



Manual 2

Legislation, policy and compliance



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Background

This manual provides an overview of veterinary legislation, with reference to FMD control in South-East Asia and China, as well as a more general look at veterinary legislation as a whole. The OIE *Terrestrial Animal Health Code* forms the main reference for this manual and readers should refer to the following sections for further detail on the issues addressed: Chapters 3.1, 3.2 and 3.4. Other manuals in this series will also be referred to within this manual, and a list of further references is provided at the end of the manual.

This manual does not cover specifics of legislation for each of the SEACFMD Member Countries due to the fact that these are likely to change and develop over time, thus rendering the information in the manual outdated. The manual does, however, include information on ways in which SEACFMD Member Countries may seek help to identify weaknesses in their veterinary legislation and ways in which veterinary legislation can be strengthened.

Veterinary governance and policy makes up one of the three strategic components of Phase 5 of the SEACFMD Roadmap (2016-2020). The Roadmap recognizes the importance of veterinary legislation for control, prevention and eradication of FMD in SEACFMD Member Countries and includes plans to develop a regional policy framework and support development of legislation in Member Countries for management of animal and zoonotic diseases in their territories (SEACFMD, 2015).

Veterinary legislation is a key foundation to good governance of Veterinary Services. Therefore, appropriate legislation is critical to support Veterinary Services' protection of animal health, human health and food safety. The extensive and increasing trade in livestock and livestock products, and the associated risk of disease spread and emergence or re-emergence of diseases, including zoonoses, underlines the importance of this issue.

Veterinary legislation: an overview

OIE (2014) described veterinary legislation as an essential element of a nation's governance capacity and that legislation is an essential pre-requisite for good governance of Veterinary Services. Adequate legislation is needed such that Veterinary Services can effectively carry out their necessary functions and must, at a minimum, provide a basis for competent authorities to meet their obligations

as defined by the OIE *Terrestrial Animal Health Code* (OIE, 2015).

As described above, veterinary legislation and its enforcement provides the powers and authorities necessary for Veterinary Services to carry out their key functions. These include: epidemiological surveillance; early detection and reporting of animal diseases, including zoonoses; rapid response to and prevention and control of animal disease and food safety emergencies; animal product food safety; the welfare of animals; and certification of the health status of animals and animal products for export (OIE, 2014). It also regulates the practices of veterinarians and veterinary para-professionals, to protect public interests by ensuring that such personnel are suitably qualified and competent to carry out their role.

In recognition of the importance of legislation in supporting the work of the Veterinary Services, standards on veterinary legislation were developed and incorporated into the OIE *Terrestrial Animal Health Code* in 2012. Further detail is provided on these standards later in this manual.

Enforcement of veterinary legislation

The OIE Standard for veterinary legislation includes a definition of the quality of veterinary legislation, namely "the technical relevance, acceptability to society, sustainability in technical, financial and administrative terms and provision of a basis for effective implementation of laws". This implies that, when developing veterinary legal standards, it is important to carefully consider not only their technical relevance but also their social, economic and administrative impact and, most importantly, the capacity of operators and controllers to sustainably finance their implementation and supervision (OIE, 2016a).

As suggested in the previous paragraph, veterinary legislation is of little value if the means for implementation and enforcement are lacking. It is essential, therefore, that such aspects are considered during the drafting phase rather than once the legislation has been passed. For countries which are recognized as free from FMD, with or without vaccination, and those with an OIE endorsed official FMD control program, an emergency preparedness and response plan should be in place, together with supporting legislation. Within this plan there should be details of how legislation will be implemented and enforced in the event of an FMD outbreak. For FMD endemic countries, control measures implemented during an outbreak, such as movement

controls and emergency vaccination, or preventive measures such as animal quarantine and preventive vaccination, will also need to be supported by legislation. The means and resources for enforcing that legislation must also be determined and available. Therefore, legislation impact assessments, which can assist in determining the human, financial and infrastructural resources required for effective enforcement of the proposed law should be conducted during the drafting stage of that law.

Multiple agencies/organisations may be responsible for enforcing different components of veterinary legislation, and these agencies/organisations should be identified within the legislation itself. Such agencies/organisations responsible for enforcement of veterinary legislation may include the following:

- The veterinary authority
- Local councils/local government authorities
- Veterinary Statutory Bodies
- Police

Veterinary legislation: FMD legislation

FMD is included in the OIE list of diseases and, therefore, Member Countries have an obligation to report cases of this disease according to the responsibilities outlined in Chapter 1.1. of The *Terrestrial Animal Health Code* (see also Manual 7). The obligation to report notifiable diseases, along with a list of those diseases, should be included in the country's veterinary legislation.

