

Terrestrial Animal Health Standards Commission February 2016

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 ~~adopt a higher level of protection than that provided by those in~~ international standards, texts if these are deemed necessary to protect animal or human health and are scientifically justified by a risk analysis ~~there is a scientific justification~~ or if the level of protection provided by the relevant international texts is considered to be inappropriate. In such circumstances, Members are subject to obligations relating to risk assessment and to should adopt a consistent approach of to *risk management*.

The SPS Agreement encourages Governments to make a wider use of risk analysis: WTO Members shall undertake an assessment as appropriate to the circumstances of the actual risk involved.

In order to promote transparency, ~~The the~~ SPS Agreement, in Article 7, obliges WTO Members to notify changes in, and provide relevant information on, *sanitary measures* which 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 on to the judgement determination of the equivalence of sanitary measures

The importation of *animals* and animal products involves a degree of *risk* to the animal health status and human health status of in an *importing country*. The estimation of that *risk* and the choice of the appropriate *risk management* option(s) are made more difficult by differences among the animal health management systems and animal production systems in Member Countries. However, it is now recognised that significantly different animal health and production systems and measures can provide may achieve equivalent animal and human health protection for the purposes of *international trade*, with benefits to both the *importing country* and the *exporting country*.

These The recommendations in this chapter are intended to assist Member Countries to determine whether *sanitary measures* arising from different animal health and production systems may provide achieve the same level of animal and human health protection. They discuss principles which might that may be utilised in a judgement determination of equivalence, and outline a step-wise process for trading partners to follow in determining ~~facilitating a judgement of equivalence~~. These provisions are applicable whether equivalence applies at the level of to specific measures or on a systems-wide basis, and whether equivalence applies to specific areas of trade or *commodities*, or in generally general.

Article 5.3.3.

General considerations on the judgement determination of the equivalence of sanitary measures

Before trade in *animals* or their products may occur, an *importing country* must be satisfied assured that its *animal health status* and *human health* will be appropriately protected. In most cases, the *risk management* measures adopted drawn-up will rely in part on judgements made about the *animal health management* and *animal* production system(s) in the *exporting country* and the effectiveness of *sanitary measures* procedures applied undertaken 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 with respect to in infrastructure, policies and/or operating procedures, *laboratory* systems, approaches to control of the pests and diseases present, border security and internal movement controls.

International recognition of the legitimacy of different approaches to achieving the importing country's appropriate level of protection (ALOP) has led to the principle of equivalence being included in trade agreements, including the SPS Agreement of the WTO.

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 tailoring allowing sanitary measures to be tailored animal health measures 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 in bilateral or multilateral agreements.

The *Terrestrial Code* recognises equivalence by recommending alternative *sanitary measures* for many *diseases, infections* and *infestations* pathogenic agents. Equivalence may be gained 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 judgement determination of equivalence, Member Countries should base their *sanitary measures* on the OIE standards, and guidelines and recommendations of the OIE.

It is essential to apply a scientific Member Countries should use risk analysis to the extent practicable in establishing the basis for a judgement determination of equivalence.

Article
5.3.4.**Prerequisite considerations in a judgement for the determination of equivalence**1) Application of risk assessment

Application of the discipline of *risk Risk* assessment provides a structured basis for judging equivalence among different *sanitary measures* as it allows a comparison close examination to be made of the effect of a measure(s) on a particular step(s) in the importation pathway, and the relative with the effects of a proposed alternative measure(s) on the same or related steps.

A judgement determination of equivalence should needs to assess compare the effectiveness of the *sanitary measures* in terms of its effectiveness against regarding the particular *risk* or group of *risks* against which it the measure is they are designed to protect. Such an assessment may include the following elements: the purpose of the measure, the level of protection achieved by the measure and the contribution the measure makes to achieving the ALOP of the importing country.

2) Categorisation of sanitary measures

Proposals for equivalence may be in terms of a measure comprising consider a single component of a measure (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. Multiple components or combinations of measures Measures may be applied consecutively or concurrently.

Sanitary measures are those described in each the disease-specific chapter of the *Terrestrial Code* which are used for reducing managing risks reduction and are appropriate for particular posed by that diseases, infection or infestation. *Sanitary measures* may be applied either alone or in combination and include test requirements, processing requirements, inspection or certification procedures, quarantine confinements, and sampling procedures.

For the purposes of **judging 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 national and regional animal health authorities, emergency response organisations);
- 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).

A *sanitary Sanitary measure(s)* proposed for a **judgement 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 pathogen inactivation, a comparison of specific technical requirements may suffice. In many instances, however, a judgement as to assessment of whether the same level of protection is likely to will be achieved may only be able to be determined through an evaluation of all relevant components of an *exporting country's animal health management systems* and *animal production systems*. For example, a judgement of equivalence for a specific sanitary measure at the programme design/implementation level may require a prior examination of infrastructure while a judgement of equivalence for a specific measure at the specific technical requirement level may require that the specific measure be judged in its context through examination of infrastructure and programmes.

Article
5.3.5.

