



Organisation
Mondiale
de la Santé
Animale

World
Organisation
for Animal
Health

Organización
Mundial
de Sanidad
Animal

Veterinary legislation support programme



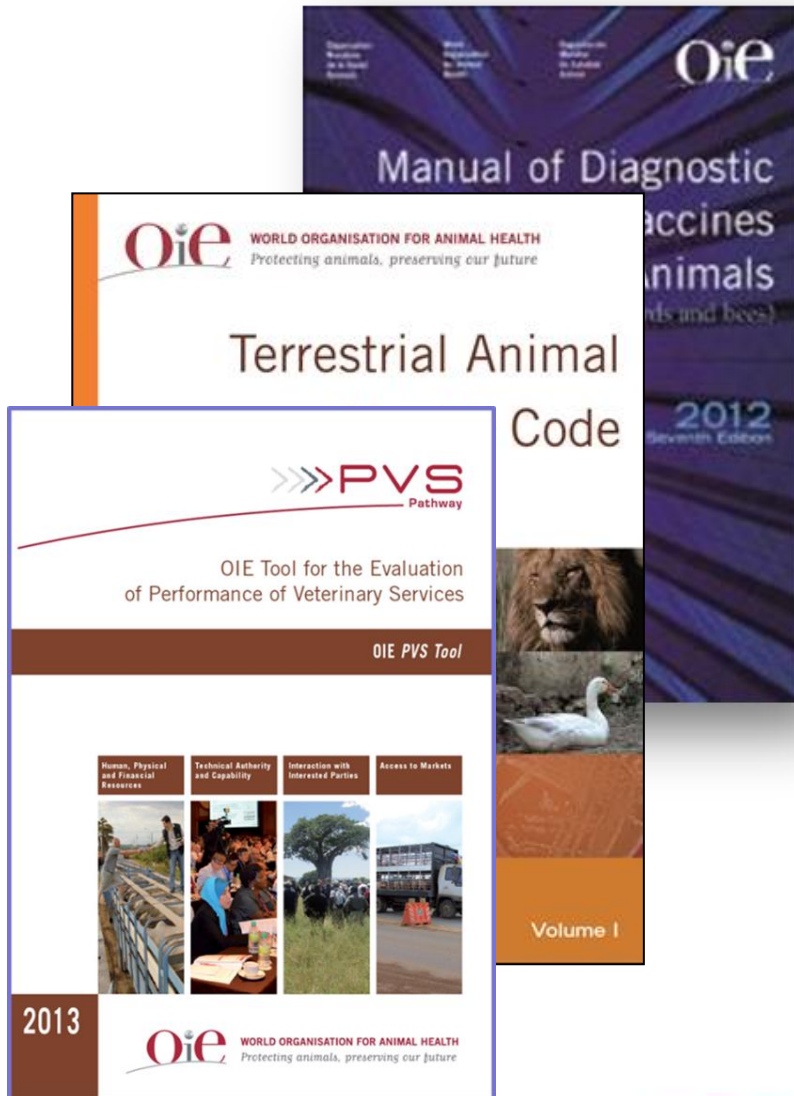
Identification Mission
Addis Ababa,
20-24 April 2015
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Outline

- 1 Introduction to Veterinary Legislation Support Programme
- 2 PVS evaluation and Gap Analysis in Ethiopia
- 3 Context of this mission
- 4 OIE standards and guidelines on veterinary legislation
- 6 Conclusions

