



THE INTERNATIONAL STANDARDS OF THE OIE

This paper provides an overview of the international standards of the OIE (the World Organisation for Animal Health) - their development, content and implementation.

Introduction

The OIE develops and publishes two types of international health standards for animals and animal products – trade standards and biological standards. These standards are developed through elected Specialist Commissions and are adopted by OIE Members during the annual OIE General Session.

The four publications containing the OIE standards are:

- the *Terrestrial Animal Health Code*
- the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*
- the *Aquatic Animal Health Code*
- the *Manual of Diagnostic Tests for Aquatic Animals*.



The *Terrestrial Animal Health Code* and *Aquatic Animal Health Code* (referred to hereafter as the *Codes*), aim to assure the sanitary safety of international trade in terrestrial animals (mammals, birds and bees) and aquatic animals (amphibians, fish, crustaceans and molluscs) and their products. This assurance is achieved by detailing the health measures to be used by the veterinary services or other competent authorities of importing and exporting countries in establishing health regulations for the safe importation of animals and animal products. Such measures aim to avoid the transfer of agents pathogenic for animals and/or humans, without the imposition of unjustified trade restrictions.

Veterinary services and other competent authorities should bear in mind that the *Codes* are the primary references for international trade and that the adoption of these standards allows countries and territories that are Members of the World Trade Organization (WTO) to meet their relevant obligations under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement).

The *Codes* are also essential tools for supporting the mandate of the OIE in the area of improving animal health and welfare world wide through the application of the standards on animal disease surveillance and recommended control methods.

While the *Codes* have traditionally addressed the OIE responsibilities for animal health and zoonoses, they have in recent years expanded to cover animal welfare (*Terrestrial and Aquatic Codes*) and food safety (*Terrestrial Code*) within the framework of the new mandate of the OIE which is 'to improve animal health worldwide'.

The *Terrestrial Animal Health Code* was first published in 1968 and the current edition is available on the OIE Web page in English, French and Spanish ([Terrestrial Code in English](#), [Terrestrial Code in French](#), [Terrestrial Code in Spanish](#)). It is also published in Russian and Arabic. In 2008 the *Terrestrial Code* was published in two volumes. Volume one contains recommendations that apply to a wide range of species, production sectors and/or diseases ('horizontal standards') and Volume two contains recommendations on specific diseases ('vertical standards'), including recommendations on agent inactivation, disease surveillance and risk assessment.

The *Aquatic Animal Health Code* was first published in 1995 and the current edition is available on the OIE Web page in English, French and Spanish ([Aquatic Code in English](#), [Aquatic Code in French](#), [Aquatic Code in Spanish](#)).

The health measures in the *Codes* are developed in light of the commodity and, as appropriate to the commodity, the animal health status of the exporting country. The health measures normally make reference only to the animal health situation in the exporting country as the assumption is that the pathogen of interest either is not present in the importing country or, if it is present, that it is the subject of an official control or eradication programme, consistent with obligations of WTO Members under the WTO SPS Agreement.

The following general principles apply throughout the *Codes*:

- The importing and exporting countries are in compliance with relevant WTO obligations.
- The latest scientific information is used.
- Health measures are based on an assessment of the risks appropriate to the commodity traded.
- An evaluation of the performance of veterinary services or, as appropriate, other competent authorities has been conducted.
- Zoning and compartmentalisation are being applied where deemed appropriate.
- Claims by importing and exporting countries regarding their health status are based on sound epidemiological information collected using surveillance systems that are consistent with OIE standards

The *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* and the *Manual of Diagnostic Tests for Aquatic Animals* (referred to hereafter as the *Manuals*), provide a harmonised approach to disease diagnosis by describing internationally agreed laboratory diagnostic techniques. The *Terrestrial Manual* also includes requirements for the production and control of biological products (mainly vaccines).

The *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* was first published in 1989 and the current edition is available on the OIE Web page in English, French and Spanish ([Terrestrial Manual in English](#), [Terrestrial Manual in French](#), [Terrestrial Manual in Spanish](#)).

The *Manual of Diagnostic Tests for Aquatic Animals* was first published in 1995 and the current edition is available on the OIE Web page in English and Spanish: [Aquatic Manual in English](#) and [Aquatic Manual in Spanish](#).

The aims of the *Manuals* are to provide general information on sampling methods, good laboratory practice, etc., and detailed information for laboratory technicians on diagnostic tests. The *Terrestrial Manual* also provides information on the principles of veterinary vaccine production and, where appropriate, the requirements for vaccines or diagnostic biologicals.

Development and updating of OIE standards

The OIE process for developing and updating standards is flexible and rapid, compared to the procedures of some other international organisations. Importantly, it provides a basis for continuous improvement to standards as new scientific information comes to light.

