Annex 9

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 and the recommendations 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~~ related 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~~ especially 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 for use when formulating or modernising *veterinary legislation* so as to comply with OIE standards and other relevant international 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~~.

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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, to ensure that the primary legislation provides the legal basis for the application and enforcement of the 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 and other relevant stakeholders to ensure that the resulting legislation ~~has been evaluated through an impact analysis, as appropriate, and~~ is scientifically, technically and legally sound. The resulting draft legislation should be evaluated through an impact analysis as appropriate.

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

5. Quality of legislation and legal certainty

*Veterinary legislation* should be clear~~,~~ and coherent, ~~and stable~~ ~~and transparent~~, and should provide legal certainty and protect citizens, animals and the environment against unintended adverse side effects of legal instruments. ~~It~~The legislation should be stable but regularly evaluated and updated as appropriate to ~~be~~ ensure that it is technically relevant, acceptable to society, able to be ~~effectively~~ implemented effectively 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~~ powers, rights, responsibilities and obligations (i.e. ‘normative’);

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~~2)~~ ~~be unambiguous, with clear and consistent syntax and vocabulary;~~

~~3~~2) ~~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 unnecessary duplication ~~or ambiguity~~;

5) include a clear statement of scope and objectives;

6) provide for the application of proportionate and dissuasive penalties and sanctions, either criminal or administrative, as appropriate to the situation; ~~and~~

7) when relevant, make provision for the collection, use and disclosure of information gathered under the *veterinary legislation*;

~~7~~8) 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~~.~~; and

~~8~~9) indicate when the legislation comes into effect and its impact on similar pre-existing legislation, in particular ~~regulations~~ secondary legislation.

Article 3.4.5.

**Competent Authorities**

*Competent Authorities* should be legally mandated, ~~capacitated~~ have the necessary technical, administrative and infrastructure capacity and be organised to ensure that all necessary actions are taken ~~quickly~~ in a timely, ~~and~~ coherent~~ly~~ ~~to~~ and effective~~ly~~ manner to 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.~~ as short as possible, and 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~~ for example 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, including clarifying the role of each *Competent Authority*.

*Competent Authorities* should appoint technically qualified officials to take any actions needed for implementation, review ~~or~~ and 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 and in accordance with professional standards;

*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 and transparency, as appropriate; and

*d)* at least the following powers are available through the primary legislation:

*i)* access to premises and *vehicles/vessels* for carrying out inspections;

*ii)* access to documents;

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*iii)* ~~taking samples;~~ application of specific *sanitary measures* such as:

‒ taking samples;

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

*~~v)~~* ‒ seizure of *commodities* and fomites; ~~and~~

‒ destruction of *~~animals~~*~~, products and food of animal~~~~origin~~ *commodities* and fomites;

*~~vi)~~* −suspension of one or more activities of a~~n inspected~~ ~~establishment~~ facility;

*~~vii)~~* − temporary, partial or complete closure of ~~inspected~~ ~~establishments~~ facilities; ~~and~~

*~~viii)~~* − suspension or withdrawal of authorisations or approvals~~.~~; ~~and~~

‒ restrictions on the movement of *commodities*, *vehicles/vessels* and, if required, other fomites and people~~.~~;

~~‒~~ ~~establishment of compensation mechanisms;~~

‒ listing disease for mandatory reporting; and

‒ ordering of *disinfection, disinfestation* or pest control~~.~~;

*iv)* establishment of compensation mechanisms.

These essential powers ~~must~~ should be clearly identified ~~as~~ because 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 powers and tasks related to official activities. The specific powers and tasks delegated, the competencies required, the bodies or officers to which the powers and 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 paraprofessionals**

~~1.~~ ~~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~~*~~;~~

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*~~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:~~

*~~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;~~

*~~c)~~* ~~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~~ provide ~~basic~~ principles for or regulate the following matters:

*i)* ~~describe the~~ various ~~categories~~ professional categories ~~specialisations~~ of *veterinarians* (e.g. specialisations) and categories of *veterinary paraprofessionals* recognised in the country in accordance with its needs, notably in animal health, animal welfare and food safety;

*ii)* ~~define the~~ prerogatives of the various ~~categories~~ professional categories ~~specialisations~~ of *veterinarians* (e.g. specialisations) and categories of *veterinary paraprofessionals* that are recognised in the country;

*iii)* ~~define the~~ minimum initial and continuous educational requirements and competencies for the various ~~categories~~ professional categories ~~specialisations~~ of *veterinarians* (e.g. specialisations) and categories of *veterinary paraprofessionals*;

*iv)* ~~prescribe the~~ conditions for recognition of the qualifications for *veterinarians* and *veterinary paraprofessional~~s~~*;

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*v)* ~~define the~~ conditions ~~to~~ for performing the activities of veterinary medicine/science, including the extent of supervision for each category of *veterinary paraprofessionals*;

*vi)* ~~prescribe the~~ powers to deal with issues of conduct and competence ~~issues~~, including licensing requirements and mechanisms to appeal, that apply to *veterinarians* and *veterinary paraprofessionals*;

*vii)* ~~identify the exceptional situations, such as epizootics,~~ ~~define the~~ conditions (except those that are under the ~~responsibilities~~ responsibility of the *Competent Authority*) under which persons other than *veterinarians* can undertake activities that are normally carried out by *veterinarians*.

2. ~~If the~~ *~~veterinary legislation~~* ~~does not create~~ In the event that a Member Country is yet to 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.

