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OIE Standards on Veterinary Legislation: Chapter 3.4 of the OIE Terrestrial Animal Health Code

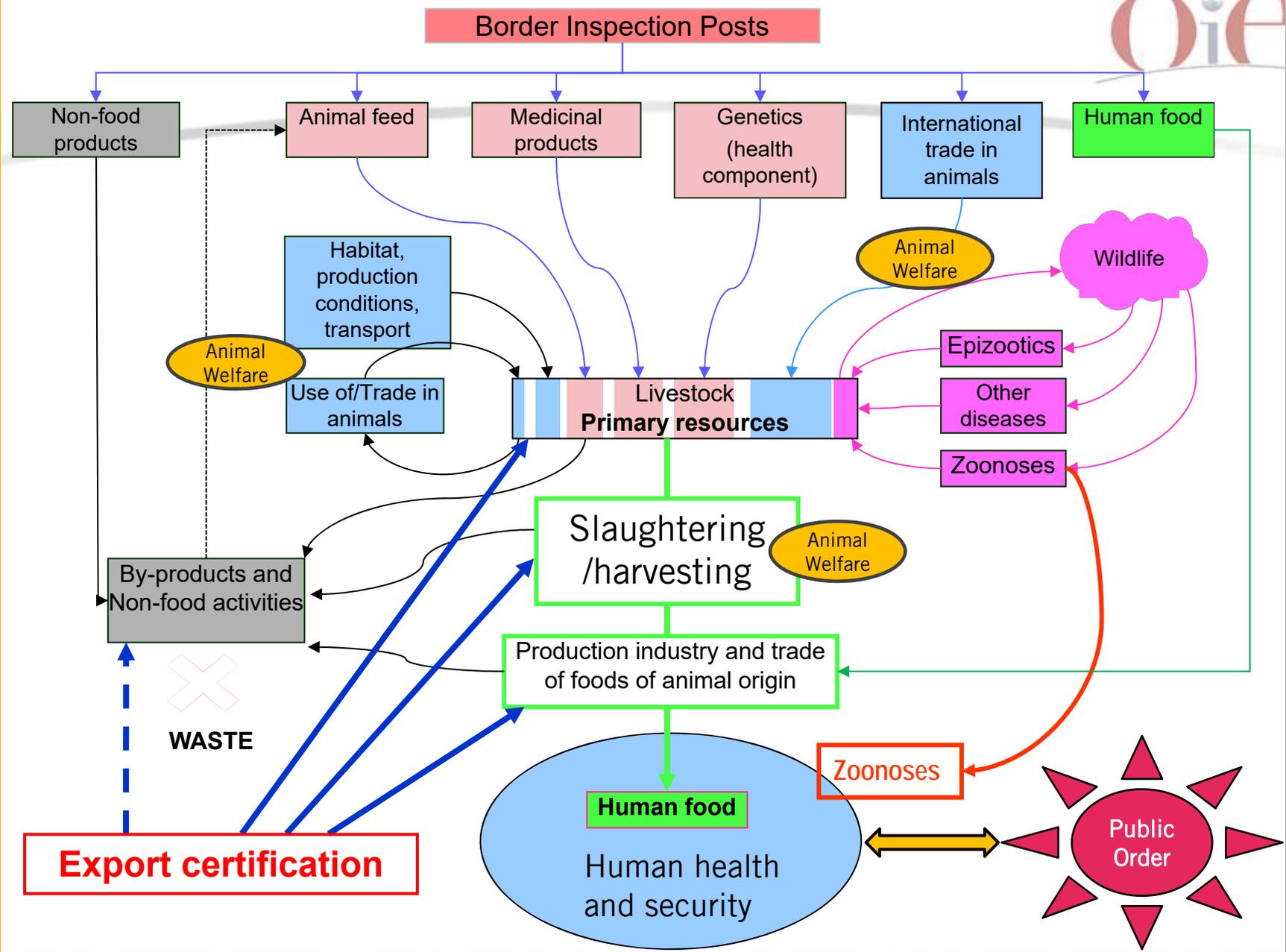
**REGIONAL SEMINAR FOR MEMBER STATES OF THE
COMMON MARKET FOR EASTERN AND SOUTHERN AFRICA (COMESA)
ON REGIONAL HARMONISATION OF LEGISLATION IN THE VETERINARY DOMAIN**