PVS Pathway



Terrestrial Animal Health Code

Section 3 'Standards for Veterinary Services' is the legal base for the

OIE PVS Tool

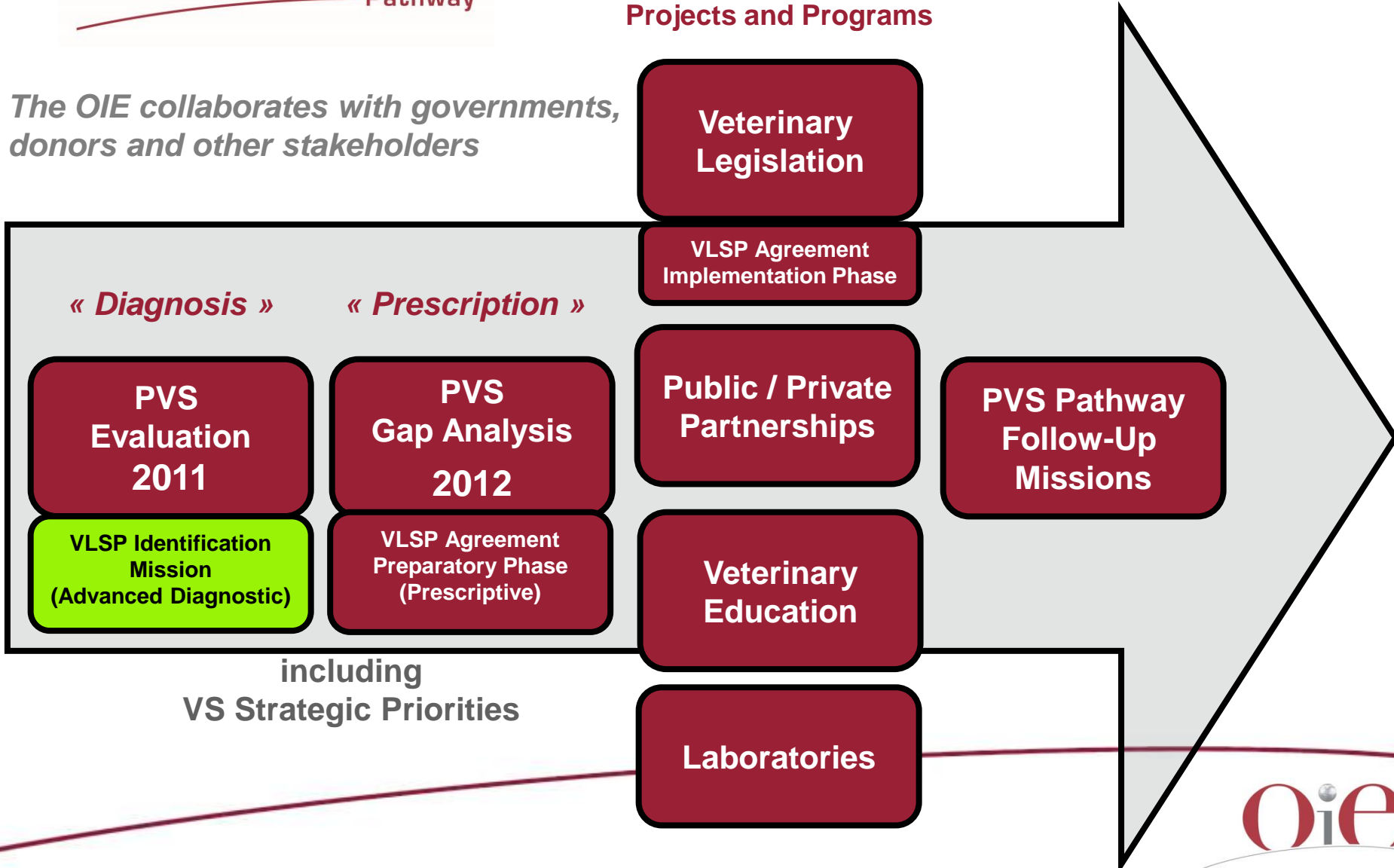
Code Chapter 3.4: standards for veterinary legislation.



« Treatment »

Capacity Building
Specific Activities
Projects and Programs

The OIE collaborates with governments,
donors and other stakeholders



« Diagnosis »

« Prescription »

**PVS
Evaluation
2011**

**VLSP Identification
Mission
(Advanced Diagnostic)**

**PVS
Gap Analysis
2012**

**VLSP Agreement
Preparatory Phase
(Prescriptive)**

**Public / Private
Partnerships**

**Veterinary
Education**

Laboratories

**PVS Pathway
Follow-Up
Missions**





including
VS Strategic Priorities

State of play with the VLSP global Programme

	OIE Members	Mission requests received	Missions implemented	Mission reports received	Agreement requested
Africa	54	39	22	22	7
Americas	29	7	6	6	2
Asia, the Far East and Oceania	32	6	5	5	2
Europe	53	5	3	2	1
Middle East	12	4	4	4	1
TOTAL	180	61	40	39	13

to 23 March 2015

PVS evaluation (2011)

