

CHAPTER 5.3.

OIE PROCEDURES RELEVANT TO THE AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES OF THE WORLD TRADE ORGANIZATION

Article 5.3.1.

The Agreement on the Application of Sanitary and Phytosanitary Measures and role and responsibility of the OIE

The *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement) specifically encourages the Members of the World Trade Organization (WTO) to base their *sanitary measures* on international standards, guidelines and recommendations, where they exist. Members may choose to implement *sanitary measures* more stringent than those in international standards, if these are deemed necessary to protect *aquatic animal* or human health and are scientifically justified by a *risk analysis*. In such circumstances, Members should adopt a consistent approach to *risk management*.

To promote transparency, the SPS Agreement, in Article 7, obliges WTO Members to notify changes in, and provide relevant information on, *sanitary measures* that may, directly or indirectly, affect *international trade*.

The SPS Agreement recognises the OIE as the relevant international organisation responsible for the development and promotion of international animal health standards, guidelines, and recommendations affecting trade in *aquatic animals* and *aquatic animal products*.

Article 5.3.2.

Introduction to the determination of the equivalence of sanitary measures

The importation of *aquatic animals* and *aquatic animal products* involves a degree of *risk* to *aquatic animal* and human health in an *importing country*. The estimation of that *risk* and the choice of the appropriate *risk management* options are made difficult by differences among the *aquatic animal* health management systems and *aquatic animal* production and processing systems in Member Countries. However, significantly different systems and measures may achieve equivalent *aquatic animal* and human health protection for the purposes of *international trade*.

The recommendations in this chapter are intended to assist Member Countries to determine whether *sanitary measures* arising from different systems achieve the same level of *aquatic animal* and human health protection. Principles are provided that may be utilised in a determination of equivalence, and outline a step-wise process for trading partners to follow. These provisions are applicable whether equivalence applies to specific measures, specific *commodities* or on a systems-wide basis

Article 5.3.3.

General considerations on the determination of the equivalence of sanitary measures

Before trade in *aquatic animals* or their *products* occurs, an *importing country* should be assured that *aquatic animal* and human health in its *territory* will be appropriately protected. In most cases, the *risk management* measures adopted will rely in part on judgements made about the *aquatic animal* health management and *aquatic animal* production systems in the *exporting country* and the effectiveness of *sanitary measures* applied there. Systems operating in the *exporting country* may differ from those in the *importing country* and from those in other countries with which the *importing country* has traded. Differences may be in infrastructure, policies or operating procedures, laboratory systems, approaches to control of *diseases*, border security and internal movement controls.

If trading partners agree that the measures applied achieve the same level of health protection, these measures are considered equivalent. Benefits of applying equivalence may include:

- 1) minimising costs associated with *international trade* by allowing *sanitary measures* to be tailored to local circumstances;
- 2) maximising *aquatic animal* health outcomes for a given level of resource input;
- 3) facilitating trade by achieving the required health protection through less trade restrictive *sanitary measures*; and
- 4) decreased reliance on relatively costly testing.

The *Aquatic Code* recognises equivalence by recommending alternative *sanitary measures* for many *diseases*. Equivalence may be achieved, for example, by enhanced *surveillance* and monitoring, by the use of alternative test, treatment or isolation procedures, or by combinations of the above. To facilitate the determination of equivalence, Member Countries should base their *sanitary measures* on the OIE standards and guidelines.

Member Countries should use *risk analysis* to establish the basis for a determination of equivalence.

Article 5.3.4.

Prerequisite considerations for the determination of equivalence

1. Application of risk assessment

Risk assessment provides a structured basis for judging equivalence among different *sanitary measures* as it allows a comparison of the effect of a measure on a particular step in the importation pathway with the effect of a proposed alternative measure.

A determination of equivalence should compare the effectiveness of the *sanitary measures* against the particular *risk* or group of *risks* against which they are designed to protect.