Figure 1 illustrates the process.

Draft texts for new or updated standards are developed by small groups of independent experts drawn from all regions. Draft texts are reviewed by the relevant Specialist Commissions then circulated to OIE Members for comment. These comments are reviewed by the experts and the Specialist Commissions, and appropriate changes made before the texts are resubmitted to OIE Members for adoption. Although the normal cycle for the adoption of new or updated standards is two years, the OIE process allows for the introduction of new standards more quickly, where an emergency situation warrants, and for the modification of standards on an annual basis as appropriate.

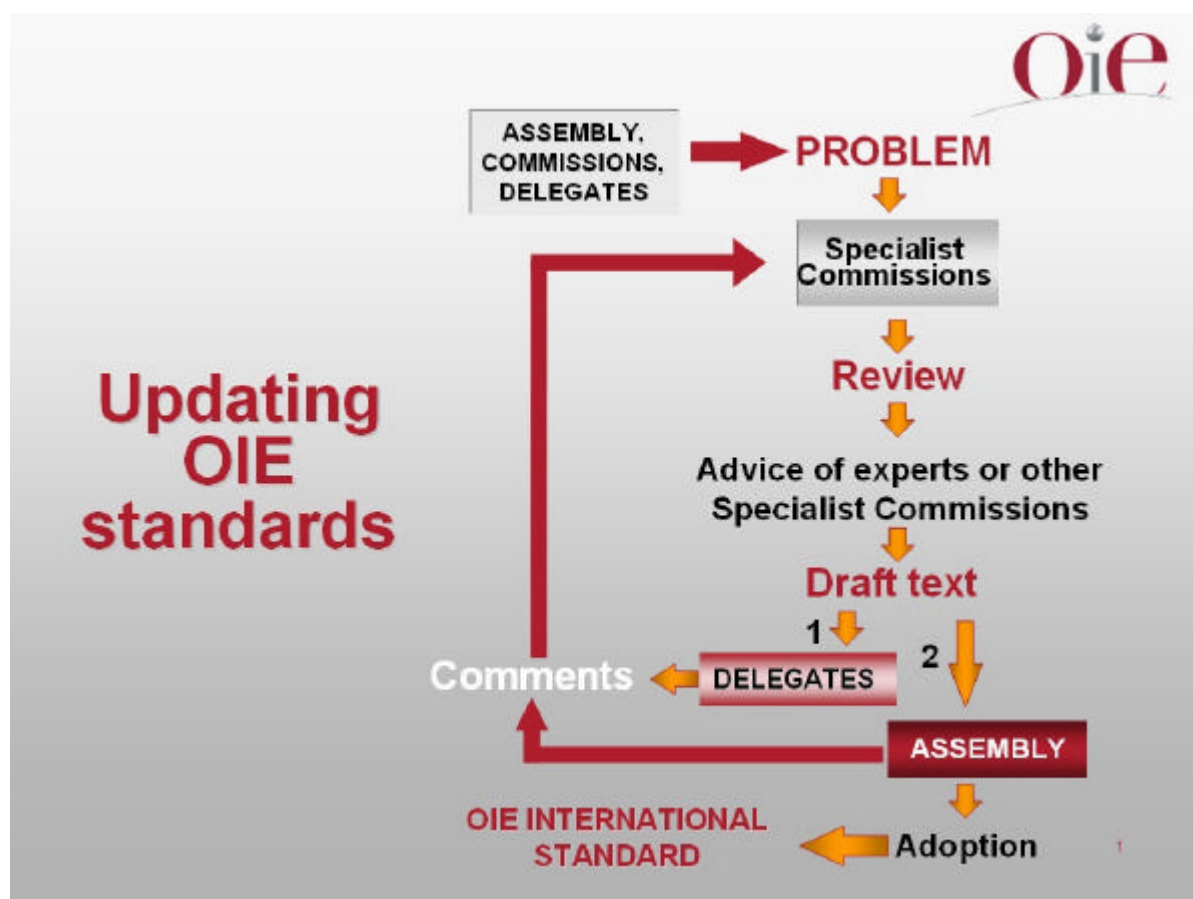


Figure 1: OIE standards development process

Development of new or revised texts

Requests for the development of a new chapter or the revision of an existing chapter of an OIE international standard may come from various sources, including OIE Delegates, individual scientists and other international organisations, industry organisations and non governmental organisations.

When a decision is made to develop a new chapter or revise an existing chapter, the OIE Director-General decides how the work on the chapter will be progressed ie. which Specialist Commission will have responsibility (on the basis of the terms of reference defined for each Specialist Commission), and the terms of reference and membership of any *ad hoc* Group or Working Groups¹ of experts that will carry out the technical work. In convening such a group, the Director-General attempts to obtain the broadest regional representation, as well as diversity of high level expertise.