PVS results summary of Ethiopia	Central level of VS	2nd level of VS	Field level of VS	Global Result
I. HUMAN, PHYSICAL AND FINANCIAL RESOURCES				
I.1.A. Staffing: Veterinarians and other professionals	3	2	2	2
I.1.B. Staffing: Veterinary paraprofessionals and other	4	4	4	4
I.2.A. Professional competencies of veterinarians	3	2	2	2
I.2.B. Competencies of veterinary paraprofessionals	3	3	3	3
I-3. Continuing education	4	4	4	4
I-4. Technical independence	3	3	3	3
I-5. Stability of structures and sustainability of policies	4	4	4	4
I-6.A. Internal coordination (chain of command) 	2	2	2	2
I-6.B. External coordination	3	3	3	3
I-7. Physical resources	3	3	3	3
I-8. Operational funding	4	4	4	4
I-9. Emergency funding	3	3	3	3
I-10. Capital investment	3	3	3	3
I-11. Management of resources and operations	3	3	3	3
II. TECHNICAL AUTHORITY AND CAPABILITY				
II-1. Veterinary laboratory diagnosis	4	4	3	4
II-2. Laboratory quality assurance 	2	2	1	2
II-3. Risk analysis 	2	2	1	2
II-4. Quarantine and border security (note-only relevant to international airport)	3	-	-	3
II-5.A. Passive epidemiological surveillance 	2	2	2	2
II-5.B. Active epidemiological surveillance	3	3	2	3
II-6. Early detection and emergency response	3	3	3	3

PVS evaluation (2011)

II-7. Disease prevention, control and eradication		3	3	2	3
II-8.A. Ante and post mortem inspection		3	3	2	3
II-8.B. Inspection of collection, processing and distribution		2	2	2	2
II-9. Veterinary medicines and biologicals		3	3	3	3
II-10. Residue testing		1	1	1	1
II-11. Emerging issues		3	3	3	3
II-12. Technical innovation		2	2	1	2
II-13.A. Animal identification and movement control		3	3	3	3
II-13.B. Identification and traceability of animal products		2	2	2	2
II-14. Animal welfare		2	2	2	2
III. INTERACTION WITH STAKEHOLDERS					
III-1. Communications		3	3	3	3
III-2. Consultation with stakeholders		2	2	2	2
III-3. Official representation		3	3	3	3
III-4. Accreditation/authorisation/delegation		2	2	2	2
III-5.A. Veterinary Statutory Body Authority		1	1	1	1
III-5.B. Veterinary Statutory Body Capacity		1	1	1	1
III-6. Participation of producers and other stakeholders in joint programmes		2	2	2	2
IV. ACCESS TO MARKETS					
IV-1. Preparation of legislation and regulations		3	3	3	3
IV-2. Implementation of legislation and regulations and stakeholder compliance		2	2	2	2
IV-3. International harmonisation		4	4	4	4
IV-4. International certification		3	3	3	3
IV-5. Equivalence and other types of sanitary agreement		3	3	3	3
IV-6. Transparency		4	4	4	4
IV-7. Zoning		1	1	1	1
IV-8. Compartmentalisation		1	1	1	1

CC IV-1 Preparation of legislation

The authority and capability of the Veterinary Services to actively participate in the preparation of national legislation and regulations in domains that are under their mandate, in order to guarantee its quality...

CC IV-2 Implementation of legislation and compliance

The authority and capability of the Veterinary Services to assure compliance with legislation and regulations under the VS mandate.

<p>CC IV-1</p> <p>Preparation of legislation and regulations.</p> <p>includes collaboration with relevant authorities, including other ministries and Competent Authorities, national agencies & decentralised institutions that share authority or have mutual interest in relevant areas.</p>	<p>Levels of advancement</p>
	<p>1. The VS have neither the authority nor the capability to participate in the preparation of national legislation and regulations, which result in legislation that is lacking or is out-dated or of poor quality in most fields of VS activity.</p>
	<p>2. The VS have the authority and the capability to participate in the preparation of national legislation and regulations and can largely ensure their internal quality, but the legislation and regulations are often lacking in external quality.</p>
	<p>3. The VS have the authority and the capability to participate in the preparation of national legislation and regulations, with adequate internal and external quality in some fields of activity, but lack formal methodology to develop adequate national legislation and regulations regularly in all domains.</p>
	<p>4. The VS have the authority and the capability to participate in the preparation of national legislation and regulations, with a relevant formal methodology to ensure adequate internal and external quality, involving participation of interested parties in most fields of activity.</p>
<p>5. The VS regularly evaluate and update their legislation and regulations to maintain relevance to evolving national and international contexts.</p>	

