

PROCEDURES USED BY THE OIE TO SET STANDARDS AND RECOMMENDATIONS FOR INTERNATIONAL TRADE, WITH A FOCUS ON THE *TERRESTRIAL AND AQUATIC ANIMAL HEALTH CODES*

1. Introduction

This paper provides an overview of the procedures used by the OIE to set standards and recommendations for international trade, with a focus on the *Terrestrial* and *Aquatic Animal Health Codes* (the *Codes*). The texts in these publications are developed and revised using an established procedure. There is only one pathway for adoption of OIE standards, i.e. approval by the World Assembly of Delegates (World Assembly) meeting annually at the OIE General Session.

The World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures recognises the OIE standards as fundamental references for animal health and zoonotic diseases. Application and use of the standards by WTO Members is important to facilitate safe international trade in animals and their products.

The OIE procedures provide a basis for rapidity, responsiveness, scientific rigour and transparency in the setting of standards. Important features of the standard-setting procedures are outlined in this paper.

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2. OIE standards and recommendations for international trade

2.1. The OIE publications

The publications that are commonly referred to, collectively, as the OIE standards are:

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

2.2. International trade in animals and their products

The *Terrestrial Code* and the *Aquatic Code* contain science-based recommendations for disease reporting, prevention and control and for assuring safe international trade in terrestrial animals (mammals, birds and bees) and aquatic animals (amphibians, fish, crustaceans and molluscs) and their products. The *Codes* detail the sanitary measures for animal diseases, including zoonoses, which should be used by the Veterinary Services and other Competent Authorities of importing and exporting countries. Correctly applied, these measures prevent the introduction and spread, via animals and their products, of agents that are pathogenic for animals and/or humans.

2.3. Diagnostic tools and vaccines

The *Terrestrial Manual* and the *Aquatic Manual* contain OIE international standards on quality management in testing laboratories, principles of validation and quality control of diagnostic assays, and diagnostic testing methods for specific diseases including official tests listed in the *Terrestrial* and *Aquatic Codes*. The *Terrestrial Manual* also provides generic and specific guidance on vaccine quality. In addition to the *Manual*, the OIE publishes a list of approved Standard Sera (reagents) produced by OIE Reference Laboratories, validates and certifies commercially-available diagnostic assays, and publishes a list of the tests certified ‘fit for purpose’ in the OIE Register of Diagnostic Tests. Assessment of diagnostic tools for terrestrial animals is carried out under the auspices of the OIE Biological Standards Commission (Laboratories Commission). For aquatic animals, assessment of diagnostic tools is the responsibility of the Aquatic Animal Health Standards Commission (Aquatic Animals Commission).

2.4. Official disease status of OIE Member Countries

The OIE recognises the official disease status of Member Countries for foot and mouth disease, bovine spongiform encephalopathy and contagious bovine pleuropneumonia. The currently recognised official disease status for the specified diseases is published on the OIE website at: <http://www.oie.int/en/animal-health-in-the-world/official-disease-status/>.

3. The Procedures for the Elaboration of the OIE *Terrestrial and Aquatic Animal Health Codes*

3.1. General considerations

The procedures for developing and updating the *Terrestrial Code* and the *Aquatic Code* are responsive, transparent and rapid. Importantly, they provide a basis for continuous improvement to standards as new scientific information comes to light, and for 'fast track' adoption of new standards when Member Countries need to address important new risks to human and animal health on an urgent basis.

Each one of the 178 OIE Member Countries has an equal voice in the development and adoption of standards and each Member Country has a responsibility to engage with the OIE in this important work.

Specialist Commissions play a central role in the OIE standard setting procedures. They comprise six members (normally), elected by the World Assembly for a three year mandate, in compliance with the terms of reference established in the OIE Organic Texts, which provide for scientific excellence and geographic balance.

Recommendations on new standards and on significant revisions of existing standards are developed by small groups of independent experts (*ad hoc* Groups), which report to a Specialist Commission. Reporting may be direct to the Specialist Commission or, depending on the topic, via a permanent OIE Working Group, which in turn reports to Specialist Commissions. Membership of Working Groups is proposed by the Director General and is endorsed by the World Assembly. All draft texts are reviewed by the relevant Specialist Commission, then provided to OIE Member Countries for comment. All comments submitted by Member Countries are reviewed by the Specialist Commissions, who may deal with comments directly or may send them to the *ad hoc* Group and/or Working Group for consideration and advice, as appropriate. The reports of *ad hoc* Groups submitted to Specialist Commissions, as well as the Commission's review of Member Country comments are documented in the meeting report of the Specialist Commission, which is sent to Member Countries after each meeting and is also placed on the OIE website. In March of each year, as part of the meeting report of the Specialist Commissions that have met by February, all texts proposed for adoption at the General Session (held in May) are sent to Member Countries for consideration prior to presentation to the World Assembly in May for adoption. Twice yearly, following distribution of Specialist Commission reports, OIE Member Countries have the opportunity (normally during a 60 day period) to submit written comments. Although there is no provision for written comments to be presented to the General Session, there is opportunity to make oral statements and to request clarification of texts before adoption.