2. Categorisation of sanitary measures

Proposals for equivalence may consider a single component (e.g. an isolation or sampling procedure, a test or treatment requirement, a certification procedure) or multiple components (e.g. a production system for a *commodity*) of a *sanitary measure*, or a combination of *sanitary measures*. *Sanitary measures* may be applied consecutively or concurrently.

Sanitary measures are described in each disease-specific chapter of the *Aquatic Code* to manage the *risk* posed by that *disease*.

For the purposes of determining equivalence, *sanitary measures* can be broadly categorised as:

- a) infrastructure including the legislative base (e.g. *aquatic animal* health law) and administrative systems (e.g. organisation of Veterinary Services or *Aquatic Animal Health Services*);
- b) programme design and implementation including documentation of systems, performance and decision criteria, laboratory capability, and provisions for certification, audit and enforcement;
- c) specific technical requirement including requirements applicable to the use of secure facilities, treatment (e.g. retorting of cans), specific test (e.g. ELISA) and procedures (e.g. pre-export inspection).

Sanitary measures proposed for a determination of equivalence may fall into one or more of these categories, which are not mutually exclusive.

In some cases, such as a method for inactivation of *pathogenic agents*, a comparison of specific technical requirements may suffice. In many instances, however, assessment of whether the same level of protection will be achieved may only be determined through an evaluation of all relevant components of an *exporting country's aquatic animal* health management systems and *aquatic animal* production systems.

Article 5.3.5.

Principles for determination of equivalence

Determination of the equivalence of *sanitary measures* should be based on application of the following principles:

- 1) an *importing country* has the right to set the level of protection it deems appropriate in relation to human and animal life and health in its *territory*; this may be expressed in qualitative or quantitative terms;

- 2) the *importing country* should be able to describe the reason for each *sanitary measure* i.e. the level of protection intended to be achieved by application of the identified measure against a *risk*;
- 3) an *importing country* should recognise that *sanitary measures* different from the ones it has proposed may be capable of achieving the same level of protection; in particular, it should consider the existence of *free zones* or *free compartments*, and of safe *aquatic animal products*;
- 4) the *importing country* should, upon request, consult with the *exporting country* with the aim of facilitating a determination of equivalence;
- 5) any *sanitary measure* or combination of *sanitary measures* can be proposed for determination of equivalence;
- 6) an interactive process should be followed that applies a defined sequence of steps, and utilises an agreed process for exchange of information, so as to limit data collection to that which is necessary, to minimise administrative burden, and to facilitate resolution of claims;
- 7) the *exporting country* should be able to demonstrate objectively how the alternative *sanitary measures* proposed as equivalent will provide the same level of protection;
- 8) the *exporting country* should present a submission for equivalence in a form that facilitates determination by the *importing country*;
- 9) the *importing country* should evaluate submissions for equivalence in a timely, consistent, transparent and objective manner, and in accordance with appropriate *risk assessment* principles;
- 10) the *importing country* should take into account any knowledge of and prior experience with the *Veterinary Authority* or other *Competent Authority* of the *exporting country*;
- 11) the *importing country* should take into account any arrangements it has with other *exporting countries* on similar issues;
- 12) the *importing country* may also take into account any knowledge of the *exporting country's* arrangements with other *importing countries*;
- 13) the *exporting country* should, upon request, provide the *importing country* access to information on the procedures or systems that are the subject of the equivalence determination;
- 14) the *importing country* should be the sole judge of equivalence, but should provide to the *exporting country* a full explanation for its judgement;
- 15) to facilitate a determination of equivalence, Member Countries should base their *sanitary measures* on relevant OIE standards and guidelines, where these exist. However, they may choose to implement more stringent *sanitary measures* if these are scientifically justified by a *risk analysis*;
- 16) to allow the determination of equivalence to be reassessed if necessary, the *importing country* and the *exporting country* should keep each other informed of significant changes to infrastructure, health status or programmes that may bear on the determination of equivalence; and
- 17) appropriate technical assistance from an *importing country*, following a request by an *exporting country*, may facilitate the successful completion of a determination of equivalence.