An OIE Member may offer to provide an initial draft of a new or revised chapter based on the work its experts have been doing on the particular disease or procedure.

The Director-General may also request that a 'supporting document' be drafted by an expert, usually an official from an OIE Reference Laboratory or Collaborating Centre. This 'supporting document' contains the latest scientific information relevant to the topic, particularly relating to infective period, host distribution, transmission mechanisms, available treatments and controls, etc. to be used by the *ad hoc* Group or Working Group as the scientific basis for its work.

During their bi-annual meetings, the Specialist Commissions examine the various submissions from OIE Members and other sources, the reports of Working Groups and of *ad hoc* Groups the OIE has convened, and determine how to incorporate the scientific recommendations into the *Code* or *Manual* format. While the OIE places the greatest weight on submissions from OIE Members, it also considers scientific information from other sources, including the private sector and non-governmental organisations, in order to ensure that the recommendations of the Specialist Commissions are based on comprehensive and up-to-date scientific information. For each OIE Member, participation in the OIE standards development and adoption process is coordinated through the official Delegate, who is in most cases the Chief Veterinary Officer (CVO). The Delegate may be supported in his/her work by focal points, who may be nominated to address OIE activities relating to disease reporting, wildlife, aquatic animals, veterinary medications, animal welfare and animal production food safety. Experts, industry groups and organisations wishing to participate in the process may send submissions direct to the OIE but they are encouraged to provide their input through the relevant Delegate.

The reports of Commission meetings include Working Group and *ad hoc* Group reports in their entirety, as well as explanations on how the various submissions were addressed. On a twice yearly basis, OIE Members and organisations with which the OIE has formal agreements are requested to comment on the recommendations in these reports. Thus, the routine two-year cycle affords at least four opportunities for comment. All Commission reports (in English, French and Spanish) are placed on the OIE Web page.

If the comments received indicate that there is widespread support for the recommendations, the Commission will submit the chapter for adoption at the next OIE General Session of the Delegates of OIE Members. If however significant concern is expressed or if the comments indicate that further technical work is needed, the *ad hoc* Group may be asked to re-examine the issues. Another round of consultation with OIE Members follows this further review.

Standards can only be adopted (by consensus or vote) at the annual OIE General Session. There is no other pathway for adoption.

Content of OIE standards

Generic chapters in the Terrestrial and Aquatic Codes

Key terms and expressions used in the *Codes* are defined in the Glossary. This includes terms such as 'disease', 'establishment', 'incubation period', 'official veterinarian', 'stamping-out policy' and 'zone'. Some definitions apply only to particular sections or chapters in the *Codes* and may be found in those locations.

¹ Working Group membership is endorsed by the World Assembly of Delegates. Currently the OIE has Working Groups on wildlife diseases, animal production food safety and animal welfare.

Notification and Epidemiological Information

These chapters describe the obligation of OIE Members to provide to other Members, through the OIE, whatever information is necessary to minimise the international spread of important animal diseases and to assist in achieving better worldwide control of these diseases. To achieve this, OIE Members should comply with the notification requirements specified in Chapters 1.1. of the *Codes*. These requirements address the first occurrence or re-occurrence of a listed disease, the occurrence of a new strain of a listed disease, a significant change in the epidemiology of a listed disease, or the detection of an emerging disease. OIE Members are also required to report on the evolution of a notified incident until it has been resolved. All Members have to notify on a six-monthly basis on the absence or presence, and evolution of diseases listed by the OIE and, on an annual basis, provide information on their Veterinary Services and any other information of significance to other OIE Members.

Obligations and ethics in international trade

Chapters 5.1. and 5.2. of the *Codes* address the responsibilities of importing and exporting countries in exchanging up-to-date health information, setting import regulations and providing accurate health certification.

Import risk analysis

The importation of animals and animal products involves a degree of disease risk to the importing country, and the principal aim of import risk analysis is to provide countries with an objective and defensible method of assessing and managing the disease risks associated with the importation. The *Codes* describe the components of import risk analysis: hazard identification, risk assessment, risk management and risk communication, and provide guidelines for conducting risk analyses.

The principles and methods are described in Section 2 of the *Codes*. The methodology is further elaborated in a separate OIE publication, the *Handbook on Import Risk Analysis* which discusses both qualitative and quantitative approaches.

Equivalence

The estimation of the risk associated with the importation of animals and animal products, and the choice of the appropriate risk management option(s) are made more difficult by differences among the animal health and production systems between OIE Members. It is now recognised that significantly different animal health and production systems can provide equivalent animal and human health protection for the purpose of international trade, with benefits to both importing and exporting countries.

