

TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION
FEBRUARY 2011 REPORT

USA COMMENTS

CHAPTER 3.3.

VETERINARY LEGISLATION

Article 3.3.1.

General principles

1. Respect of the hierarchy of Acts

Veterinary legislation should scrupulously respect the separation between the primary legislation, represented by primary acts (laws), and the secondary legislation derived from regulations or rule books, as laid down in the Constitution or fundamental texts of the country.

2. Legal basis

The competent authorities should have the necessary primary and secondary legislation adopted for their activities at all levels of their functional or territorial organisation.

3. Inventory of the veterinary legislation

The competent authorities should establish and maintain a complete and up to date inventory of veterinary legislation.

The use of computerised databases is recommended, on the condition that their completeness, currency, accessibility and continuity can be guaranteed.

4. Communication

The competent authorities should ensure communication of veterinary legislation and subsequent documentation to stakeholders.

5. Codification

Veterinary legislation should be collected and codified so as to make it readily accessible and intelligible and provide the capability for updating and modification as appropriate.

6. Participation in the process of developing legislation

The drafting of new and updated veterinary texts should involve the competent authorities that are responsible for the scientific and technical content, together with the necessary legal expertise to ensure that the resulting texts are legally sound.

Conversely, the competent authorities should be consulted on all proposals to develop or modify texts that have a bearing on veterinary legislation.

7. Consistency of the legislation

Veterinary legislation should be consistent with civil, penal and administrative laws and the associated procedures as appropriate.

Article 3.3.2.

The form of veterinary legislation

1. Normative character

Veterinary legislation should be normative and should be drafted in a manner that prevents ambiguity in interpretation.

General comment: The word ‘Normative’ is not one that is in general use in the English language and its intended use here would benefit from further clarification. Perhaps the word “regulatory” would be more appropriate.

2. Style and precision

The syntax and vocabulary should be clear and consistent so as to avoid any ambiguity.

Precision and accuracy should take precedence over style even if this results in repetition and a cumbersome style.

3. Definitions

Definitions should refer to the precise subjects and texts to which they pertain.

Definitions in secondary legislation should not create any conflict or ambiguity with definitions in primary legislation.

4. Competent authority

The definition of ‘competent authority’ or ‘competent authorities’ should be consistent with the OIE standards in order to assure an efficient chain of command and reliability in the provision of veterinary certification.

5. Objectives of veterinary legislation

Veterinary legislation should include a clear statement of scope.

The legislation should as a minimum include instruments to enable protection of relevant guidelines in order to protect:

- a. animal health and food security;
- b. food safety;
- c. public health (zoonotic diseases) and security (stray animals);
- d. animal welfare, as defined by the OIE.

6. Penalties and sanctions

Veterinary legislation should provide for penalties and sanctions at the level required for proper implementation of the overall strategy, as follows:

- a. penalty sanctions, to be applied by the competent jurisdictions according to current penalty procedures;
- b. administrative sanctions that are designed for immediate application in the case of activities posing a risk to animal health, animal welfare or public health.

Veterinary legislation should distinguish between significant penalties established in primary legislation and ~~those less strong that depend on~~ lesser penalties established by secondary legislation.

Rationale: Alternative wording is suggested for improved clarity

Veterinary legislation should include additional specific sanctions which would be applied on the basis of a decision from the court, notably a ban on the use of animals or the conduct of activities posing a risk to public or animal health or animal welfare.

7. Powers of the competent authority

Where official veterinary matters are the responsibility of more than one administration (multiple competent authorities), a reliable system of coordination and cooperation between the different authorities should be put in place.

The competent authorities should be organised ~~in such a way as to provide for taking~~ to ensure that action is taken quickly and coherently when such action is key to success, notably in case of implementation of animal health emergency measures or veterinary public health crises.

Rationale: Alternative wording is suggested for improved clarity

The legislation should provide for a clear chain of command that is as effective as possible (i.e. short, with all responsibilities clearly defined).

For this purpose, the responsibilities and power of the competent authorities, from the central level to those responsible for the implementation of legislation in the field, should be clearly defined.