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Veterinary Legislation & the Veterinary Domain

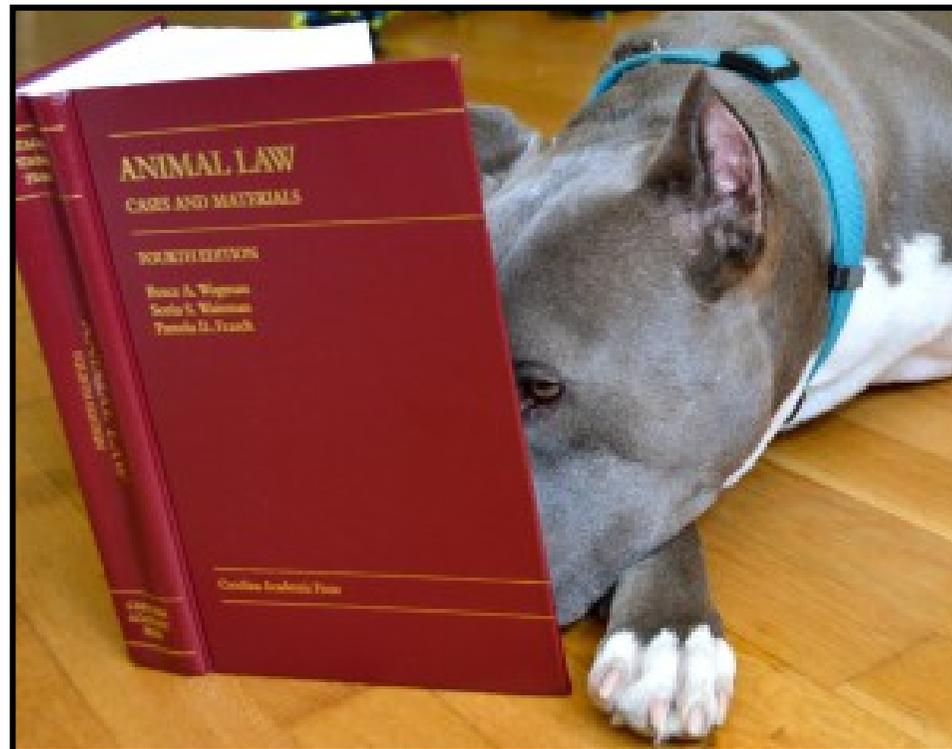


- ***Veterinary legislation:*** means the collection of specific legal instruments (primary & secondary legislation) required for the governance of the veterinary domain.
- ***Veterinary domain:*** means all the activities that are directly or indirectly related to *animals*, their products & by-products, which help to protect, maintain & improve the health & welfare of humans, including by means of the protection of animal health & welfare, & food safety.



Chapter 3.4

Veterinary Legislation



Overview of Chapter 3.4 Veterinary Legislation



General matters

- Introduction & objectives
 - Definitions
 - General principles
 - The drafting of veterinary legislation
-

Specific matters

- Competent authorities
- Veterinarians & veterinary para-professionals
- Laboratories in the veterinary domain
- Health provisions relating to animal production
- Animal diseases
- Animal welfare
- Veterinary medicines & biologicals
- Human food production chain
- Import & export procedures & veterinary certification

Introduction & Objectives



- Good governance is a recognised global public good and is of critical importance to OIE Members.
- Legislation is a key element in achieving good governance.
- Chapter 3.4 of the Terrestrial Code provides the framework for the OIE standards on veterinary legislation.
- The objective of Chapter 3.4 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.