The normal cycle for the adoption of new texts in the *Codes* is two years, meaning that the development of a new text is the subject of consultation with OIE Member Countries on two to four occasions during that period. In the case of emergency situations warranting a more rapid procedure, standards may be developed within a shorter period. Less significant modifications to existing texts may also be undertaken in a one year period, if Member Countries agree to the proposed modifications.

There is only one pathway for the adoption of OIE standards, i.e. approval by the World Assembly, meeting annually at the OIE General Session. Revisions to the *Codes* are adopted via resolutions. In almost all cases, standards are adopted by consensus. In a small minority of cases, where it is not possible to achieve consensus, standards have been adopted after a vote. Voting is normally done by a show of hands and a two-thirds majority is sufficient for the adoption of a standard. More than half the Delegates representing Member Countries must be present in order to have a quorum for the adoption of standards.

Each OIE Member Country has an equal voice in the adoption of standards. Partner organisations may attend technical sessions of the General Session in an observer capacity but they do not have the right to participate in the adoption of standards. Discussion and decisions of the World Assembly on the adoption of standards are recorded in a report presented for adoption at the end of the General Session. This report is provided to Delegates and is placed on the OIE website accessible to the public.

Additional information on the OIE Organic Rules, General Rules, structure and organisation may be found on the OIE website at <http://www.oie.int/about-us/key-texts/basic-texts/>.

Detailed information on the work of the Specialist Commissions and Working Groups may be found on the OIE website at <http://www.oie.int/en/international-standard-setting/overview/>.

3.2. The work programme for setting standards

Requests for the development of a new standard or the revision of an existing standard come to the OIE from various sources. Proposals from OIE Delegates are given highest priority, particularly if several OIE Member Countries support the request. Proposals from international and regional organisations that have official agreements with the OIE are also given priority. Requests from other organisations, be they scientific, industry or non-governmental organisations (NGO), are also considered but generally as a lower priority. A Specialist Commission may propose new work to be undertaken by itself or by another Specialist Commission. Proposals for developing new or revised standards are identified in the work programmes of the Specialist Commissions and permanent working groups, which are submitted to OIE Delegates for information annually at the General Session.

The OIE Strategic Plan sets out the priorities, strategies and overall direction of the OIE's work programme, including for standard setting. It is developed under the direct supervision of the Director-General in consultation with the OIE Council (the Board) and submitted by him to the World Assembly for approval once every five years. The current OIE Strategic Plan (2011–2016) was adopted in May 2010.

The five Regional Commissions (Asia, Far East and Oceania; Americas; Europe; Africa and Middle-East) provide important input to the strategic planning process and to identifying priorities for standard setting. The Recommendations adopted by Regional Commissions, and those voted at OIE Global Conferences, often identify a need for the OIE to develop standards relevant to matters of strategic importance. These recommendations are presented to the World Assembly for endorsement at each General Session.

The work programmes of the Specialist Commissions are established within the overall framework of the OIE Strategic Plan. Proposals received by these Commissions are evaluated in terms of:

- i) the likely extent of Members' support, as evidenced from comments relevant to the request; and
- ii) the availability of scientific information needed to develop a standard.

In the case of the Terrestrial Animal Health Standards Commission (Code Commission), the opinions of the Scientific Commission on Animal Diseases (Scientific Commission) and the Laboratories Commission are critical in determining whether there is sufficient scientific information to support the development of a new or revised standard. In effect, the absence of key information, notably on disease aetiology or diagnostic methods, prevents the development of a new standard. The Code Commission and the Scientific Commission regularly hold a one-day joint meeting to discuss matters of common interest and harmonise work programmes on the development of standards. Communications between Specialist Commissions are documented in their meeting reports.

The reports of the Code and Aquatic Animals Commissions, along with their work programmes, are adopted annually by the World Assembly. In the period between General Sessions, opportunities are also provided for comment.