Chapter 5.3. in the *Terrestrial Code* provides information to assist OIE Members to determine whether sanitary measures arising from different animal health and production systems may provide the same level of animal and human health protection. The chapter mentions principles which can be utilised in a judgement of equivalence, and outline a step-wise process for trading partners to follow in facilitating a judgement of equivalence. The same principles apply regardless of whether equivalence applies at the level of specific measures or on a systems-wide basis, and whether equivalence applies to specific areas of trade or commodities, or generally.

Similar principles apply to trade in aquatic animals and their products.

Import / export procedures

Chapters 5.4. to 5.9. of the *Codes* describe, in general terms, the animal health measures applicable before and at departure from an exporting country, during transit and on arrival in an importing country. These chapters cover issues such as animal identification, the safe transport of aquatic animals and aquatic animal products, the need to meet the requirements of the importing country and of any transit country, the use of border posts / quarantine stations, and the containment of pathogens during transportation.

The generic issues addressed in these chapters should be implemented in conjunction with the health measures detailed in the disease specific chapters.

Model international veterinary and aquatic animal health certificates

An international veterinary or aquatic animal health certificate is a document, drawn up by the exporting country in accordance with Chapters 5.1. and 5.2. of the *Codes*, describing the animal health requirements and, where appropriate, the public health requirements, for the exported commodity. The assurance given to the importing country that diseases will not be introduced through the importation of animals or animal products depends, *inter alia*, on the quality of the exporting country's veterinary services and its disease surveillance systems.

International veterinary or aquatic animal health certificates are intended to facilitate trade and care should be taken to avoid imposing unjustified health conditions. In all cases, the exporting and importing countries should refer to the health conditions recommended in the *Codes* as they develop and finalise a health certificate.

Chapters 5.10. to 5.12. of the *Terrestrial Code* provide model international veterinary certificates for live animals, hatching eggs and products of animal origin. Chapter 5.10. of the *Aquatic Code* provides similar model international aquatic animal health certificates.

Quality of veterinary services

The quality of the veterinary services of an OIE Member depends on a range of factors, including fundamental ethical, organisational and technical principles. Veterinary services should strive to conform to these fundamental principles, regardless of the political, economic or social situation. Should the responsibility for establishing or applying animal health measures, or issuing international animal health certificates be exercised by an organisation other than the veterinary services (for example such as in the field of aquatic animal diseases), or by an authority or agency on behalf of the veterinary services, the same fundamental principles apply. These principles are described in Chapter 3.1. of the *Codes*.

The quality of the veterinary services of an OIE Member can be ascertained through an evaluation, the principles of which are described in Chapter 3.2. of the *Terrestrial Code*. These principles apply whether an OIE Member is evaluating its own veterinary services (self evaluation) or the veterinary services of another OIE Member, or asking for an OIE official opinion. The purpose of evaluation may be to assist a national authority in the decision-making process regarding resources and priorities for its own veterinary services or as part of a risk analysis to determine the health measures to be applied to imports from another OIE Member. The relative importance of the criteria described in this chapter may vary according to circumstances. In all cases, the evaluation should aim to determine whether the veterinary services have the capability for effective knowledge of and control over the health status of animals and animal products, either generally or for specific commodity groups.

The OIE *Tool for the Evaluation of Performance of Veterinary Services* (OIE PVS Tool) should be used in making an evaluation of consistency with the standards set out in Chapter 3.2. of the *Terrestrial Code*. Information on the OIE PVS Tool may be found at:

(http://www.oie.int/eng/oie/organisation/EN_OIE%20PVS%20Tool_2008.pdf).

Similar principles apply to the evaluation of competent authorities other than veterinary services.

Zoning and compartmentalisation

The principles underpinning these important concepts are discussed in Chapter 4.3. of the *Terrestrial Code* and Chapter 4.1. of the *Aquatic Code*. The sequence of steps to be taken in establishing a zone/compartment and having it recognised for international trade purposes is described in Article 5.3.7. of the *Terrestrial Code*.

Zoning and compartmentalisation are procedures implemented by an OIE Member to define animal sub-populations of distinct health status within its territory, in accordance with the recommendations in the *Codes*. Zoning applies to an animal sub-population defined on a geographical basis (using natural, artificial or legal boundaries) while compartmentalisation applies to an animal sub-population defined by management

practices related to biosecurity. Nevertheless, spatial considerations and good management practices are relevant to the application of both concepts. Establishing and maintaining a compartment requires a partnership between the veterinary services or other competent authorities of an OIE Member and the relevant enterprise/industry. The producers are responsible for managing the compartment in a biosecure manner and the government for supervising and ensuring that the correct biosecurity practices are being implemented.

Zoning and compartmentalisation allow resources to be focused on activities that have the greatest chance of success in controlling or eradicating a disease, or in gaining or maintaining market access for certain commodities. They are particularly important in situations where freedom of the whole territory of the OIE Member from the disease(s) or pathogen(s) is not possible or practicable.