According to the OIE standards on veterinary legislation, Competent Authorities should be legally mandated, capacitated and organised to ensure that all necessary actions are taken quickly and coherently, to address effectively animal health, public health and animal welfare emergencies (see also Manual 11). The existence of legislation, that is appropriately resourced, implemented and enforced, should form part of the FMD emergency preparedness and response plan.

In most cases, the legislation which would be applied to FMD control and prevention, would be of a general nature (i.e. applicable to all infectious, notifiable livestock diseases) and may include categories such as:

- Animal movement controls
- Quarantine
- Slaughter/destruction of animals for the purposes of disease control (where relevant)

- Compensation for livestock keepers who have stock destroyed for disease control purposes (where relevant)
- Surveillance and diagnosis

In terms of general veterinary legislation, the OIE has identified certain 'essential powers' which are recommended (OIE *Terrestrial Animal Health Code*) to ensure that the Competent Authority has the legislative support to provide a minimum set of powers essential to carrying out their functions. These are outlined in chapter 3.4 of the *Terrestrial Animal Health Code* and described in more detail in a later section of this manual.

Specific policy instruments may be used to cover certain components of FMD control and prevention, the detail of which may not be included in primary legislation. For example, policy instruments regarding vaccination against FMD would need to be specific in terms of when animals would be vaccinated, the vaccine to be used (source/antigenic composition, etc.), when vaccination is prohibited, etc. It is likely that components of these policy instruments would need to be changed over time in response to, *inter-alia*: changing FMD situation, introduction of new strains, new control strategies, etc. Therefore, it is important that the policy instruments can be amended by the Veterinary Authority rather than requiring drafting and implementation of new legislation by government. Usually such conditions are laid out in regulations or rules (secondary legislation).

OIE Standards for veterinary legislation

In May, 2012 a new chapter on veterinary legislation (Chapter 3.4) was adopted for inclusion in the OIE *Terrestrial Animal Health Code* (OIE, 2016a). The standards set out in this chapter stipulate the aspects that veterinary legislation should cover to enable the Veterinary Services to strengthen their contribution to food security, animal production, food safety, public health and the reduction of biological risks, in particular by increasing the reliability of certification and the safety of trade in animals and animal products (OIE, 2016a).

The objective of the OIE Standards on veterinary legislation is to provide advice and assistance to Member Countries when formulating or modernizing veterinary legislation so as to comply with OIE standards. Further detail on strengthening veterinary legislation is provided in a later section of this manual.

The OIE standard on veterinary legislation, as well as providing technical guidelines, also acts as a reference for the OIE Veterinary Legislation Support Programme (VLSP), an aspect of the OIE's PVS Pathway which provides methodological support for Member Countries wishing to modernise the quality and scope of their veterinary legislation (OIE, 2016a). This programme is described in more detail later in this manual.

The OIE standards on veterinary legislation include specific definitions of terms and general principles of veterinary legislation. Given the many different types of legal systems existent in countries throughout the world, this manual is not prescriptive of how the legislation itself should look but rather provides guidance on what the resulting legislation should achieve. Box 1 outlines the general principles presented in the OIE standards on veterinary legislation.

For further information on specific definitions refer to the *Terrestrial Animal Health Code*, article 3.4.2.

Box 1: General Principles of Veterinary Legislation
OIE Terrestrial Animal Health Code (Article 3.4.3)

1. Respect for the hierarchy of legislation
 - Veterinary legislation should scrupulously respect the hierarchy between primary legislation and secondary legislation.
2. Legal basis
 - Competent Authorities should have available the primary legislation and secondary legislation necessary to carry out their activities at all administrative and geographic levels.
 - Veterinary legislation should be consistent with national and international law, as appropriate, including civil, penal and administrative laws.
3. Transparency
 - Veterinary legislation should be inventoried and be readily accessible and intelligible for use, updating and modification, as appropriate.
 - Competent authorities should ensure communication of veterinary legislation and related documentation to stakeholders.
4. Consultation
 - The drafting of new and revised legislation relevant to the veterinary domain should be a consultative process involving Competent Authorities and legal experts to ensure that the resulting legislation is scientifically, technically and legally sound.
 - To facilitate implementation of the veterinary legislation, Competent Authorities should establish relationships with stakeholders, including taking steps to ensure that they participate in the development of significant legislation and required follow-up.
5. Quality of legislation and legal certainty
 - Veterinary legislation should be clear, coherent, stable and transparent and protect citizens against unintended adverse side effects of legal instruments. It should be technically relevant, acceptable to society, able to be effectively implemented and sustainable in technical, financial and administrative terms. A high quality of legislation is essential for achieving legal certainty.