If they are not under the responsibility of a unique competent authority, the responsibility for each element of the public veterinary domain should be attributed to a specific competent authority.

8. Interventions by inspectors

The competent authority should appoint technically qualified inspectors to take any actions needed for implementation or verification of compliance with the veterinary legislation.

The veterinary legislation should ensure that:

- a. inspectors have the legal authority to intervene in accordance with the legislation and the penal procedures in force in the State;
- b. the field of competence and the role of each inspector are prescribed according to their technical qualifications;
- c. inspectors are protected against legal action and physical harm.

9. Powers

The rights of inspectors should be explicitly and thoroughly listed to protect the rights of stakeholders against any abuse of authority.

The powers of inspectors and rules of inspections should be prescribed, notably the authorisation and conditions for obtaining access to professional and private premises and to vehicles.

Inspectors should have powers and procedures to:

- a. gain access to documents;
- b. take samples;
- c. retain (set aside) animals and goods, pending a decision on final disposition.

10. Obligations

The obligation of inspectors to respect confidentiality should be defined.

When attributing a field of competence or sector of responsibility, the competent authority should respect the principles of independence and impartiality prescribed in the OIE *Terrestrial Animal Health Code* (the *Terrestrial Code*) (see Article 3.1.2.).

11. Administrative and enforcement actions

For the purposes of administrative and enforcement actions the following elements should be prescribed in the veterinary legislation:

- a. seizure of animals, products and food of animal origin;
- b. suspension of one or more activities of an inspected establishment;
- c. the temporary, partial or complete closure of inspected establishments;
- d. suspension or withdrawal of authorisations or approvals.

Means of compulsion enabling inspection to be performed should be provided for.

The rights of appeal against an action or a decision of an inspector should be established according to the laws of the State.

12. Financing

Veterinary legislation should provide for the sources, levels and conditions of financing required for the execution of all the activities of the competent authority, notably inspection, sampling and analysis and the procedures of authorisation or approval in all domains covered by the veterinary legislation.

Article 3.3.3.

Veterinary and para-veterinary professions

Rationale: Suggest using the term ‘veterinary para-professional’ here in this section since that is the term found in the OIE Code glossary

1. Veterinary medicine

In order to ensure the quality 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 practice of veterinary medicine;
- c. define the minimum initial and continuous educational requirements for the professionals;
- d. prescribe the conditions for recognition of diplomas for veterinarians and para-veterinarians;
- e. define the conditions for the exercise of veterinary and para-veterinary professions;
- f. define the professional responsibilities of veterinarians and persons working under their control;
- g. prescribe the situations where persons other than qualified veterinarians can undertake activities that are normally to be carried out by veterinarians e.g. in exceptional circumstances such as epizootics.

2. The control of the professions

In order to control the veterinary and para-veterinary professions, the veterinary legislation should:

- a. describe the general system of control in terms of the political, administrative and geographic configuration of the State;
- 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;
- d. prescribe the disciplinary powers that apply to the relevant professions.

Article 3.3.4.

Laboratories in the veterinary field1. 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 State for carrying out the analysis of official samples;
- c. laboratories recognised by the State as fit to conduct compulsory analyses by the private sector.

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 address the elements listed below:

- a. procedures for authorising the reagents that are used to perform official analyses;
- b. surveillance of marketing of reagents, where these can affect the quality of analyses required by the veterinary legislation;
- c. quality assurance of reagents by manufacturers.

Article 3.3.5.

Delegation of powers1. General principles

The veterinary legislation should provide for the possibility of the competent authorities delegating 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.

2. Animal health delegation

The veterinary legislation should provide for the possibility of the competent authority delegating specific tasks in the sector of animal health to individual professional veterinarians who are not civil servants.

For that 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 financing of the delegation;

- c. define the procedures for making delegations;
- d. define the competencies to be held by persons receiving delegation;
- e. define the conditions of withdrawals of delegations.