CC IV-2 Implementation of legislation and regulations and compliance thereof	Levels of advancement
	1. The VS have no or very limited programmes or activities to ensure compliance with relevant legislation and regulations.
	2. The VS implement a programme or activities comprising inspection and verification of compliance with legislation and regulations and recording instances of non-compliance, but generally cannot or do not take further action in most relevant fields of activity.
	3. Veterinary legislation is generally implemented. As required, the VS have a power to take legal action / initiate prosecution in instances of non-compliance in most relevant fields of activity.
	4. Veterinary legislation is implemented in all domains of veterinary competence and the VS work to minimise instances of non-compliance.
5. The compliance programme is regularly subjected to audit by the VS or external agencies.	

PVS Gap Analysis (2012)

Strategic priorities for strengthening the Veterinary Services in the 5 years to come:

- Livestock identification system – from farm to the retail outlet, to control and/or eradicate animal diseases of national importance
- Strengthen consultation mechanisms and adopt a cost recovery approach in some areas to contribute to sustainability
- Strengthen coordination and leadership role of APHRD; improve linkages between central authorities and field level structures and activities (linked to export facilitation)
- Improve management systems: e.g. participatory approach, scientific basis, merit-based recruitment...

PVS Gap Analysis (2012)

Strategic priorities (cont'd):

- Strengthen capacity building efforts for a more technically competent VS and delivery
- Improve cross-sectoral and transversal cooperation with national ministries and agencies
- Expedite the passage of proclamations and regulations and (where possible) review legislation for harmonisation with international standards
- Maintain structured collaboration with relevant regional and international organisations...engagement in standards development and participation in international and regional fora.

SPS Market access prioritisation

SPS MAP Tool (2013)

The SPS MAP work, supported by COMESA, USAid and USDA, identified 16 priorities for SPS investment on the basis of decision criteria and weights agreed by the stakeholders involved.

FMD management is in the top 5 of the 16 priorities. Other SPS priorities relevant to the livestock sector are:

- (i) livestock animal traceability;
- (ii) cold chain for meat exports;
- (iii) veterinary drug and residue testing; and
- (iv) creation of a FMD free compartment supporting the export of live animals and meat.