3.3. Role of OIE headquarters

OIE headquarters staff are responsible to ensure that the *Terrestrial* and *Aquatic Codes* are kept up to date on an ongoing basis. Non-significant revisions, including modifications to ensure consistency of chapters within the *Codes*, and harmonisation between the *Aquatic Code* and the *Terrestrial Code* are undertaken by the OIE International Trade Department in liaison with the responsible Commission. When a proposal is made to develop a new standard or to significantly revise an existing standard, the Director General of the OIE decides how the work will be managed, with reference to the terms of reference of the four OIE Specialist Commissions and the human resources at OIE headquarters.

The Director General of the OIE decides the terms of reference and membership of *ad hoc* Groups convened to prepare draft texts on specific topics. In taking this decision, he takes into account any opinions of relevant Specialist Commissions and the comments of OIE Members as appropriate. OIE Member Countries are informed of these matters at the annual General Session. *Ad hoc* Groups may address specific diseases or 'horizontal issues' (relating to diseases in general; or to cross cutting themes). When convening Working Groups (of which the membership is endorsed by the World Assembly) and *ad hoc* Groups, the Director General seeks experts with internationally recognised knowledge of the topic and to obtain the broadest regional representation. As a priority he draws upon the experts within the global network of more than 250 OIE Reference Centres worldwide.

The Director General may request that a 'supporting document' be drafted by an expert, usually an official from an OIE Reference Centre. Supporting documents contain the latest scientific information relevant to the topic, e.g. relating to infective period, host distribution, transmission mechanisms, diagnostic methods, treatment and control. They are a valuable resource for *ad hoc* Groups and Working Groups and key scientific references for OIE Member Countries.

The Director General forwards the reports of Working Groups and *ad hoc* Groups to relevant Specialist Commissions for further consideration.

Each *ad hoc* Group, Working Group and Specialist Commission receives logistic and secretariat support from staff at OIE headquarters. To facilitate consistency in the drafting of texts intended for adoption in the *Codes* and *Manuals*, Groups may consult a guidance document prepared by OIE headquarters. All experts and members of *ad hoc* Groups, Working Groups and Specialist Commissions must sign a declaration attesting to confidentiality and to the absence of conflict of interest.

According to the OIE Staff Regulations approved by the World Assembly, all headquarters staff are obliged to be impartial and to respect the confidentiality of information provided by Members.

3.4. Role of OIE Specialist Commissions

- The Terrestrial Animal Health Standards Commission is responsible for the *Terrestrial Animal Health Code*.
- The Aquatic Animal Health Standards Commission is responsible for the *Aquatic Animal Health Code* and the *Manual of Diagnostic Tests for Aquatic Animals*.
- The Scientific Commission for Animal Diseases is responsible for drafting texts for eventual inclusion in the *Terrestrial Animal Health Code* and for the recognition of Member Countries' official disease status.
- The Biological Standards Commission is responsible for the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* and for the approval of standard sera and the certification of diagnostic assays.

Specialist Commissions play a key role in the OIE standard setting procedures. Commissions normally have six members, who are elected by the World Assembly on the basis of excellence and geographical balance. Regional Commissions propose candidates and the World Assembly elects the members of Specialist Commissions for a three year term. The general functioning of Specialist Commissions is described in the Basic Texts of the OIE (<http://www.oie.int/about-us/key-texts/basic-texts/specialist-commissions/>) and is not, therefore, described in detail in this paper. However, some aspects that are relevant to standard setting are described below.

The Specialist Commissions meet twice each year. At their bi-annual meetings, the Specialist Commissions examine submissions made by OIE Member Countries and submissions from other sources, and the reports of relevant Working Groups and *ad hoc* Groups that have held meetings in the preceding semester. The Code Commission also considers submissions from the Scientific Commission on draft texts for possible inclusion in the *Terrestrial Code*. The two Commissions responsible for the *Codes* regularly consult on the harmonisation of horizontal aspects.

The Commissions determine how to incorporate scientific recommendations into the new or revised standard. While submissions from OIE Member Countries and OIE Reference Centres are of greatest importance, Commissions also consider scientific information from other sources, including OIE partner organisations and both private sector and non-governmental organisations, in order to ensure that the proposed standards are based on comprehensive and up-to-date scientific information.

Each Specialist Commission compiles a meeting report that includes, as annexed documents, the reports of all Working Groups and *ad hoc* Groups considered by the Commission. The meeting report also explains how the various submissions were addressed. OIE Member Countries and others submitting comments are encouraged to provide a scientific rationale for their comments, to facilitate analysis by Specialist Commissions.

On a twice yearly basis, OIE Member Countries are invited to comment on the recommendations in the reports of Specialist Commissions. Organisations with which the OIE has formal agreements may also be invited to provide advice, depending on the relevant areas of expertise.