There are *Code* recommendations for zones and compartments for diseases for which the concepts are appropriate; these concepts cannot be applied in all situations. The recommendations depend on the epidemiology of the disease, environmental factors, biosecurity measures and surveillance. Compartmentalisation may be applicable in situations where zoning cannot provide the required assurances, for example in intensive industries where production systems are vertically integrated.

If an exporting country wishes to define a free zone or compartment within its territory for a particular disease, its veterinary services or other competent authorities need to implement the recommendations in the *Codes* for setting up and maintaining such a zone or compartment. The exporting country needs to document the measures it has taken to identify the animal sub-population, and to define and maintain its distinct health status. An importing country should then recognise the existence of this zone or compartment, and apply the appropriate recommendations in the *Codes* with regard to the importation, or transit through its territory, of commodities from that zone or compartment. Where an importing country does not recognise the zone or compartment established by a trading partner, it should clearly document the reasons for this and provide recommendations as to steps the exporting country could take to facilitate recognition. The OIE provides guidance on how importing and exporting countries can work together to facilitate the process of recognition².

Disease surveillance

The ability of veterinary services or other competent authorities to substantiate their reports of the animal health situation in their territory by sound surveillance programmes is essential to safe trade in animals and animal products. A national surveillance system should address key epidemiological features of significant pathogens, including descriptions of host populations and environmental assessment.

The *Terrestrial Code* provides general principles and specific guidelines for surveillance systems for animal diseases aimed at determining the animal health status of a country, zone or compartment.

Chapter 1.4. of the *Terrestrial Code* (Animal health surveillance) provides general principles for declaring freedom from a disease/pathogen in relation to the date of most recent occurrence, and for recognising historical freedom.

Specific recommendations address the necessary mechanisms for recognising historical freedom from a disease, and the establishment or the regaining of recognition for a disease free country, zone or compartment and are included in each disease chapters. Diseases covered include currently foot and mouth disease, rinderpest, contagious bovine pleuropneumonia, scrapie, classical swine fever, avian influenza and bovine spongiform encephalopathy (BSE).

Chapter 1.4. of the *Aquatic Code* provides guidelines for aquatic animal health surveillance.

² The OIE has procedures for the official recognition of Member Countries' or zones' status for FMD, BSE, CBPP and rinderpest. The resulting list of free countries and zones is published by the OIE.

Collection and processing of semen and embryos

The purpose of official control of the animal health aspects of semen and *in vivo* derived embryos intended for international trade is to ensure that specific pathogens, which could be associated with semen or embryos, are controlled and the transmission of infection to recipient animals and their progeny is avoided.

Chapters 4.5. and 4.6. of the *Terrestrial Code* cover the collection, processing and storage of ruminant and pig semen. Chapters 4.7. to 4.10. provide recommendations for trade in embryos. Chapter 4.11. provides recommendations on animal health aspects of production animals derived from somatic cell nuclear transfer in production livestock and horses.

The International Embryo Transfer Society (IETS) regularly reviews research and field information on infectious diseases regarding the likelihood of their transmission via *in vivo* derived embryos. As a result of these reviews, the IETS has grouped pathogenic agents into four categories, based on the likelihood of transmission. These lists are taken fully into account in the disease specific chapters of the *Terrestrial Code*.

Animal production food safety

Chapter 6.1. of the *Terrestrial Code* provides guidance in regard to the role and responsibilities of the Veterinary Services in food safety and Chapter 6.2. of the *Terrestrial Code* provides guidelines for the control of biological hazards of animal health and public health importance through ante- and post-mortem meat inspection. Chapter 6.3. of the *Terrestrial Code* provides guidance on animal feeding in relation to animal health. The OIE is developing additional chapters on animal production food safety.

Animal traceability

Chapters 4.1. and 4.2. of the *Terrestrial Code* provide standards on the identification and traceability of live animals. Animal identification and animal traceability are important for effective management of disease outbreaks and food safety incidents, implementation of vaccination programmes, herd/flock husbandry, zoning and compartmentalisation, disease surveillance, early response and notification systems, animal movement controls, and inspection and certification procedures.

Antimicrobial resistance

Prudent use of antimicrobial agents is essential to safeguard this important therapeutic tool and to protect against risks associated with the development of antimicrobial resistance in animals and, possibly, in humans.

Chapters 6.7. to 6.11. of the *Terrestrial Code* contain standards for:

- the harmonisation of antimicrobial resistance surveillance and monitoring programmes;
- the monitoring of the quantities of antimicrobials used in animal husbandry; and
- the responsible and prudent use of antimicrobial agents in veterinary medicine.

These chapters also discuss risk analysis for antimicrobial resistance.

