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 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 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 live animals and animal products.

Article 5.3.2.

Introduction to the determination of the equivalence of sanitary measures

The importation of animals and animal products involves a degree of risk to 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 animal health management systems and animal production and processing systems in Member Countries. However, significantly different systems and measures may achieve equivalent animal and human health protection for the purpose 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 animal and human health protection. They discuss principles 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 or on a systems-wide basis, and whether equivalence applies to specific areas of trade or commodities, or in general.

Article 5.3.3.

General considerations on the determination of the equivalence of sanitary measures

Before trade in animals or their products occurs, an importing country should be assured that 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 animal health management and 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, infections and infestations present, border security and internal movement controls.
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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 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 commodity testing and isolation procedures.

The Terrestrial Code recognises equivalence by recommending alternative sanitary measures for many diseases, infections and infestations. 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 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 measure, or a combination of measures. Measures may be applied consecutively or concurrently.

Sanitary measures are described in the disease-specific chapter of the Terrestrial Code to manage risks posed by that disease, infection or infestation.

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

a) infrastructure: including the legislative base (e.g. animal health law) and administrative systems (e.g. organisation of Veterinary 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 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 animal health management systems and 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 commodities;
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 provide access to enable the procedures or systems that are the subject of the equivalence determination to be examined and evaluated upon request of the importing country;

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 animal health management system or 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 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 Terrestrial Code have the same meaning as ‘region’, ‘area’ and ‘regionalisation’ in the SPS Agreement of the WTO.

The establishment of a disease-free zone or compartment is described in Chapter 4.4. and should be considered by trading partners when establishing sanitary measures for trade. Recommended steps are:
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1. For zoning
   a) The exporting country identifies a geographical area within its territory, which, based on surveillance, it considers to contain an animal subpopulation with a distinct health status with respect to a specific disease, infection or infestation.
   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 Terrestrial Code.
   c) The exporting country provides:
      i) the above information to the importing country, with an explanation of why the area can be treated as an epidemiologically separate zone for international trade purposes;
      ii) access to enable the procedures or systems that establish the zone to be examined and evaluated upon request by the importing country.
   d) The importing country determines whether it accepts such an area as a zone for the importation of animals or animal products, taking into account:
      i) an evaluation of the exporting country's Veterinary Services;
      ii) the result of a risk assessment based on the information provided by the exporting country and its own research;
      iii) its own 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 by using an agreed mechanism such as the OIE informal procedure for dispute mediation (Article 5.3.8.).
   g) The Veterinary Authorities of the importing and exporting countries should enter into an agreement recognizing the zone.

2. For compartmentalisation
   a) Based on discussions with the relevant industry, the exporting country identifies within its territory a compartment comprising an animal subpopulation contained in one or more establishments, and other premises operating under common management practices and a biosecurity plan. The compartment contains an identifiable 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 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 4.4. and 4.5.
   d) The exporting country provides:
      i) the above information to the importing country, with an explanation of why such a subpopulation can be treated as an epidemiologically separate compartment for international trade purposes; and
      ii) access to enable the procedures or systems that establish the compartment to be examined and evaluated upon request by the importing country.
   e) The importing country determines whether it accepts such a subpopulation as a compartment for the importation of animals or animal products, taking into account:
      i) an evaluation of the exporting country's Veterinary Services;
      ii) the result of a risk assessment based on the information provided by the exporting country and its own research;
      iii) its own animal health situation with respect to the disease 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 by using an agreed mechanism such as the OIE informal procedure for dispute mediation (Article 5.3.8.).

h) The Veterinary Authorities of the importing and exporting countries should enter into an agreement recognizing the compartment.

Article 5.3.8.

The OIE informal procedure for dispute mediation

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 2003; MOST RECENT UPDATE ADOPTED IN 2017.