Thus, the 'two-year standard setting cycle' may afford as many as four opportunities for comment. All Commission reports, in English, French and Spanish, are placed on the OIE website:

(see <http://www.oie.int/international-standard-setting/specialists-commissions-groups/>).

In reviewing draft new or revised standards in the *Terrestrial* and *Aquatic Codes*, the relevant Commissions consider the extent to which OIE Member Countries support the recommendations and the rationale provided, particularly in the case of criticisms of a draft text. If, after at least two rounds of comment, there is widespread support for the proposed new or revised standard, the relevant Commissions may decide to submit the chapter for adoption at the following OIE General Session. If, however, significant concern is expressed or if Member Country comments suggest a need for further technical work, the relevant Commissions may re-examine the issue. If scientific or technical questions outside its expertise are raised, the Commissions will normally ask the Working Group or the relevant *ad hoc* Group to re-examine the issues and provide advice to the relevant Commissions. Another round of consultation with OIE Member Countries will then be undertaken.

In reviewing draft new or revised standards in the *Terrestrial* and *Aquatic Manuals*, the Laboratories Commission and the Aquatic Animals Commission rely on the preparatory work done by one or more OIE Experts or an *ad hoc* Group. When Commissions consider that after one round of comments a draft standard is ready for adoption, they submit the draft standard to the World Assembly. Thus, OIE Member Countries have the opportunity to comment on at least two occasions before final adoption. As of September 2011, the structure and organisation of the OIE *Manuals* was under review.

3.5. Role of OIE Working Groups

The OIE currently has three 'permanent' Working Groups, which are responsible for the general management and oversight of the OIE work programme in three thematic areas:

The Animal Welfare Working Group reports to the Code or Aquatic Animals Commissions, as relevant to the topic.

The Animal Production Food Safety Working Group reports to the Code or Aquatic Animals Commissions, as relevant to the topic.

The Working Group on Wildlife Diseases reports to the Scientific Commission.

OIE Working Groups play an important role in setting standards in the three thematic areas. The work programme of each Working Group is presented to the relevant Specialist Commission and, via the report of the Commissions, to the World Assembly for information and comment annually.

To assist in addressing new themes and significant developments, Working Groups may take responsibility for drafting discussion papers and strategy papers to establish key principles and directions for the OIE to follow in standard setting. In all cases, these papers, along with the recommendations of Specialist Commissions, are provided to OIE Member Countries for information and comment. Once endorsed, Working Group papers can provide a framework and key principles for OIE standard setting.

Members of Specialist Commissions may participate in Working Groups as observers to facilitate communication between these Working Groups and the relevant Commission. However, a member of a Specialist Commission may not chair a Working Group.

In addition to being circulated with the reports of Specialist Commissions, Working Group reports, after approval by the relevant Commission, are put on dedicated pages on the OIE website along with other information relevant to the theme (e.g. <http://www.oie.int/animal-welfare/animal-welfare-key-themes/>). The terms of reference and membership of OIE Working Groups are included on these thematic website pages. The members of the Working Groups are nominated by the Director General of the OIE and endorsed by the World Assembly annually at the General Session. In addition to representation from the five OIE regions, relevant public and private sector partners of the OIE may participate in Working Groups.

3.6. Role of OIE *ad hoc* Groups

As described above, the initial drafting of a new standard and any significant revision of an existing standard is normally undertaken by a group of experts specifically convened to an *ad hoc* Group tasked with the work in question. OIE *ad hoc* Groups normally comprise up to six scientists with internationally recognised expertise in a disease or topic. OIE Reference Centres (comprising Reference Laboratories and Collaborating Centres) are a common source of experts but participants are also drawn from academia, industry organisations, NGOs and OIE partner organisations. OIE Member Countries and organisations having an official agreement with the OIE also submit lists of experts for various topics, which are held on file at OIE headquarters.

OIE *ad hoc* Groups may meet once or several times. A few *ad hoc* Groups, especially those tasked with the evaluation of disease status, meet regularly, once or twice a year, depending on the number of applications received from OIE Member Countries. The composition and terms of reference may change from one meeting to another if needed. In addition to preparing a first draft text for consideration by the relevant Specialist Commission, they may be re-convened to advise Specialist Commissions on submissions and on draft texts submitted by Member Countries.

The members of *ad hoc* Groups are nominated on the basis of excellence and geographical balance by the Director General, who takes into account any recommendations that OIE Member Countries may have provided, in addition to ensuring that participants are drawn from all five OIE regions, to the extent that this is practicable. Members of Specialist Commissions and Working Groups may participate as observers in *ad hoc* Groups to facilitate communication between these Groups and the relevant Commission. However, a member of a Specialist Commission may not chair an *ad hoc* Group.