Animal welfare

Section 7 of the *Terrestrial Code* dedicated to animal welfare contains general principles relevant to animal welfare, and standards for the land and sea transport of animals, the slaughter of animals for human consumption and the killing of animals for disease control purposes.

Chapter 7.4. was developed in coordination with the International Air Transport Association (IATA) and specifies requirements for the international transport of domestic animals and wildlife by air.

Section 7 of the *Aquatic Code* provides introductory guidelines on the welfare of farmed fish and a Chapter on the welfare of farmed fish during transport.

Disease specific chapters

The health measures described in the Volume 2 of the *Terrestrial Code* and in Sections 8 to 11 of the *Aquatic Code* are designed to prevent the disease in question being introduced into an importing country, by taking into account the nature of the commodity and the animal health status of the exporting country. The measures are based on the latest scientific information, and diagnostic and vaccination techniques. When correctly applied, the measures provide optimal animal health safeguards for trade.

The recommendations on surveillance described for the most significant diseases enable the countries that apply them to be better informed of their animal health situation and to apply the necessary controls.

As stated above, these measures make reference only to the animal health situation in the exporting country, and it is assumed that the disease either is not present in the importing country or, if it is present, that it is the subject of an official control or eradication programme.

In general, each chapter in Volume 2 of the *Terrestrial Code* addresses a single disease and is structured as follows (Note: not all chapters contain all elements described below):

- a brief description of the disease (strains of the pathogen, infective period, standards for diagnostic tests and vaccines, and epidemiology relevant to the measures in the chapter);
- a list of commodities³ in regard to which no disease-specific measures are required, regardless of the status of the exporting country for the disease in question;
- information on the measures that should be applied to other commodities⁴;
- information on the factors that should be taken into account in assessing the risks presented by the exporting country for that disease;
- information on the requirements to be met by a country/zone/compartiment to achieve a specified disease status e.g. free country, free zone with vaccination, free flock;
- articles on methods that can be used to inactivate disease agents;
- articles on methods for disease surveillance;
- articles on the appropriate means to conduct a risk assessment.

When a particular commodity is not mentioned in a chapter, it means that the OIE has not yet developed relevant health measures. An OIE Member should base its import regulations for that commodity on a scientific risk assessment.

Chapter 11.6. of the *Terrestrial Code* on BSE is an example of a disease specific chapter that contains recommendations on all aspects identified above.

In the *Aquatic Code*, chapters in Sections 8 to 11 (Recommendations applicable to specific diseases) address individual diseases and contain:

³ Commonly traded commodities include live animals, semen/embryos/hatching eggs, fresh meat and meat products, milk and milk products, hides/skins/hair/feathers, and products for pharmaceutical or industrial purposes.

⁴ see footnote 3.

- a brief description of the disease, the susceptible host species, and standards for diagnostic tests and vaccines;
- lists of the requirements which should be met by a country, zone or compartment in order to achieve a certain disease status e.g. free country, free establishment, restoration of free status;
- articles containing the recommended health measures to be applied to commonly traded commodities, taking into account the likelihood of the pathogen being transmitted through that commodity and the disease status of the exporting country, zone or compartment.

Inactivation of pathogens and vectors

Chapter 4.13. of the *Terrestrial Code* contains some brief general recommendations on disinfection and disinsection. For easy reference, recommended procedures for the inactivation of the agents of foot and mouth disease (FMD), transmissible spongiform encephalopathy, avian influenza and classical swine fever (CSF) virus are included in the relevant disease specific chapters.

In Chapter 4.2., the *Aquatic Code* provides some general recommendations on disinfection and further information is available in Chapter 1.1.5. of the *Aquatic Manual*.

Diagnostic tests for international trade

In many of the *Code* chapters relating to specific diseases, the reader is referred to the relevant *Manual* for detailed information on the relevant diagnostic tests and vaccines. The table in Chapter 1.3. shows the diagnostic tests that can be used when the *Terrestrial Code* recommends a testing procedure.

The Terrestrial and Aquatic Manuals

The eleven introductory chapters in the *Terrestrial Manual* (Part 1) deal with a variety of general subjects of interest to veterinary laboratory diagnosticians:

- Collection and shipment of diagnostic specimens
- Biosafety and biosecurity in the veterinary microbiology laboratory and animal facilities
- Quality management in veterinary testing laboratories
- Principles of validation of diagnostic assays for infectious diseases
- Validation and quality control of polymerase chain reaction methods used for the diagnosis of infectious diseases
- Laboratory methodologies for bacterial antimicrobial susceptibility testing
- Biotechnology in the diagnosis of infectious diseases and vaccine development
- Principles of veterinary vaccine production
- Tests for sterility and freedom from contamination of biological materials
- Guidelines for international standards for vaccine banks, and
- The role of official bodies in the international regulation of veterinary biologicals.