Objectives of veterinary legislation

Food safety and food security

Public health and security

Animal health

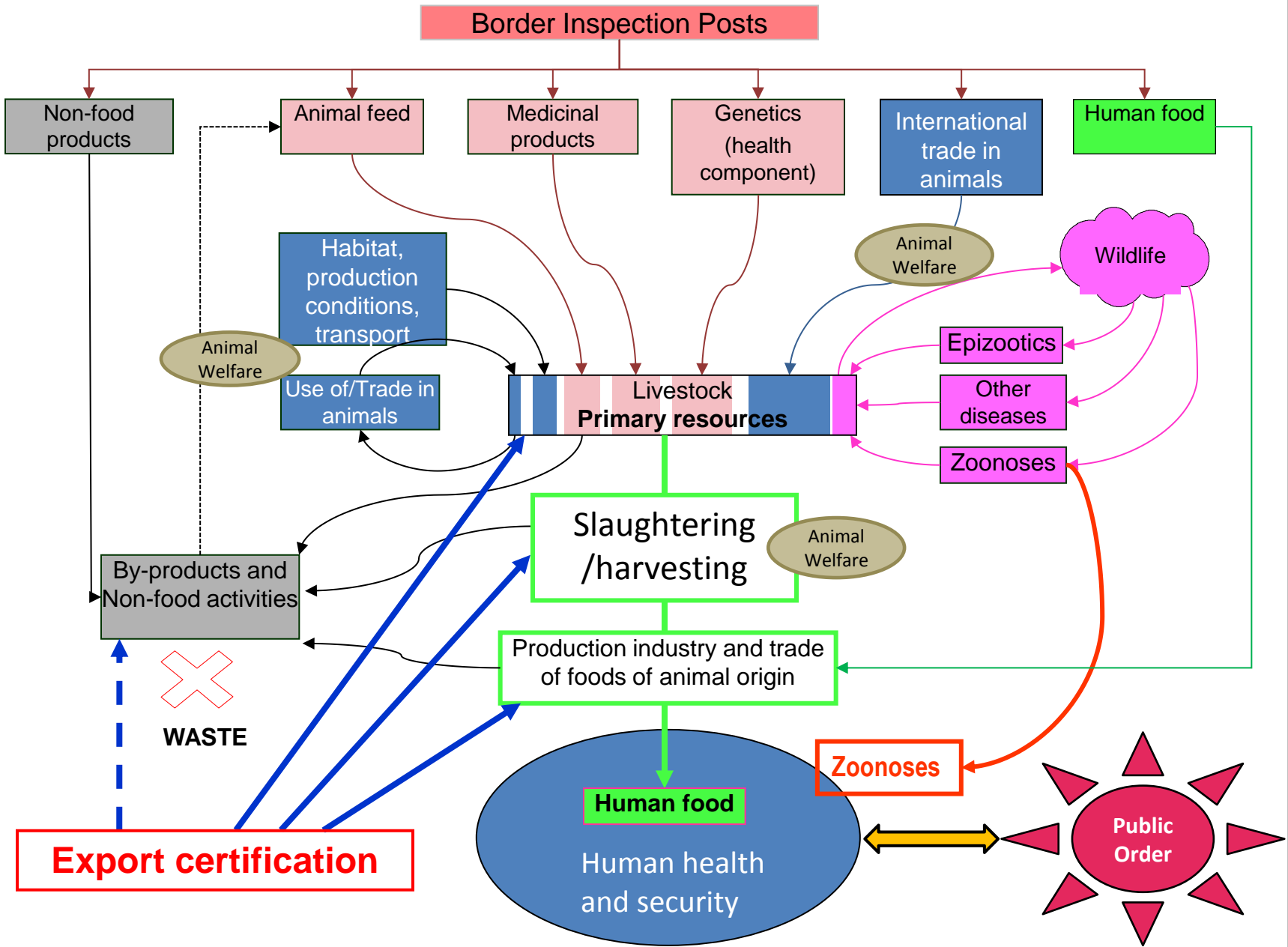
Animal welfare

In the face of growing global demand for food of animal origin, increasing world trade, shifting patterns of disease associated with climate change and the emergence and re-emergence of diseases that can rapidly spread across international borders, the VS must be supported by effective and modern legislation.

Key terms defined in the Terrestrial Code

Veterinary legislation: means the collection of specific legal instruments (primary and 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 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.



Overview of Code Chapter 3.4

General matters

- Introduction and objectives
 - Definitions
 - General principles
 - Drafting 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 and biological products
- Human food production chain
- Import / export procedures and veterinary certification

General Principles

Respect for the hierarchy of legislation

between primary and secondary legislation

Legal basis

Competent Authorities should have the primary and secondary legislation needed to carry out their activities at all administrative and geographic levels

Transparency

There should be an inventory and legislation should be readily accessible, and communicated to stakeholders

Consultation

For drafting good quality legislation, technical and legal expertise is required, and stakeholder participation.

Drafting veterinary legislation

- Establish clear rights, responsibilities, obligations
- Be precise and accurate; avoid ambiguity
- Include a clear statement of scope and objectives.
- Provide for the application of penalties and sanctions, criminal or administrative.
- Make provision for the financial support that the Competent Authorities require for the execution of their activities.

Competent Authorities

Definitions in the Terrestrial Code

Competent Authority means the **Veterinary Authority** or other Governmental Authority of a Member Country having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations in the **Terrestrial Code** .. in the whole territory.

Where more than one CA is involved (e.g. food safety), a reliable system of coordination and cooperation should be in place.

Competent Authorities

Definitions in the Terrestrial Code

The CA 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 a **chain of command** that is as effective as possible: short, with all responsibilities clearly defined.