3. Delegation of functions relating to veterinary certification

Veterinary legislation should conform with Section 5 of the OIE Terrestrial Code concerning certification procedures, especially on the:

- a. conditions of appointment or recognition of certifying officials;
- b. role and responsibilities of the certifying officials;
- c. conditions of certification;
- d. means of supervision and financing of certification;
- e. define the conditions of withdrawal of the delegation.

4. Delegation of functions relating to the identification of animals and traceability

- a. Veterinary legislation should provide for the possibility of delegating operations, under the supervision of the competent authority, to the operators that are best placed to carry out and manage the identification systems.
- b. Veterinary legislation should define the conditions of withdrawal of the delegation.

5. Relationships with stakeholders

To ensure transparency and facilitate implementation of the veterinary legislation, the competent authority should establish relationships with stakeholders, including by:

- a. taking steps to ensure that stakeholders participate in the development of significant legislation and required follow up;
- b. supporting, as appropriate, participation of stakeholders in international discussions-fora such as OIE and Codex Alimentarius Commission.

Article 3.3.6.

Health provisions relating to animal production

1. Identification and traceability

Veterinary legislation should address the following elements:

- a. the objectives and scope of animal identification;
- b. the possibility to make animal identification compulsory for certain species, regions or functions;

- c. the power of the competent authority to control movements of animals and record changes of ownership;
- d. identification includes the marking of animals or groups of animals and the recording of corresponding data;
- e. the use of identification data for veterinary matters;
- f. the equipment and methods to be used and the qualifications of operators for the marking or tracing of animals as appropriate to each situation;
- g. the type of data to be recorded and the responsibilities of each party, notably those of animal keepers;
- h. for the conduct of checks and corrections, as may be required to ensure the reliability of information in the database, notably in respect of animals that have died or have been slaughtered for any reason;
- i. respect for constitutional liberties by restricting the use, security and confidentiality of data.

2. Animal markets and other gatherings

Veterinary legislation should address the following elements:

- a. registration of all permanent or temporary animal markets and other animal gatherings;
- b. health measures to prevent disease transmission, including procedures for cleaning and disinfection, and animal welfare measures;
- c. provision for compulsory veterinary checks at animal gatherings.

3. Animal reproduction

Except where the animals or reproductive material are only used in a single holding, the veterinary legislation should address the elements listed below:

- a. the health regulation of animal reproduction as appropriate;
- b. health regulations may be implemented at the level of animals, genetic material, establishments or operators.

4. Animal feed

Veterinary legislation should address the elements listed below:

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

5. Animal by-products (i.e. products not used for human consumption)

Veterinary legislation should address the elements listed below:

- a. definition of the animal by-products subject of 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;
- d. definition of the rules to be applied by animal owners as appropriate.

6. Disinfection

Veterinary legislation should address the following elements:

- a. the regulation of products and methods that are used for disinfection relating to animal diseases;
- b. the use of disinfection at all critical points, notably during the transportation of animals.

Article 3.3.7.

Animal diseases

1. Surveillance

Veterinary legislation should address the following elements:

- a. collection, transmission and utilisation of epidemiological data relevant to listed diseases;
- b. an early warning system.

2. Disease prevention

Veterinary legislation should address the following elements:

- a. specific rules for each listed disease;
- b. support to stakeholders in proposing joint programmes;
- c. the direct control by the competent authority of some disease prevention programmes;
- d. compulsory programmes for some disease prevention when necessary.

3. Disease control

a. Veterinary legislation should address the following elements:

- i. different lists of diseases, with provision (as appropriate) for:
 - i. emergency measures in accordance with established contingency plans;

- ii. measures for prevention, control or eradication, including carcass disposal;
 - iii. surveillance measures;
 - ii. the specification of mandatory control measures for certain diseases;
 - iii. arrangements for the declaration of animal diseases including on the grounds of suspicion;
 - iv. immediate technical measures including on the grounds of suspicion;
 - v. measures for official disease surveillance;
 - vi. conditions for confirmation of diseases;
 - vii. precautionary measures.
- b. Veterinary legislation should provide for the following general measures:
- i. definition of areas in which health measures are applied;
 - ii. official publicising of measures;
 - iii. listing of all measures requiring a legal basis;
 - iv. measures to be implemented by the public force;

Comment: The intent of these last two items above is unclear.