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~~ registered by the *Competent Authority* for carrying out the analysis of official samples; and

*c) laboratories* ~~recognised by the~~ *~~Competent Authority~~* ~~to~~ that 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~~ laboratory*, 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 following 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 for other purposes approved by the *Competent Authority*; and

*c)* ~~surveillance~~ oversight 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, including their disposal when applicable, as described in Chapter 5.8. of the *Terrestrial* *Code* and Chapter 1.1.4. of the *Terrestrial Manual*.

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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 point 6~~)~~ of Article ~~4.2.3.~~ 4.3.3.

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 following elements ~~listed below~~:

*a)* definition of the animal feed subject to the legislation;

b) standards for the production, composition, packaging, labelling and quality control of animal feed in relation to the biological, chemical and physical *risks* ~~of disease transmission~~;

*~~b~~c)* registration and, if necessary, approval of ~~establishments~~ facilities and the provision of health requirements for relevant operations; ~~and~~

*~~c~~d)* distribution and use of animal feed in relation to the biological, chemical and physical *risks*; and

*e)* 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 following elements ~~listed below~~:

*a)* definition of the animal by-products subject to the legislation;

*b)* rules for sourcing, collection, transport, processing, use and disposal of animal by-products;

*c)* registration and, if necessary, approval of ~~establishments~~ facilities 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*.

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Article 3.4.9.

**Animal diseases**

*Veterinary legislation* should provide a basis for ~~the~~ *Competent Authorities* to manage diseasesof importance to the country, present or not, ~~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 and mandatory reporting of diseases of importance to the country. It should also provide powers for the *Veterinary Authority* to access information needed to comply with its *notification* obligations to the OIE.

1. Surveillance

*Veterinary legislation* should provide a basis for the collection, transmission, dissemination 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 diseasesand, if necessary, additional or specific measures such as *surveillance*, establishment of a regulatory programme or emergency response for particular diseaseslisted ~~in the country~~ by the *Competent Authority*.

*b)* The legislation should also provide a basis for ~~contingency~~ emergency response plans for use in responding to disease, to include the following ~~for use in disease~~~~responses~~:

*i)* the~~administrative~~ administration and logistic~~s~~ ~~organization~~ necessary to activate, implement and coordinate activities;

*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~~ alternatively, 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 or products,using a risk-based approach.

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 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 cruelty or neglect ~~by animal keepers~~.

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2. Stray dogs and ~~other free-roaming~~ abandoned domestic 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, as described in Chapters 6.7. to 6.11.

1. General measures

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

*a)* definition of *veterinary* ~~medicines and biologicals~~ *medicinal products*, including any specific exclusions; and

*b)* regulation of the authorisation, importation, manufacture, ~~safety, efficacy,~~ ~~distribution~~ wholesale, retail, and usage of, ~~and~~ commerce in, and disposal of safe and effective *veterinary* ~~medicines and biologicals~~ *medicinal products*~~, including laboratory biosafety and biosecurity measures~~.

2. Raw materials for use in veterinary ~~medicines and biologicals~~ medicinal products

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

*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~~

*~~c~~b)* ~~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) veterinary medicinal products* incorporated into ~~medicated~~ feed;

*ii)* products prepared by authorised *veterinarians* or authorised pharmacists; ~~and~~

*iii)* emergencies and temporary situations; ~~and~~

*iv)*  establishment of maximum residue limits for active substances and withdrawal periods for relevant *veterinary medicinal products* containing these substances ~~and maximum residue limits for the active substance contained in each such product.~~; and

*v)* restrictions of use of *veterinary medicinal products* for food-producing animals.

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*c) Veterinary legislation* should address the technical, administrative and financial conditions associated with the granting, suspension, renewal, refusal and withdrawal of authorisations.

*d)* In defining the procedures for seeking and granting, or refusing, 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;~~

*~~c)~~* ~~qualifications of experts involved in trials; and~~

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

~~5~~4. ~~Establishments~~ Facilities 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, exporting, 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;

*c)* good manufacturing practices and good distribution practices as appropriate;

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

*e)* mechanisms for traceability and recall.

~~6~~5. 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, including appropriate labelling;

*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;

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*~~d~~e)* the supervision by an authorised professional of organisations approved for the holding and use of *veterinary* ~~medicines and biologicals~~ *medicinal products*;

*~~e~~f)* the regulation of advertising claims and other marketing and promotional activities~~, including a system of~~ *~~surveillance~~* ~~for falsification~~; ~~and~~

*~~f~~g)*  a system of *surveillance* of the quality of *veterinary medicinal products* marketed in the country, including a system of *surveillance* for falsification; and

*h)* a system forthereporting 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 6.2.

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* in accordance with Chapter 6.3.;

*~~a~~b)* controls over all stages of the production, processing and distribution of food of animal origin;

*~~b~~c)* recording all significant animal and public health events that occur during primary production ~~including~~ and *slaughter*;

*~~c~~d)* giving operators of food production ~~premises~~ facilities the primary responsibility for compliance with food safety requirements, including traceability established by the *Competent Authority*;

*~~d~~e)* inspection for compliance with food standards, where this is relevant to health or safety;

*~~e~~f)* inspection and audit of ~~premises~~ facilities;

*~~f~~g)* prohibition of the marketing of products not fit for human consumption; and

*~~g~~h)* 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;~~

*~~c~~a)* health standards including measures to control diseases, and monitoring and enforcement of maximum residue levels (MRL); ~~and~~

*~~d~~b)* the ~~application~~ use of ~~health identification marks that are visible to the intermediary or and final user~~ visible marks that indicate the product ~~has been inspected~~ complies with the health standards.

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The *Competent Authority* should have the necessary powers and means ~~to~~ rapidly to 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~~ facilities 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~~ facilities 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 Section~~s~~ 2 Risk Analysis and Section 5 Trade measures, import/export procedures and veterinary certification.

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