Article 5.3.6.

Sequence of steps to be taken in determination of equivalence

There is no single sequence of steps that should be followed in all determinations of equivalence. The steps that trading partners choose will generally depend on the circumstances and their trading experience. Nevertheless, the interactive sequence of steps described below may be useful for assessing any *sanitary measures* irrespective of their categorisation as infrastructure, programme design and implementation or specific technical requirement components of an *aquatic animal* health management system or *aquatic animal* production system.

This sequence assumes that the *importing country* is meeting its obligations under the WTO SPS Agreement and has in place a transparent measure based either on an international standard or a *risk analysis*.

Recommended steps are:

- 1) the *exporting country* identifies the measure for which it wishes to propose an alternative and requests from the *importing country* a reason for its *sanitary measure* in terms of the level of protection intended to be achieved against a *risk*;
- 2) the *importing country* explains the reason for the measure in terms that would facilitate comparison with an alternative *sanitary measure* and consistent with the principles set out in these provisions;
- 3) the *exporting country* demonstrates the case for equivalence of an alternative *sanitary measure* in a form that facilitates evaluation by an *importing country*;

- 4) the *exporting country* responds to any technical concerns raised by the *importing country* by providing relevant further information;
- 5) determination of equivalence by the *importing country* should take into account as appropriate:
 - a) the impact of biological variability and uncertainty;
 - b) the expected effect of the alternative *sanitary measure*;
 - c) OIE standards and guidelines;
 - d) the results of a *risk assessment*;
- 6) the *importing country* notifies the *exporting country* of its judgement and its reasons within a reasonable period of time. The judgement:
 - a) recognises the equivalence of the *exporting country's* alternative *sanitary measure*; or
 - b) requests further information; or
 - c) rejects the case for equivalence of the alternative *sanitary measure*;
- 7) an attempt should be made to resolve any differences of opinion over judgement of a case by using an agreed mechanism such as the OIE informal procedure for dispute mediation (Article 5.3.8.);
- 8) depending on the category of measures involved, the *importing country* and the *exporting country* may informally acknowledge the equivalence or enter into a formal agreement of equivalence giving effect to the judgement.

An *importing country* recognising the equivalence of an *exporting country's* alternative *sanitary measure* should ensure that it acts consistently with regard to applications from third countries for recognition of equivalence applying to the same or a very similar measure. Consistent action does not mean however that a specific measure proposed by several *exporting countries* should always be judged as equivalent because a measure should not be considered in isolation but as part of a system of infrastructure, policies and procedures, in the context of the *aquatic animal* health situation in the *exporting country*.

Article 5.3.7.

Sequence of steps to be taken in establishing a zone or compartment and having it recognised for international trade purposes

The terms 'zone' and 'zoning' in the *Aquatic Code* have the same meaning as 'region', 'area' and 'regionalisation' in the SPS Agreement of the WTO.

The requirements for establishing a *zone* or a *compartment* declared free of a *disease* are described in Chapter 4.1. and in each disease-specific and should be considered by trading partners when establishing *sanitary measures* for trade. The requirements include:

1. For zoning

- a) The *exporting country* identifies a geographical area within its *territory*, which, based on *surveillance*, it considers to contain an *aquatic animal subpopulation* with a distinct health status with respect to a specific *disease*.
- b) The *exporting country* describes in the *biosecurity plan* for the *zone* the measures applied to distinguish such an area epidemiologically from other parts of its *territory*, in accordance with the recommendations in the *Aquatic Code*.
- c) Upon request, the *exporting country* provides to the *importing country*:
 - i) an explanation of why the area, as described in points a) and b) above, can be treated as an epidemiologically separate *zone* for *international trade* purposes;
 - ii) access to information on the procedures or systems that establish the *zone*.
- d) The *importing country* determines whether it accepts such an area as a *zone* for the importation of *aquatic animals* or *aquatic animal products*, taking into account:
 - i) an evaluation of the *exporting country's* Veterinary Services or *Aquatic Animal Health Services*;
 - ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;
 - iii) its own *aquatic animal* health situation with respect to the *disease* concerned; and
 - iv) other relevant OIE standards or guidelines.
- e) The *importing country* notifies the *exporting country* of its judgement and its reasons, within a reasonable period of time, being:
 - i) recognition of the *zone*; or
 - ii) request for further information; or
 - iii) rejection of the area as a *zone* for *international trade* purposes.
- f) An attempt should be made to resolve any differences over recognition of the *zone*, either in the interim or finally, by using an agreed mechanism such as the OIE informal procedure for dispute mediation (Article 5.3.8.).
- g) The *Veterinary Authorities* or other *Competent Authorities* of the *importing* and *exporting countries* should enter into an agreement recognising the *zone*.