(iii) Legal basis- Suggest clarification to indicate the 'listing of all measures requiring a legal basis' means that all authorities of the VS need to be clearly defined. As written it appears to mean that a specific legal document will need to be created for each of these specified actions.

(iv) Does 'measures to be implemented by the public force' mean actions that will require enforcement by other entities such as police or military? The meaning of the public force is unclear.

- v. epidemiological investigations;
 - vi. provisions for wild or protected animals;
 - vii. conditions for restocking;
 - viii. commercial restrictions.
- c. Contingency plans should be developed for certain diseases and, in addition to the general measures, should provide for:
- i. administrative and logistic organisation;
 - ii. exceptional powers of the competent authority;

- iii. special and temporary measures to address all identified risks to human or animal health.
- d. Veterinary legislation should provide for the financing of animal disease control measures, notably:
 - i. operational expenses;
 - ii. production losses;

General note: Compensation for production losses may be very difficult and costly to achieve. The compensation for the value of animals seized or destroyed as part of disease control measures is an important element for compliance, cooperation and success of a program; however any additional compensation for production losses may not always be feasible.

- iii. owners compensation in the event of killing or slaughtering of animals, seizure or destruction of carcasses, meat, animal feed or other things.

4. Emerging disease

Measures allowing for investigation of and response to emerging diseases.

Article 3.3.8.

Animal welfare measures

1. General provisions

Veterinary legislation should address the elements listed below:

- a. general principles to ensure the protection of animals against cruelty, abuse, abandonment and avoidable suffering, in line with the OIE *Terrestrial Code*;
- b. legal definition of cruelty as an offense, subject to penal action;
- c. direct intervention of the competent authority in the case of neglect by animal keepers;
- d. accepted practices for livestock, pets, animals used in scientific experiments, sport and leisure, and for wild animals, notably in relation to:
 - i. transport and handling;
 - ii. animal production and housing;
 - iii. slaughtering and killing;
 - iv. scientific experiments;
 - v. use in games, shows, exhibitions and zoos;
- e. certain activities relating to animals may be restricted to the holders of appropriate qualifications or approvals.

2. Free-roaming and stray domestic animals

Note: the issue of handling stray animals is also often handled by other official authorities.

Veterinary legislation should address the elements listed below:

- a. prohibition of abandonment of animals and of allowing animals to stray;
- b. establishments where stray animals can be held and the conditions governing their operation;
- c. the circumstances and the conditions of capture and of holding of stray animals;
- d. the outcomes for these animals, including arrangements for veterinary interventions (including euthanasia in compliance with OIE standards), and for the transfer of ownership.

Article 3.3.9.

Veterinary products

1. Objectives

Veterinary legislation should address the following elements:

- a. avoiding the presence of harmful residues in the food chain;
- b. ensuring that the use of veterinary products does not give rise to human health risks.

2. General measures

Veterinary legislation should address the elements listed below:

- a. definition of veterinary products, including any specific exclusions;
- b. regulation of the importation, manufacture, distribution and usage of, and commerce in, veterinary products.

3. Raw materials and veterinary products

Veterinary legislation should address the elements listed below:

- a. quality standards for raw materials used in the manufacture or composition of veterinary products and arrangements for checking quality;
- b. establishment of the withdrawal periods and maximum residue limits for veterinary products as appropriate;
- c. requirements for any substances that may interfere with the conduct of veterinary checks.

4. Authorisation of veterinary products

- a. Veterinary legislation should ensure that only authorised veterinary products may be placed on the market.
- b. Special provisions should be made for:
 - i. veterinary products that do not present any risk of residues or interference with the conduct of disease prevention and control programmes;
 - ii. medicated feed;
 - iii. products prepared by veterinarians or pharmacists;
 - iv) 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 functioning of the competent authority concerned;
 - ii) establish rules providing for the transparency of decisions.
- e. Veterinary legislation may provide for the possibility of recognition of the equivalence of authorisations made by other countries.