As well as general principles and specific definitions, the OIE standard on legislation also provides a regulatory framework relating to the following categories:

- powers of the competent authorities;
- veterinary medicine and control of the veterinary profession including veterinary para-professionals;
- laboratories in the veterinary domain;
- health provisions relating to animal production;
- regulations relating to transmissible animal diseases;
- animal welfare;
- veterinary medicines and biologicals;
- the health quality of products of animal origin intended for human consumption or animal feed, and;
- import and export procedures and veterinary certification (OIE, 2016a)

While all of these categories are of great importance to countries developing and improving veterinary legislation, not all of these areas will be covered in detail in this manual. Readers are referred to Chapter 3.4 of the OIE *Terrestrial Animal Health Code* for further information.

Powers of the competent authorities

The Competent Authority is 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 OIE *Terrestrial Animal Health Code* in the whole territory (OIE *Terrestrial Animal Health Code*, 2015).

Competent Authorities should be legally mandated, capacitated and organized to ensure that all necessary actions are taken quickly and coherently to address effectively animal health, public health and animal welfare emergencies (OIE, 2015). Much of the organization to ensure that the Competent Authority responds effectively to such emergencies should be outlined in emergency preparedness and response plans (see Manual 11) but it is essential that there is adequate legislation to support the organizational structures and activities outlined in such plans.

In support of the role of the Competent Authority to respond to (and prevent) animal health/human health/animal

welfare emergencies, the veterinary legislation must include certain essential powers. These essential powers enable the Competent Authority to carry out their functions of disease control, prevention, surveillance, etc. It is recommended that Member Countries include legislation to provide Competent Authorities with at least the following powers:

- Access to premises and vehicles for carrying out inspections
- Access to documents
- Taking samples
- Retention (setting aside) of animals and goods, pending a decision on final disposition
- Seizure of animals, products and food of animal origin
- Suspension of one or more activities of an inspected establishment
- Temporary, partial or complete closure of inspected establishments and
- Suspension or withdrawal of authorizations or approvals

In addition to outlining the powers available to the Competent Authority, the OIE standard also states that veterinary legislation should provide the possibility for Competent Authorities to delegate specific tasks related to official activities. The specific tasks delegated, the body or bodies to which the tasks are delegated and the conditions of supervision by the Competent Authority should be defined within the legislation. Further information is provided in the OIE *Terrestrial Animal Health Code* (article 3.4.5.).

Regulating the veterinary profession: Veterinary Statutory Bodies

This section of the manual covers information on the regulation of the veterinary profession with the purpose of ensuring quality and public confidence in the conduct of veterinary medicine/science by veterinarians and veterinary para-professionals. It describes the role of Veterinary Statutory Bodies (VSBs) and initiatives for developing/strengthening VSBs in OIE Member Countries. For further information on this, refer to article 3.4.6. of the OIE *Terrestrial Animal Health Code*.

The role of VSBs were outlined by Economides (2007) thus:

- To safeguard the health and welfare of animals through the regulation of the educational, ethical and clinical standards of veterinarians and veterinary para-professionals

- To exercise discipline
- To improve veterinary public health
- To protect the interests of those dependent on animals
- To ensure that the professional standards set are met
- To manage the registration of veterinarians
- To hear and examine complaints
- To promote and sustain public confidence in veterinary medicine

What is a Veterinary Statutory Body? (OIE, 2016b and OIE, 2017)

A VSB is a professional organisation, the role of which is to oversee the quality and competence of veterinarians and veterinary para-professionals in a country. A competent VSB, autonomous from any political or commercial interests, can ensure the excellence of the veterinary profession through appropriately licensing or registering veterinary professionals, and providing minimum standards for (initial and continuing) education and professional conduct. The functional and legislative framework within which a VSB exercises its regulatory capacity is defined in Article 3.2.12. of the OIE *Terrestrial Animal Health Code*.

The VSB should be independent of the official Veterinary Service, but recognized by the government to maintain a register of veterinarians, to prepare ethical guidance for the profession and to oversee professional conduct (FAO, 1991). Article 3.4.6. of the OIE *Terrestrial Animal Health Code* states that legislation should provide for the possibility of delegation of powers (relating to control of the veterinary profession) to a professional organization such as a VSB and, where powers have been so delegated, describe the prerogatives, the functioning and responsibilities of the mandated professional organization.