Definitions



- Six definitions are provided for clarity of text in Chapter 3.4
- Two of particular note for this discussion
- **Primary legislation:** means the legal instruments issued by the **legislative body** of a Member.
- **Secondary legislation:** means the legal instruments issued by the **executive body** of a Member under the authority of primary legislation.
 - Primary – authority to establish reportable disease list
 - Secondary – Identify the reportable diseases on the list

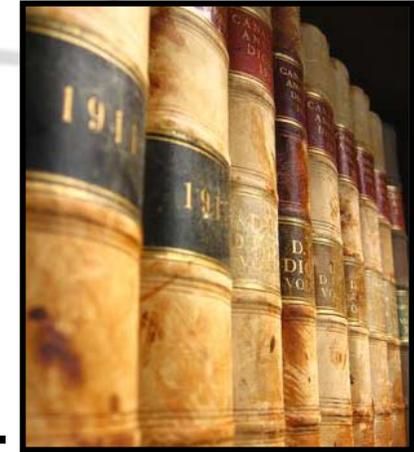
General Principles

- Respect for the hierarchy of legislation
 - between primary and secondary legislation
- 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
- Transparency
 - Legislation should be inventoried and be readily accessible
 - Communicated by competent authorities to stakeholders
- Consultation
 - Competent Authorities and legal experts required for drafting
 - Participation of stakeholders is essential for drafting effective legislation



Drafting of Veterinary Legislation

- Establish clear rights, responsibilities obligations.
- Be unambiguous, precise and accurate.
- Include a clear statement of scope and objectives.
- Provide for the application of penalties and sanctions, either criminal or administrative.
- **Make provision for the financing needed for the execution of all activities of Competent Authorities**



Competent Authorities



- ***Competent Authorities*** should be legally mandated, capacitated and organised to ensure that all necessary actions are taken quickly and coherently to address animal health and public health 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).
- Where more than one *Competent Authority* is involved, e.g., food safety matters, a reliable system of **coordination and cooperation** should be in place.

Necessary Powers of the Competent Authority



- Legal authority to intervene in accordance with the legislation and the penal procedures.
- Officials are protected against legal action and physical harm while carrying out their mandate.
- Powers and functions of officials are explicitly listed to protect the rights of stakeholders and the general public against abuse of authority.

Necessary Powers of the Competent Authority

- **At the minimum:**
- Access to documents
- Taking of samples
- Access to premises & vehicles for inspection
- Retention of animals & goods pending disposition
- Seizure of animals, products & foods of animal origin
- Suspension of activities in inspected establishments
- Closure of inspected establishments
- Suspension or withdrawal of authorisations or approvals



Delegation of Powers by the Competent Authority

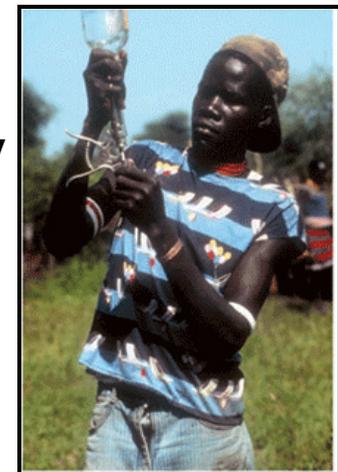


- The veterinary legislation should provide the possibility for Competent Authorities to delegate specific tasks related to official activities.
- For this purpose, the veterinary legislation should:
 - define the field of activities & the specific tasks covered by the delegation;
 - provide for the control, supervision &, when appropriate, financing of the delegation;
 - define the procedures for making delegation

Veterinarians & Veterinary Para-professionals



- Two parts – conduct & control
- The conduct of veterinary medicine/science
 - Prerogatives of veterinarians & of the various categories of veterinary para-professionals
 - Minimum initial & continuous educational requirements & competencies for each category
 - Conditions for recognition of their qualifications
 - Conditions to perform the activities of veterinary medicine/science for each category
 - Identify the exceptional situations where others might undertake the activities of veterinarians



Veterinarians & Veterinary Para-professionals



- Legislation should provide the basis for regulation
 - Describe the various categories of *veterinary para-professionals* recognised & for each prescribe the required training, qualifications, tasks & extent of supervision;
 - Prescribe the powers to deal with conduct & competence issues, e.g., licensing requirements
 - Provide for the possibility of delegation of powers to a professional organisation, e.g., a ***veterinary statutory body***
 - Describe the prerogatives, the functioning & responsibilities of the mandated professional organisation.