5. Quality of veterinary products

To give effect to the objectives identified above, veterinary legislation should address the elements listed below:

- a. the conduct of clinical and non clinical trials to verify all claims made by the manufacturer, including analysis and dosage methods;
- b. conditions for the conduct of trials;
- c. qualifications of experts involved in trials;
- d. surveillance for adverse effects arising from the use of veterinary products.

6. Establishments producing, storing and selling veterinary products

Veterinary legislation should address the following elements:

- a. registration or authorisation of all operators importing, storing, processing, selling or otherwise distributing veterinary products or raw materials for use in making veterinary products;
- b. definition of the responsibilities of operators;
- c. good manufacturing practices as appropriate;

- d. arrangements for informing the competent authority on adverse effects of products and on traceability and recalling procedures. about traceability of products and adverse effects.

7. Commerce, distribution, use and traceability of veterinary products

Veterinary legislation should address the following elements:

- a. control over the circulation and distribution of veterinary products and arrangement for traceability and condition of use;
- b. establishment of rules of prescription and provision of veterinary products to the end user;
- c. restricting to authorised professionals all commerce in veterinary products that are subject to prescription;
- d. the supervision by an authorised professional of organisations approved for holding and use of veterinary products;
- e. the regulation of advertising claims and other marketing and promotional activities.

Article 3.3.10.

Safeguards for the food production chain and traceability

1. Objectives

Veterinary legislation should address the following elements:

- a. the control of the manufacturing process at all relevant levels in the food production chain;
- b. requirements to assure food safety for the purpose of (i)

Note: it is unclear which item point (i) in this sentence is referring to.

In addition, procedures may be implemented to allow food production appropriate to the economic situation.

2. General

Veterinary legislation should address the following elements in order to ensure the food safety of animal products:

- a. recording all significant health events that occur during primary production;
- b. prohibition of the marketing of infected products or products likely to be contaminated or hazardous for the consumer or for animal health;
- c. inspection for food safety and food composition;
- 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. establish that operators of food production premises have the primary responsibility for food safety;
- g. obligations for producers to withdraw from the marketplace all products likely to be hazardous for human or animal health.

3. Products of animal origin intended for human or animal consumption

Veterinary legislation should address the following elements:

- a. arrangements for inspection;
- b. the conduct of inspection on the basis of veterinary expertise;
- c. relevant health standards;
- d. application of health identification marks, which 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.

4. Regarding operators in premises and establishments pertaining to the food chain

Veterinary legislation should address the following elements as appropriate:

- a. recording the coordinates of operators working within the food chain;
- b. the implementation by operators of procedures based on HACCP principles;
- c. prior authorisation of operators whose activities are likely to constitute a significant risk to human or animal health.

Rationale: Since this section refers to the actual operators of the premises and establishment, the added words provides clarity to the section.

International movements and trade

1. Importation

Veterinary legislation should address the following elements:

- a. the coordinates of importers and, as appropriate, their approval by the competent authority of the importing country;
- b. the establishment by the competent authority of:

- i. the list of goods to be subject to veterinary checks;
 - ii. the importation check points officially designated for each kind of goods;
 - iii. the kinds and procedures of checks to be performed;
 - iv. the standards with which animals and commodities proposed for importation must comply;
- c. prevention of entry of listed goods and consignments into the country unless such goods have been subjected to the required veterinary checks;
 - d. objectivity and independence of inspectors.

2. Exports

Veterinary legislation should specify the conditions governing the provision of veterinary certification and any prohibitions, in conformity with relevant provisions of the OIE and of the Codex Alimentarius Commission.

It should also include provisions ensuring national involvement ~~to in relevant~~ activities ~~relevant of to~~ the work of the OIE and the Codex Alimentarius and, if necessary, interministerial coordination allowing the harmonization of the positions taken by the country in these international organizations.

Rationale: Improved grammar