Powers of the Competent Authority

Legal authority to take action 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.

Powers of the Competent Authority

At the minimum:

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

Delegation of powers by the CA

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 and the specific tasks covered by the delegation;
- provide for the control, supervision and, when appropriate, financing of the delegation;
- define the procedures for making the delegation.

Regulation of the veterinary profession

Definitions in the Terrestrial Code

Veterinarian means a person with appropriate education, registered or licensed by the relevant veterinary statutory body of a country to practice veterinary medicine/science in that country.

Veterinary statutory body means an autonomous regulatory body for veterinarians and veterinary para-professionals.

Veterinary para-professional (VPP) means a person who, for the purposes of the Terrestrial Code, is authorised by the VSB to carry out certain designated tasks (dependent upon the category of VPP) in a territory, and delegated to them under the responsibility and direction of a veterinarian. The tasks for each category of VPP should be defined by the VSB depending on qualifications and training, and according to need.

Regulation of the veterinary profession

The legislation should:

- Set the prerogatives of veterinarians and the various categories of veterinary para-professionals.
- Set minimum initial and continuous educational requirements and competencies for each category.
- Set conditions for recognition of their qualifications.
- Set conditions to perform the activities of veterinary medicine/science for each category, and
- Identify exceptional situations where others might undertake the activities of veterinarians.



Regulation of the veterinary profession

Legislation should provide for the establishment of an independent, autonomous Veterinary Statutory Body:

- Describe its prerogatives, functioning and responsibilities
- Enable it to establish the categories of veterinarians and veterinary para-professionals to be recognised;
- Prescribe its powers to deal with conduct and competence issues e.g. licensing, penalties.

Veterinary professional association may carry out some similar activities but is not a VSB.



Laboratories

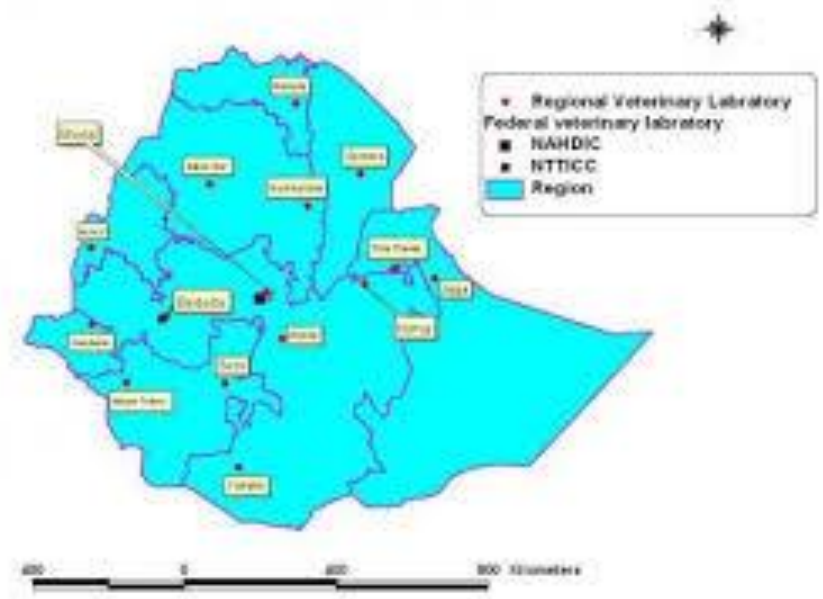
With respect to facilities, the veterinary legislation should define the role, responsibilities, obligations and quality requirements for:

- reference laboratories
- laboratories designated to analyse official samples
- laboratories recognised to conduct analyses required under the legislation for quality control.

For reagents: procedures

For the authorisation of:

- reagents used;
- quality assurance;
- surveillance of marketing.



Health provisions for animal production

Identification and traceability

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

With respect to animal markets and other gatherings, provisions for:

- Registration of markets
- Prescribed disease - prevention measures
- Veterinary inspections

Animal reproduction

Provisions applying to animals, genetic material, establishments or operators, as appropriate.



Health provisions for animal production

Animal feed

- Standards for production, composition and quality control
- Registration of establishments and 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 and disposal
- Registration of establishments and health requirements

Disinfection

a basis to regulate the use of products and methods of *disinfection* relating to the prevention and control of animal *diseases*.