Laboratories



- **Facilities** - Veterinary legislation should define the role, responsibilities, obligations & quality requirements for
 - *Reference* laboratories
 - laboratories designated to carry out the *analysis of official samples*;
 - laboratories recognised to conduct analyses required under the legislation for *quality control*
- **Reagents** - Veterinary legislation should provide a basis to address
 - Procedures to authorize reagents used
 - Quality assurance & surveillance of marketing

Health Provisions for Animal Production



- Identification & traceability



- Address all the elements in Article 4.2.3., point 6, i.e., the legal framework for an animal identification system

- Animal markets & other gatherings

- Registration of markets
- Prescribe disease prevention measures
- Provision of veterinary checks



- Animal reproduction

- Regulation at the level of animals, genetic material, establishments or operators

Health Provisions for Animal Production



- Animal feed
 - Standards for the production, composition & quality control
 - Registration of establishments & provision of health requirements
 - Recall from the market of any hazardous product
- Animal by-products (i.e., not for human consumption)
 - Definition of the animal by-products subject to the legislation
 - Rules for collection, processing, use & disposal
 - Registration of establishments & provision of health requirements
- Disinfection
 - a basis to regulate the use of products & methods of *disinfection* relating to the prevention & control of animal *diseases*.

Animal Diseases



- Basis for the Competent Authority to manage diseases of importance to the country & to list those diseases
- Surveillance
 - Legal basis to collect, transmit & utilise epidemiological data relevant to diseases listed by the *Competent Authority*
- Disease prevention & control
 - Include general animal health measures applicable to all diseases & specific measures for particular diseases
 - Legal basis for contingency plans, e.g., exceptional powers for CA
 - provide for the **financing** of animal disease control measures, e.g., operational expenses & owner compensation funds
- Emerging diseases
 - Powers to investigate & respond to emerging diseases



Animal Welfare



- General provisions
 - Veterinary legislation should provide a basis for actions to address the animal welfare related requirements in Section 7 of the *Terrestrial Code*.
 - At a minimum, legislation should provide a legal definition of cruelty as an offence, & provisions for direct intervention of the *Competent Authority* in the case of neglect by animal keepers
- Stray dogs & other free-roaming animals
 - Legal basis to address the requirements of Chapter 7.7 - Stray dog population control

Aspects of Animal Welfare Covered in Section 7 of the Terrestrial Code



- Guiding principles for animal welfare
- The **transport** of animals by land
- The **transport** of animals by sea
- The **transport** of animals by air
- The **slaughter** of animals for human consumption
- The **killing** of animals for disease control purposes
- The **control** of **stray dog** populations
- The **use** of animals in **research & education**
- Animal welfare & **beef cattle productions systems**
- Animal welfare & **broiler chicken production systems**



Veterinary medicines & biologicals



- General measures
 - Definition of veterinary medicines & biologicals
 - Provide legal basis for regulation of importation, manufacture, distribution, use & commerce
- Raw materials used in manufacture
 - Quality standards for raw materials used
 - Establishment of withdrawal periods & residue limits
 - Requirements for substances that may interfere with the conduct of veterinary checks

Veterinary medicines & biologicals



- Authorisation
 - Ensure that only authorised products are placed on the market including medicated feeds, compounded drugs
 - Basis to address emergency situations & equivalence of authorisations made by other countries.
- Quality
 - Conduct of clinical & non-clinical trials to verify all claims made by the manufacturer
 - Conditions of trials & qualifications of experts
 - Surveillance for adverse effects

