment of rules for the prescription and provision of veterinary medicines and biologicals to end users;

c) restriction to authorised professionals and, as appropriate, authorized veterinary paraprofessionals of commerce in veterinary medicines and biologicals that are subject to prescription;

d) the supervision by an authorised professional of organisations approved for holding and use of veterinary medicines and biologicals;

e) the regulation of advertising claims and other marketing and promotional activities; and

f) 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.

1. General

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

   a) recording all significant animal health events that occur during primary production;

   b) prohibition of the marketing of products not fit for human consumption;

   c) inspection for food safety and food composition, where this is relevant to health or safety;

   d) inspection of premises;

   e) controls over the implementation of the legislation at all stages of the production, processing and distribution of food of animal origin;

   f) giving operators of food production premises the primary responsibility for compliance with food safety requirements established by the *Competent Authority*; and

   g) 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;

   b) the conduct of inspection on the basis of veterinary expertise;

   c) health standards; and

   d) the application of health identification marks that are visible to the intermediary or 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 procedures based on HACCP principles; and

c) prior authorisation of operations that are likely to constitute a significant *risk* to human or animal health.

Article 3.4.13.

Import/export procedures and veterinary certification

Veterinary legislation should provide a basis for actions to address the elements relating to import/export procedures and veterinary certification referred to in Section 5 of the *Terrestrial Code*.