The terms of reference of *ad hoc* Groups are decided by the Director General, taking into account the requests of Members, the opinion and advice of relevant Specialist Commissions and, as appropriate, Working Groups.

Reports of *ad hoc* Groups, including draft standards, reflect a consensual position of all members of the Group. Where scientific uncertainty leads to differences of opinion on the appropriate means to manage risk, options to address uncertainties are fully documented in the Group's report.

The membership and terms of reference of *ad hoc* Groups are included in their reports, which are provided to OIE Member Countries with the report of the Specialist Commissions to which the Groups report, through the Director General.

3.7. Role of OIE Experts and OIE Reference Centres

The OIE calls upon the expertise of renowned scientists in the development and significant revision of standards. The major source of OIE experts is the OIE-designated Reference Centres, comprising Reference Laboratories and Collaborating Centres, which number more than 250 institutes globally. Each OIE Reference Laboratory has an OIE-designated Expert whose competence on a specific pathogen/disease is recognised internationally. Collaborating Centres of the OIE offer experts in specific fields. The OIE also calls on institutes other than OIE Reference Centres as necessary.

The experts serving as members of the OIE Specialist Commissions, Working Groups and *ad hoc* Groups act in their personal capacity as independent scientists, not as representatives of a country or an organisation, to serve the overall interest of the OIE and its Member Countries. Upon appointment, they are required to sign a Confidentiality Undertaking and submit a declaration of interest, in accordance with the relevant rules of the OIE, to ensure proper management of transparency and potential conflict of interest and to assure the impartiality, objectivity and scientific integrity of the OIE's work. The same requirements apply to all experts, regardless of the specific mission or task. The rules governing confidentiality and conflict of interest are set out by the Director General in conformity with the provisions in the Basic Texts and as agreed with the OIE Council (the elected Board of the OIE).

The experts from OIE Reference Centres are requested to respect confidentiality of information and refrain from engaging in any work that might compromise or generate conflict with the mandate of OIE Reference Centre, including in relation to standard setting.

Recognising the need to improve the geographic distribution of Reference Centres in the world, the OIE is implementing a laboratory twinning programme, with the specific objective of strengthening the capacity of developing countries to contribute to the OIE standard setting process.

3.8. Role of OIE Member Countries and Delegates

Participation in the process of development and adoption of OIE standards is a responsibility of each OIE Member Country, as defined in the OIE Organic Rules. This activity is coordinated through the national Delegate, who is, in most cases, the Head of the national Veterinary Services. The OIE encourages national Delegates to nominate, under their authority, focal points on seven topics (disease notification; animal welfare; animal production food safety; veterinary products; wildlife; aquatic animals; and communications) to help the Delegate to meet his/her responsibilities, particularly in relation to standard setting. The OIE undertakes capacity building to support Delegates and nominated focal points, including by the regular conduct of seminars on the OIE and its standard setting procedures.

Experts, industry groups and organisations wishing to participate in the process of standards development may send submissions direct to the OIE but they are strongly encouraged to provide their input through a relevant national Delegate.

OIE Delegates are informed of new or revised draft standards and are consulted at different steps of development, as mentioned above. Their comments are the key inputs to future OIE standards. They elect members of Specialist Commissions (as well as members of the Council and members of Regional Commissions) and they endorse, on an annual basis, the membership of OIE permanent Working Groups.

The Member Countries also contribute to OIE standard setting through financial and other support of OIE Reference Centres located in their territory, most of which are government institutes.

4. Conclusions

As outlined above, the OIE procedures provide a basis for rapidity, responsiveness, scientific rigour and transparency in the development of standards. Key aspects relating to transparency are as follows:

- Standards are drafted by independent experts drawn from different OIE regions and selected on the basis of scientific excellence and geographical balance. Mechanisms are in place to ensure the neutrality and scientific integrity of experts appointed to work with the OIE.
 - All reports of *ad hoc* Groups are reviewed by Specialist Commissions, comprising elected members, and, as appropriate, by Working Groups. These reviews particularly consider the risk management options proposed.
 - Reports of Specialist Commissions, Working Groups and *ad hoc* Groups are made available to Members and the public via publication on the OIE website.
 - OIE Member Countries have scheduled opportunities to comment on draft standards.
 - Member Country comments are reviewed by the Specialist Commissions, which advise Delegates of their analysis and decisions on these comments by report on the OIE website.
 - All standards are adopted by the World Assembly, usually by consensus or, in rare cases, by a two thirds majority vote.
 - Each one of the 178 OIE Member Countries has an equal voice in the development and adoption of standards and each has a responsibility to engage with the OIE in this important work.
-