Animal Diseases

Basis for the Competent Authority to manage diseases of importance to the country (disease listing).

Surveillance for diseases

Legal basis to collect, transmit and utilise epidemiological data relevant to diseases listed by the CA.

Disease prevention and control

- Include general animal health measures applicable to all diseases and specific measures for certain diseases

Legal basis for contingency plans

Exceptional powers of the CA

Provide for the financing of disease control measures e.g. operational expenses and compensation funds.

Emerging diseases: measures to investigate and respond.

Animal Welfare

Increasingly important for international trade.

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 and provisions for intervention by the CA in the case of neglect and cruelty.

Stray dogs and other free-roaming animals - legal basis to address the requirements of Chapter 7.7 Stray dog population control.

Section 7 of the Terrestrial Code

Guiding principles

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

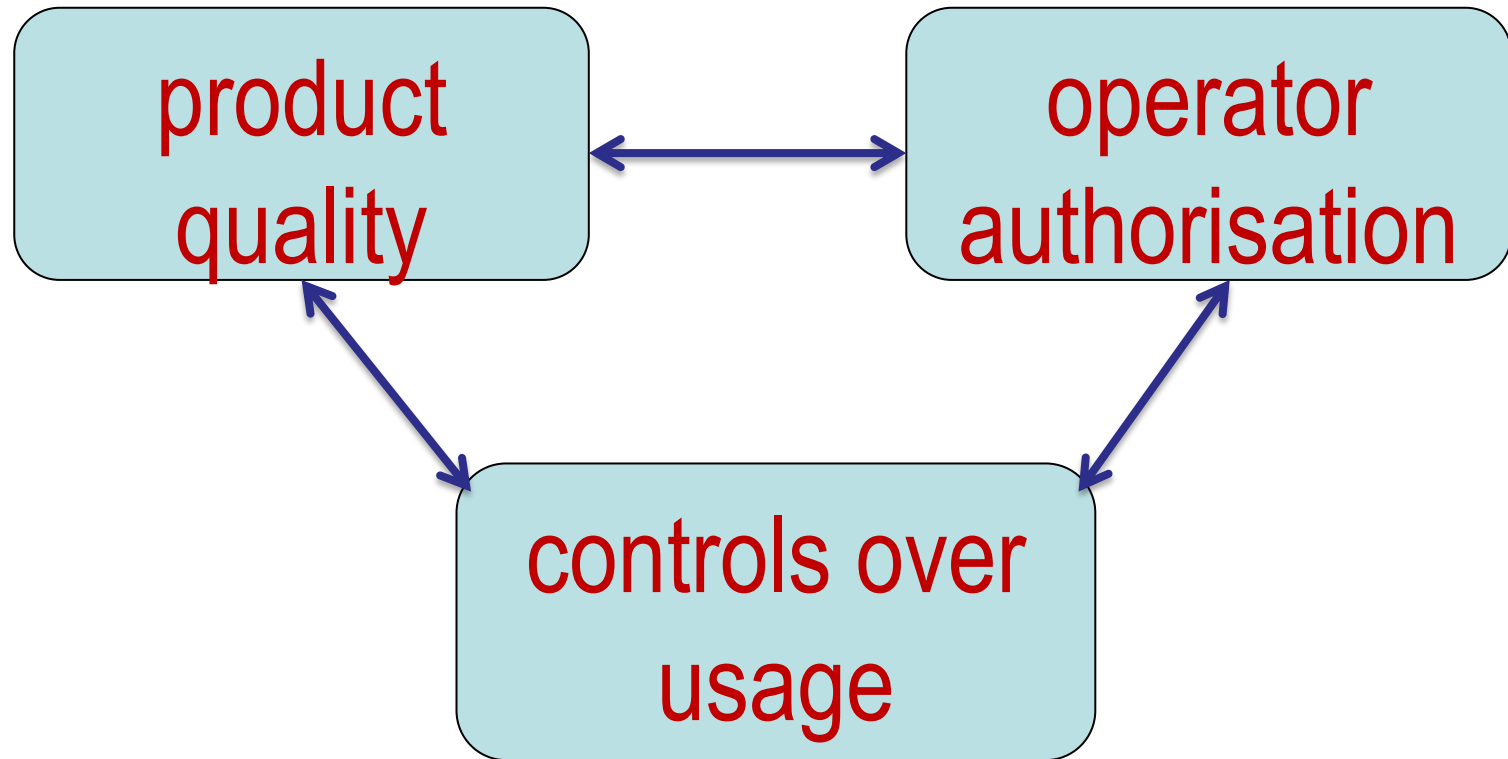
The use of animals in research and education

Animal welfare and beef cattle production systems

Animal welfare and broiler chicken production systems.