Principles for **judgement determination** of equivalence

In conjunction with the above considerations, **judgement 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 (its ALOP) in relation to human and animal life and health in its territory; this ALOP 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 **hazard risk**;
- 3) an *importing country* should recognise that *sanitary measures* different from the ones it has proposed may be capable of **providing achieving** the same level of protection, in particular, it should consider the existence of specified disease-free zones/regions or compartments;
- 4) the *importing country* should, upon request, enter into consultations with the *exporting country* with the aim of facilitating a **judgement determination** of equivalence;
- 5) any *sanitary measure* or combination of *sanitary measures* can be proposed for **judgement 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 measure(s)* 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 **judgement 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*;

10bis) the importing country should take into account any arrangements it has with other exporting countries on similar issues;

10ter) the importing country may also take into account any knowledge of the exporting country's arrangements with other importing countries;

- 11) the *exporting country* should provide access to enable the procedures or systems which that are the subject of the equivalence judgement determination to be examined and evaluated upon request of the *importing country*;
- 12) the *importing country* should be the sole determinant judge of equivalence, but should provide to the *exporting country* a full explanation for its judgement;
- 13) to facilitate a judgement 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;
- 14) to allow the judgement 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 which that may bear on the judgement determination of equivalence; and
- 15) appropriate technical assistance from an importing country, following a ~~should give positive consideration to a request by an exporting developing country, for appropriate technical assistance that would may~~ facilitate the successful completion of a judgement determination of equivalence.

Article
5.3.6.

Sequence of steps to be taken in judgement determination of equivalence

There is no single sequence of steps which that must should be followed in all judgements determinations of equivalence. The steps that trading partners choose will generally depend on the circumstances and their trading experience. Nevertheless, The the interactive sequence of steps described below may be useful for assessing any at *sanitary measures* irrespective of their categorisation as infrastructure, programme design/ and implementation or specific technical requirement components of an animal health management system or and 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(s) for which it wishes to propose an alternative ~~measure(s)~~, 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 hazard(s) risk;
- 2) the *importing country* explains the reason for the measure(s), in terms that which would facilitate comparison with an alternative *sanitary measure(s)* and consistent with the principles set out in these provisions;
- 3) the *exporting country* demonstrates the case for equivalence of an alternative *sanitary measure(s)* in a form which that facilitates evaluation analysis by an *importing country*;
- 4) the *exporting country* responds to any technical concerns raised by the *importing country* by providing relevant further information;
- 5) judgement determination of equivalence by the *importing country* should takes into account as appropriate:
 - a) the impact of biological variability and uncertainty;
 - b) the expected effect of the alternative *sanitary measure(s)* on all relevant hazards;
 - c) OIE standards and guidelines;
 - d) application of solely qualitative frameworks where it is not possible or reasonable to conduct quantitative the results of a risk assessment;
- 6) the *importing country* notifies the *exporting country* of its judgement and its the underlying reasons within a reasonable period of time. The judgement:
 - a) ~~recognition recognises~~ of the equivalence of the *exporting country's* alternative *sanitary measure(s)*; or
 - b) ~~requests for~~ further information; or
 - c) ~~rejection rejects~~ of the case for equivalence of the alternative *sanitary measure(s)*;
- 7) an attempt should be made to resolve any differences of opinion over judgement of a case, ~~either interim or final,~~ by using an agreed mechanism such as to reach consensus (e.g. the OIE informal procedure for dispute mediation), or by referral to an agreed expert (Article 5.3.8.);

- 8) depending on the category of measures involved, the *importing country* and the *exporting country* may enter into a formal or informal agreement of equivalence agreement giving effect to the judgement ~~or a less formal acknowledgement of the equivalence of a specific measure(s) may suffice.~~

An *importing country* recognising the equivalence of an *exporting country's* alternative *sanitary measure(s)* ~~needs to~~ 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(s). Consistent action does not mean however that a specific measure(s) proposed by several *exporting countries* should always be judged as equivalent because as a measure(s) 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 establishment ~~There is no single sequence of steps which should be followed in establishing of a disease-free zone or a compartment is described in Chapter 4.3 and should be considered by trading partners when establishing sanitary measures for trade. The steps that the Veterinary Services of the importing country and the exporting country choose and implement will generally depend on the circumstances existing within the countries and at their borders, and their trading history. The recommended~~ Recommended steps are:

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/specific diseases,~~ infection or infestation based on surveillance.
- b) The *exporting country* describes in the *biosecurity plan* for the *zone* the measures ~~which are being, or will be,~~ 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 and 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(s)* concerned; and
 - iv) other relevant OIE standards or guidelines.
- e) The *importing country* notifies the *exporting country* of its determination judgement and the underlying 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 ~~to reach consensus~~ 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 **formal** 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 animal *subpopulation* contained in one or more *establishments* or other premises operating under common management practices ~~and related to biosecurity~~ **plan**. The *compartment* contains an identifiable animal *subpopulation* with a distinct health status with respect to a specific disease(s). 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 ~~such the~~ disease(s) in question.
- c) The *exporting country* describes the *compartment*, in accordance with ~~the recommendations in the Terrestrial Code Chapters 4.3. and 4.4.~~
- 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 ~~and~~ 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(s) concerned; and
 - iv) other relevant OIE standards **or guidelines**.
- f) The *importing country* notifies the *exporting country* of its **determination judgement** and **the underlying 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 ~~to reach consensus~~ 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 a **an formal** agreement recognising the *compartment*.
- i) ~~The *Veterinary Authority* of the *exporting country* should promptly inform *importing countries* of any occurrence of a *disease* in respect of which the *compartment* was defined.~~

Article 5.3.8.

The OIE informal procedure for dispute mediation

OIE ~~shall~~ maintains ~~its existing~~ a voluntary in-house mechanisms **s** for assisting Member Countries to resolve differences. In-house procedures ~~that~~ which 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 **shall** submit a confidential report to the Director General of the OIE, who **will then** transmits **s** it to both parties.

— Text deleted.