These chapters are intended to give a brief introduction to their subjects, and should be regarded as background information and not as standards.

The main part of the *Terrestrial Manual* (Part 2) covers standards for diagnostic tests and vaccines for the diseases addressed in the *Terrestrial Code*. Some additional diseases, which may also be of importance to trade but which do not have a chapter in the *Terrestrial Code*, are included. Each disease chapter provides veterinary officials with an overview of the tests and vaccines available for the disease. This is followed by information intended for laboratory technicians, including details of diagnostic tests and, where appropriate, the requirements for vaccines or diagnostic biologicals.

The *Aquatic Manual* contains introductory chapters on quality management in veterinary diagnostic laboratories, the principles of validation of diagnostic assays for aquatic animal diseases and on disinfection methods

The tests in the *Manuals* should be performed according to the specifications to minimise confusion in the interpretation of results.

The OIE also publishes the OIE Quality and Guidelines for Veterinary Laboratories Conducting Tests for Infectious Diseases.

Using the *Terrestrial Manual*

In each disease chapter of the *Terrestrial Manual*, Part A gives a general introduction to the disease, Part B deals with laboratory diagnosis of the disease, and Part C (where appropriate) with the requirements for vaccines or *in-vivo* diagnostic biologicals. The information concerning production and control of vaccines or diagnostics is given as an example; it is not always necessary to follow these when there are scientifically justifiable reasons for using alternative approaches.

The *Terrestrial Manual* groups diagnostic tests into two categories: 'prescribed' and 'alternative'. 'Prescribed' tests (printed in blue) are those that are required by the *Terrestrial Code* for the testing of animals before they are moved internationally. The OIE has not yet developed prescribed tests for every disease. 'Alternative' tests do not provide the same level of confidence as prescribed tests. Nevertheless, the OIE Terrestrial Animal Health Standards Commission considers that an 'alternative' test, chosen by mutual agreement between importing and exporting countries, can provide valuable information for the diagnosis of diseases nationally or regionally, and for evaluating the risks of proposed trade in animals or animal products. When the *Terrestrial Manual* does not designate Prescribed or Alternative Tests, this is because there is no requirement in the *Terrestrial Code* for testing for that disease prior to international movements.

Although the OIE list of Prescribed and Alternative Tests gives only summary descriptions of the tests (e.g. "ELISA", or "PCR") it should not be assumed that all tests under that description are suitable for international movement. Only the method described in the *Terrestrial Manual* should be used, or else a method that has been fully validated to show equivalent performance to the designated Prescribed Test method. "Validation" in this context means compliance with the OIE validation template and the more detailed description in the validation chapter of the *Terrestrial Manual*.

Some other tests are described, which may be of some practical value in local situations or which may be under development.

OIE Reference Laboratories are recognised as centres of excellence in their specified fields. Their principal mandates include:

- to function as centres of expertise and standardisation for a designated disease(s) or topics;
- to store and distribute to national laboratories biological reference products (e.g. antisera, antigens) and any other reagents used in disease diagnosis and control;
- to develop new procedures for diagnosis and control of the designated disease(s) or topics;
- to gather, process, analyse and disseminate data relevant to their speciality;

- to place experts at the disposal of the OIE.

Currently, more than 175 Reference Laboratories, in 32 OIE Member Countries and Territories, cover more than 95 diseases and topics. The list of Reference Laboratories is updated by the World Assembly of Delegates each year and the current list is available on the OIE Web site ([list](#)).

Using the *Aquatic Manual*

For the diseases listed in the *Aquatic Code*, clinical signs in fish are not pathognomonic and subclinical infections may occur. Reliable diagnosis of fish diseases depends on the specific identification of pathogens by laboratory methods. These methods, which are suitable for the diagnosis of disease as part of national aquatic animal health surveillance/control programmes, form the main contents of the *Aquatic Manual*.

The diagnostic methods presented in the *Aquatic Manual* are all direct diagnostic methods. Due to the insufficient development of serological methodology, the detection of antibodies to pathogens in fish is not yet accepted as a routine method for assessing the health status of fish populations. Mollusc and crustacean diseases differ in some ways from fish diseases; for example, diagnostic methods must be direct because these animals do not produce antibodies to pathogens.

Implementing OIE standards

Determining import regulations

The WTO SPS Agreement allows WTO Members two options in setting health measures (in the form of import regulations) to protect against the animal and public health risks associated with the importation of animals and animal products. The SPS Agreement strongly encourages WTO Members to base their health regulations on OIE international standards such as the *Terrestrial Code* and the *Aquatic Code*. In the absence of relevant standards or when a Member chooses to adopt a higher level of protection than that provided by a standard, the use of scientific risk analysis is essential to determine whether importation of a particular commodity poses a significant risk to human or animal health and, if so, what health measures could be applied to reduce that risk to an acceptable level.