The VSB should be composed of individuals selected from various fields of expertise of veterinary professionals and veterinary para-professionals with institutional representation from Veterinary Services, Veterinary Schools and Veterinary and Veterinary Para-professional Associations (Abila and Gordoncillo, 2014). The members of the governing body of a VSB must be elected by practicing veterinarians of the country and they must have the legal powers necessary to exercise and enforce control on the conduct and practice of veterinarians and veterinary para-professionals (Economides, 2007). It is also essential that all veterinarians and veterinary para-professionals are licensed to practice by an autonomous VSB and subject to legal disciplinary provisions for any professional misconduct (Economides, 2007). Conversely, VSBs should also have the means to prosecute any person operating under the title of veterinarian/veterinary para-professional who is not qualified/registered to do so.

The importance of VSBs to the quality of Veterinary Services was recognised in the recommendations from the OIE Global Conference on Veterinary Legislation (OIE, 2010) in which it was recommended that: ‘those OIE members who had not yet done so, (should) commence the process of creating autonomous VSBs complying with the OIE *Terrestrial Animal Health Code* definition, including as a first step, providing enabling national legislation for the establishment of a VSB with clearly defined powers and objectives to regulate the whole veterinary profession, in accordance with OIE standards as contained and referred to in article 3.2.12 of the code’

OIE PVS Evaluation and Gap Analysis missions provide full, independent whole of systems performance evaluation and planning for national animal health systems, based on OIE standards. Many aspects of good governance are included in the OIE PVS Tool which forms the basis for PVS Pathway missions, including human, physical and financial resourcing, internal and external coordination, the full range of veterinary technical capacities, stakeholder interaction, and legislation. Another aspect of governance that is evaluated during a PVS Pathway mission is VSBs (and supporting legislation). Such a mission would include evaluation of the legislative and regulatory framework, the organisational structure and the functioning of the VSB (OIE, 2013). The results of such an analysis can then be used to direct activities aimed at strengthening VSBs. An example of the results of such an analysis conducted in Uganda were presented by Kauta and Sherman (2013) and provides a useful example for how PVS missions and gap analyses can be used to strengthen veterinary legislation (and VSBs).

An analysis of approximately a hundred initial PVS Evaluation reports indicated that fewer than half of all OIE Members have an effective VSB in place to regulate the registration of diplomas/degrees, the prescription of veterinary medicines and the employment of veterinarians and veterinary para-professionals (OIE, 2013). Of the 32 OIE Member Countries in Asia, Far-East and Oceania, the majority of members have regulations for veterinarians (with 23 out of 32 members having a VSB), but regulations are very limited for veterinary para-professionals (Abila and Gordoncillo, 2014). Veterinary para-professionals represent an important component of the veterinary services of South-East Asia and China, where they contribute significantly to animal health matters in some countries (Stratton *et al.*, 2015).

In addition to the PVS Pathway missions, the OIE VSB Twinning Program is another of OIE’s approaches to address the shortfall in VSBs and to reinforce the capacities of VSBs

globally to comply with international standards. This entails the establishment of links between a recognised VSB (the ‘Parent’) and the beneficiary (‘Candidate’) VSB. For further information on VSB Twinning projects, including making a project proposal, refer to OIE (2013).

Strengthening veterinary legislation

It was noted by OIE (2010) that many countries, especially developing countries and countries with in-transition economies, do not have up to date veterinary legislation and are not, therefore, well placed to meet the needs of current and future animal health challenges and societal expectations. PVS evaluations have shown that, in some cases, veterinary legislation is obsolete or inadequate (Petitclerc, date unknown). Therefore, there is a need for countries to examine their existing legislation with a view to addressing weaknesses and thus strengthening the legislation to make it more suitable to the challenges and expectations facing Veterinary Services of today.

There are a number of ways in which Member Countries may be assisted in the process of reviewing and strengthening veterinary legislation, most notably through engagement in a further step of the OIE’s global PVS Pathway, which focuses on a more sustainable, long-term strengthening of animal health systems. The first step in this process is the initial PVS Evaluation, which uses a tool to evaluate the performance of national Veterinary Services (the OIE PVS Tool) and their compliance with OIE international standards on the quality of Veterinary Services. This evaluation includes assessments related to veterinary legislation, namely the capacity to produce quality veterinary legislation and the capacity to enforce veterinary legislation.