Veterinary medicines & biologicals



- Establishments producing, storing & wholesaling veterinary medicines & biologicals
 - Registration of all operators along the supply chain
 - Define responsibilities & good manufacturing practices
 - Mechanisms for **traceability & recall**
- Retailing, use & traceability of veterinary medicines & biologicals
 - Control of distribution with **traceability & recall**
 - Rules for **prescriptions** & provision to end users
 - Restrictions on authorization to sell
 - Truth in advertising
 - Reporting of adverse effects



Human Food Production Chain



- Veterinary legislation should provide a basis for actions to safeguard the human food production chain at all critical steps,
- General provisions
 - Controls over all stages of the production, processing & distribution of foods of animal origin
 - Recording all significant animal & public health events
 - Giving operators of food production premises the primary responsibility for compliance
 - Inspection of premises for compliance of food safety standards
 - Prohibition of marketing products unfit for human consumption
 - Provisions for recall



Human Food Production Chain



- Products of animal origin intended for human consumption
 - Provide for arrangements for inspection & audit
 - Conduct of inspection & audit based on **veterinary expertise**
 - Establishment of health standards
 - Application of visible health identification marks
- Operators responsible for premises & establishments pertaining to the food chain
 - Registration by the Competent Authority
 - Use of risk-based management procedures
 - Prior authorization of operations that pose a risk to animal or human health

Import & Export Procedures & Veterinary Certification



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

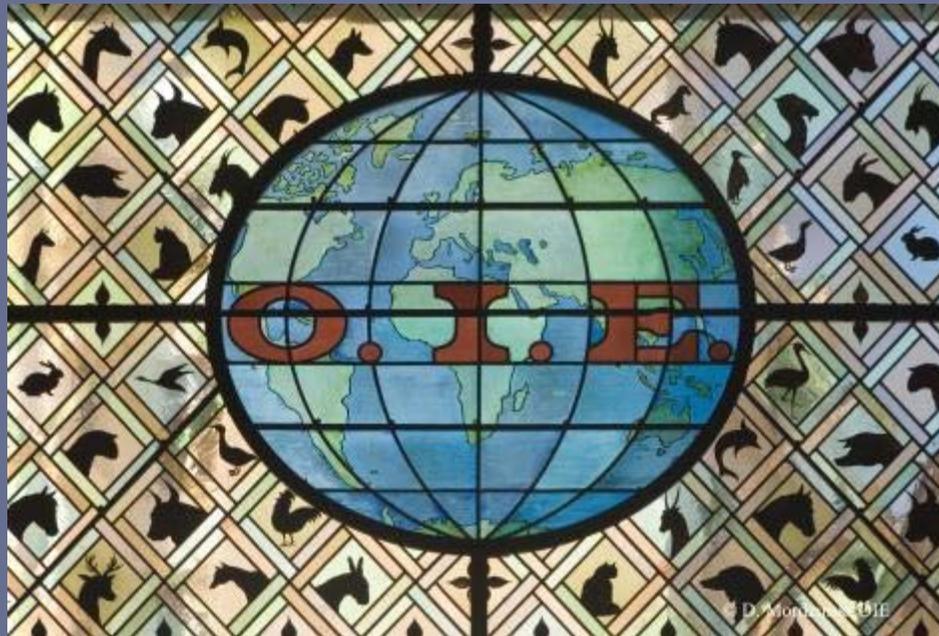


Summary



- Veterinary legislation is necessary to provide a **legal basis for the Competent Authority** to properly & effectively regulate the veterinary domain.
- Chapter 3.4 provides advice and assistance to Member Countries when formulating or modernising veterinary legislation so as to comply with OIE standards, thus ensuring good governance of the entire veterinary domain.
- Chapter 3.4 is structured around the veterinary domain and provides an overview & checklist of the essential elements that need to be addressed in veterinary legislation.
- Legal powers must be clear as some necessary actions of the Competent Authority may conflict with individual rights ascribed in fundamental laws.

Thank you for your attention



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