A risk analysis may still be necessary even if an importing country applies the health measures recommended in the *Codes*. While a full risk analysis may not be needed, establishing import regulations often requires at least a partial analysis of the risks to ensure a sound framework for linking the hazards identified for the specific commodity, the disease statuses of the exporting and importing countries, and the recommendations in the *Codes*.

With this in mind, the first step in the process of determining import regulations is to perform a hazard identification, identifying all the hazards (pathogens) that could be associated with the commodity and which are not known to be absent from the exporting country. The OIE is the main source of official information on the disease status of its Members. Up-to-date information can be obtained from the Web interface of the World Animal Health Information Database (WAHID) that is supplied by the World Animal Health Information System (WAHIS). Once this list of pathogens has been compiled, it has to be compared to the list of pathogens that are exotic to the importing country or are under official control programmes there. A final hazard list is thus determined.

Although the application of the measures contained in the *Codes* is the preferred option, the SPS Agreement recognises the right of Members to adopt more stringent measures, provided they are based on a scientific risk assessment. The import regulations determined as a result of the risk analysis process may be a combination of the health measures in the *Codes* and when relevant additional measures imposed by the importing country.

The OIE has developed a *Handbook on Import Risk Analysis for Animals and Animal Products*. This handbook outlines the international obligations with respect to the WTO SPS Agreement and provides a framework for the risk analysis process based on the standards described in the *Codes*. This is intended to ensure that stakeholders, risk analysts and decision-makers can be confident that the disease risks posed by imported animals and animal products are identified and managed effectively. Volume I of this handbook introduces

the concepts of import risk analysis and discusses qualitative risk analysis, while Volume II addresses quantitative risk analysis. More information is available at Import Risk Analysis Handbook.

In preparing an international animal health certificate importing countries should take into account the model international animal health certificates in Chapters 5.10. to 5.12. of the *Terrestrial Code* and Chapter 5.10. of the *Aquatic Code*. This provides a general framework, with the contents of each certificate being adapted to the commodity as required. Importing countries should follow the following procedures:

- compile a list of the diseases for which the country is justified in seeking protection, in view of the risks associated with the particular commodity and the measures for disease that are applied in the importing country's territory;
- list the health measures for each of these diseases, which can be determined by referring to the articles in the *Codes* relevant to the commodity; and
- when relevant, list additional health measures imposed by the importing country as a result of the risk analysis.

The OIE procedures for dispute mediation

The *Codes* summarise the responsibilities of importing and exporting countries and state that importing and exporting countries should comply with their obligations as members of the OIE and the WTO with a view to minimising unjustified trade restrictions and reducing conflicts between trading partners.

On request, an exporting country has an obligation to supply an importing country with information on its animal health situation and any changes in that situation. It should also provide information on the quality of its veterinary services and other competent authorities, the authority which they exercise, and the disease surveillance systems it has in place.

If an OIE Member believes that another Member is not meeting its obligations as a Member of the OIE (as described in the *Codes*) or is not adhering to the provisions of the WTO SPS Agreement, it may formally or informally lodge a complaint.

The *Codes* and *Manuals* may be used to challenge the scientific justification for the import regulations of trading partners.

The OIE offers a voluntary dispute mediation mechanism to OIE Members. This is a science-based approach to finding alternative solutions and resolving differences, as distinct from the law-based approach used in the formal WTO system. The role of the OIE is to assist the parties to arrive at a scientifically-sound conclusion, based on the application of the OIE standards

The mechanism is voluntary in that the agreement of both parties is needed in order for the OIE to initiate the process. As well, and distinct from the WTO process, the outcomes are not legally binding unless both parties agree to this in advance. Following agreement of both parties to the terms of reference and the scope of the dispute, the Director General of the OIE recommends experts, usually from the relevant OIE Reference Laboratories, to serve as mediators. Once approved by the disputing parties, the OIE expert(s) meet with both parties to conduct the mediation.

The experts are required to submit a confidential report on their conclusions and recommendations to the OIE Director General, who then transmits it to both parties. The cost of the mediation is covered by the disputing parties.

Use of the OIE good offices does not preclude either party from using mechanisms provided by the WTO to deal with disputes. While the outcomes of the OIE mechanism are non-binding and confidential, the views of the OIE and its experts could be called upon by the WTO in its consideration of a dispute between WTO Members and would substantially influence the outcome of WTO dispute settlement procedures.

Contacting the OIE

12 rue de Prony 75017 Paris, France

Tel: 33 (0)1 4415 1888

Fax: 33 (0)1 4267 0987

Email: oie@oie.int

<http://www.oie.int>