Veterinary medicinal products



Three pillars of control

Veterinary medicines and biologicals

General measures

Definition of veterinary medicines and biologicals

Provide legal basis for regulation of importation, manufacture, distribution, use and commerce.

Raw materials used in manufacture

Quality standards for raw materials used

Establishment of withdrawal periods and residue limits

Requirements for substances that may interfere with the conduct of veterinary checks

Veterinary medicines and biologicals

Authorisation

Ensure that only authorised products are placed on the market including medicated feeds, compounded drugs

Basis to address emergency situations and equivalence of authorisations made by other countries

Quality

Conduct of clinical and non-clinical trials to verify all claims made by the manufacturer

Conditions of trials and qualifications of experts

Surveillance for adverse effects

Veterinary medicines and biologicals

Establishments producing, storing and wholesaling veterinary medicines and biologicals

Registration of all operators along the supply chain

Define responsibilities and good manufacturing practices

Mechanisms for **traceability and recall**

Retailing, use and traceability of veterinary medicines and biologicals

Control over usage

Requirements for distribution, **traceability and recall**

Rules for **prescription** and provision to end users

Restrictions on authorization to sell

Truth in advertising

Reporting of adverse effects

Human food production chain

Terrestrial Code Chapters 6.1. and 6.2.

Codex Code of Hygienic Practice for meat.

Often the source of uncertainty as to jurisdiction and difficulties with overlap and duplication of activities.

Veterinary inspection in abattoirs is important for food safety and animal disease surveillance.

Jurisdiction over food processing establishments, food transport and storage facilities.

Need to address diverse production systems.

For exports: traceability of livestock and animal products is essential to assure health and safety, compliance with importing country requirements and credible certification.

Control over imported food products (health and safety).

Human food production chain

Veterinary legislation should establish health safeguards at all critical steps, including production, processing and distribution of foods of animal origin.

Records of all significant animal and public health events.

Inspection of premises for compliance with hygiene and safety standards.

Prohibition of marketing products that are unfit for human consumption.

Provisions for recall of unsafe and suspect foods.

Operators of food production premises should have the primary responsibility for compliance with legal requirements.



Human food production chain

Legislation should provide for inspection and audit, based on veterinary expertise.

Prior authorization of operations that pose a risk to animal or human health.

Establishment of health standards.

Application of visible health marks.

Operators responsible for premises transport vehicles and other establishments in the food chain.

Registration by the CA.

Use of risk-based management procedures.



Import / export procedures and veterinary certification

Definitions in the Terrestrial Code.

Provisions for both exports and imports.

Compliance with WTO rules.

Relevance of both OIE and Codex standards.

Bilateral and regional agreements.

Veterinary legislation should provide a basis for actions to address all the elements relating to import and export and veterinary certification – see Section 5 of the Terrestrial Code.

Steps following the mission

Finalisation of the report, in consultation with the Delegate (who may involve other parties).

On a voluntary basis, countries may request the establishment of an Agreement with the OIE.

The country makes a commitment to a work plan under the Agreement; designates a project leader and identifies a budget for the work programme.

The OIE provides methodological support but does not carry out or finance, the work: **responsibility for the work programme rests with the country.**

Conclusions

To deliver their mission, Veterinary Services need:

- Strategic vision and long term planning
- Sustainable and stable organisation
- Adequate financial and human resources.

In many countries the veterinary legislation should be updated, to address current and future challenges.

The OIE standards provide guidance on the principles to be addressed. There is no unique 'correct model'.

Rather, the OIE principles should be respected in order to meet the technical outcomes desired.

The exact form of legal texts and procedures will vary from country to country.

In all cases, long term political support is needed.

Thank you for your attention



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