2. For compartmentalisation

- a) Based on discussions with the relevant industry, the *exporting country* identifies within its *territory* a *compartment* comprising an *aquatic animal subpopulation* contained in one or more establishments, and other premises operating under common management practices and *biosecurity plan*. The *compartment* contains an identifiable *aquatic animal subpopulation* with a distinct health status with respect to a specific *disease*. The *exporting country* describes how this status is maintained through a partnership between the relevant industry and the *Veterinary Authority* or other *Competent Authority* of the *exporting country*.
- b) The *exporting country* examines the *compartment's biosecurity plan* and confirms through an audit that:
 - i) the *compartment* is epidemiologically closed throughout its routine operating procedures as a result of effective implementation of its *biosecurity plan*; and
 - ii) the *surveillance* and monitoring programme in place is appropriate to verify the status of such a *subpopulation* with respect to the *disease* in question
- c) The *exporting country* describes the *compartment*, in accordance with Chapters 4.1. and 4.2.
- d) Upon request, the *exporting country* provides to the *importing country*:
 - i) an explanation of why such a *subpopulation*, as described in points a) and b) above, can be treated as an epidemiologically separate *compartment* for *international trade* purposes; and
 - ii) access to information on the procedures or systems that establish the *compartment*.
- e) The *importing country* determines whether it accepts such a *subpopulation* as a *compartment* for the importation of *aquatic animals* or *aquatic animal products*, taking into account:
 - i) an evaluation of the *exporting country's* Veterinary Services or *Aquatic Animal Health Services*;
 - ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research
 - iii) its own *aquatic animal* health situation with respect to the *disease(s)* concerned; and
 - iv) other relevant OIE standards or guidelines.

- f) The *importing country* notifies the *exporting country* of its judgement and its reasons, within a reasonable period of time, being:
 - i) recognition of the *compartment*; or
 - ii) request for further information; or
 - iii) rejection of such a *subpopulation* as a *compartment* for *international trade* purposes
- g) An attempt should be made to resolve any differences over recognition of the *compartment*, either in the interim or finally, by using an agreed mechanism such as the OIE informal procedure for dispute mediation (Article 5.3.8.)
- h) The *Veterinary Authorities* or other *Competent Authorities* of the *importing* and *exporting countries* should enter into an agreement recognising the *compartment*.

Article 5.3.8.

The OIE informal procedure for dispute mediation

The OIE maintains a voluntary in-house mechanism for assisting Member Countries to resolve differences. In-house procedures that will apply are that:

- 1) Both parties agree to give the OIE a mandate to assist them in resolving their differences.
- 2) If considered appropriate, the Director General of the OIE recommends an expert, or experts, and a chairman, as requested, agreed by both parties.
- 3) Both parties agree on the terms of reference and working programme, and to meet all expenses incurred by the OIE.
- 4) The expert or experts are entitled to seek clarification of any of the information and data provided by either country in the assessment or consultation processes, or to request additional information or data from either country.
- 5) The expert or experts submit a confidential report to the Director General of the OIE, who then transmits it to both parties.

NB: FIRST ADOPTED IN 2013; MOST RECENT UPDATE ADOPTED IN 2018.