If the PVS Evaluation identifies problems with the development of quality legislation and its enforcement., the OIE Member Country may request participation in the OIE Veterinary Legislation Support Programme (VLSP). The Veterinary Legislation Support Programme (VLSP) was launched as part of the PVS Pathway to assist countries to strengthen veterinary legislation. The aim of the VLSP is to identify gaps in existing veterinary legislation relative to the OIE standards on veterinary legislation in Chapter 3.4 and assist member countries by providing them with elements of methodology that will build their capacity to draft or update quality veterinary legislation, rather than supplying model legislation. The objective is to enable Member Countries to produce veterinary legislation independently, that is of good quality both internally (legislative drafting) and

externally (relevant, acceptable and enforced) (Petitclerc, date unknown). Figure 1 shows the two main phases of the VLSP (identification mission and agreement) together with the activities conducted under each of these phases.

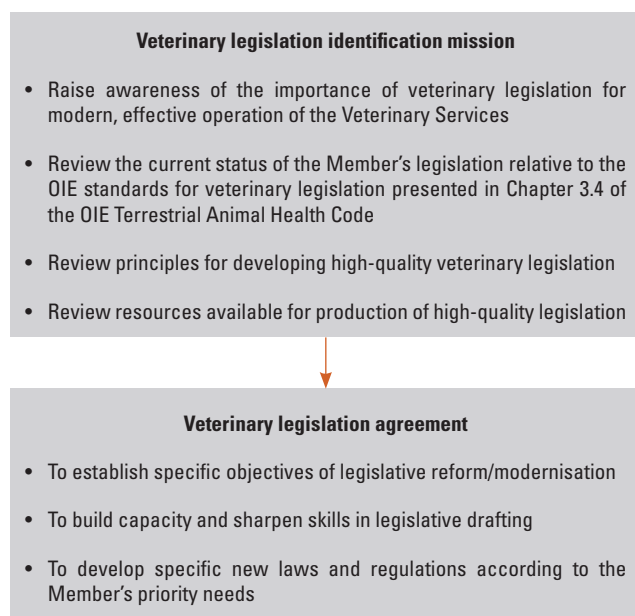


Figure 1: The main components of the VLSP and related activities (Sherman and Petitclerc, 2015)

Any member country that has completed a PVS evaluation mission can request participation in VLSP. For further details on this refer to OIE (2014); Petitclerc (date unknown); and Sherman and Petitclerc (2015).

Regional cooperation in veterinary legislation

Throughout much of this manual, veterinary legislation has been described at the national level. However, in the context of increasing international trade in livestock and livestock products, and the associated animal and human health risks, there is a need to harmonize veterinary legislation and policy across countries in order to facilitate disease prevention and control, and regional trade (OIE, 2010). This issue is particularly salient in South-East Asia and China where there is extensive movement of live

animals and animal products between countries (Smith, *et al.*, 2015).

SEACFMD Member Countries should cooperate during development of veterinary policy and legislation, particularly in areas of shared interest such as control of cross-border movements or disease control measures which may be applied in border areas. During the global conference on veterinary legislation (OIE, 2010), it was recommended that the OIE work closely with Member Countries, regional economic communities and other organisations to support efforts to develop veterinary legislation and rules that are harmonised, as appropriate, at the regional level. It was noted that the methodology should be developed in consultation with relevant international organisations in order to ensure global consistency (OIE, 2010). It was also recommended that countries, regional organisations and regional economic communities consider requesting an OIE veterinary legislation mission at the regional level, in addition to national missions to help to achieve progress in regional harmonisation, as appropriate, of veterinary legislation and rules (OIE, 2010).

Phase 5 of the SEACFMD Roadmap (2016-2020) includes a plan to assist member countries in strengthening veterinary legislation, in addition to regional harmonization of legislation/policy, through development of a regional policy framework (SEACFMD, 2015).

Also of relevance to regional harmonization of veterinary policy and legislation is the Association of South-East Asian Nations (ASEAN) Mutual Recognition Agreement (MRA) for Veterinary Science. This will provide a mechanism for agreement on the equivalence of veterinary certification procedures and qualifications across ASEAN members (Callanta, 2014) and facilitate the freer movements and employment of qualified and certified professionals between ASEAN member states (Callanta, 2014). By achieving, and agreeing upon, a certain standard of competence in the veterinary field nationally, which should also meet relevant international standards, specific working skills may be standardized (Bagja, 2014). This should also build confidence between trading nations in the quality of Veterinary Services and certification.

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