

Committee on Sanitary and Phytosanitary Measures

**DECISION ON THE IMPLEMENTATION OF ARTICLE 4
OF THE AGREEMENT ON THE APPLICATION OF SANITARY
AND PHYTOSANITARY MEASURES**

Revision¹

The Committee on Sanitary and Phytosanitary Measures,

Having regard to paragraph 1 of Article 12 of the Agreement on the Application of Sanitary and Phytosanitary Measures;

In response to the request from the General Council that the Committee examine the concerns of developing country Members regarding the equivalence of sanitary or phytosanitary measures and develop concrete options as to how to deal with them;

Reaffirming the right of Members to establish sanitary and phytosanitary measures necessary to ensure the protection of human, animal and plant life or health and the protection of their territory from other damage caused by the entry, establishment or spread of pests, in accordance with the Agreement on the Application of Sanitary and Phytosanitary Measures;

Desiring to make operational the provisions of Article 4 of the Agreement on the Application of Sanitary and Phytosanitary Measures;

Noting that equivalence of sanitary or phytosanitary measures does not require duplication or sameness of measures, but the acceptance of alternative measures that meet an importing Member's appropriate level of sanitary or phytosanitary protection;

Recognizing that equivalence can be applied between all Members, irrespective of their level of development;

Noting that Members have faced difficulties applying the provisions of Article 4 recognizing the equivalence of sanitary and phytosanitary measures;

Taking into account the specific concerns raised by developing country Members, and particularly the least developed among them, regarding their difficulties in having the equivalence of their sanitary or phytosanitary measures accepted by importing Members;

¹ This revision provides updated information with respect to actions taken pursuant to the Decision as adopted on 26 October 2001. This information is provided in footnotes to the relevant provisions in the Decision.

Recognizing the importance of minimizing possible negative effects of sanitary or phytosanitary measures on trade and of improving market access opportunities, particularly for products of interest to developing country Members;

Recognizing that transparency, exchange of information and confidence-building by both the importing and exporting Member are essential to achieving an agreement on equivalence;

Recognizing that there may be other less resource-intensive and time-consuming means for Members to enhance trade opportunities;

Decides as follows:

1. Equivalence can be accepted for a specific measure or measures related to a certain product or categories of products, or on a systems-wide basis. Members shall, when so requested, seek to accept the equivalence of a measure related to a certain product or category of products. An evaluation of the product-related infrastructure and programmes within which the measure is being applied may also be necessary.² Members may further, where necessary and appropriate, seek more comprehensive and broad-ranging agreements on equivalence. The acceptance of the equivalence of a measure related to a single product may not require the development of a systems-wide equivalence agreement.
2. In the context of facilitating the implementation of Article 4, on request of the exporting Member, the importing Member should explain the objective and rationale of the sanitary or phytosanitary measure and identify clearly the risks that the relevant measure is intended to address. The importing Member should indicate the appropriate level of protection which its sanitary or phytosanitary measure is designed to achieve.³ The explanation should be accompanied by a copy of the risk assessment on which the sanitary or phytosanitary measure is based or a technical justification based on a relevant international standard, guideline or recommendation. The importing Member should also provide any additional information which may assist the exporting Member to provide an objective demonstration of the equivalence of its own measure.
3. An importing Member shall respond in a timely manner to any request from an exporting Member for consideration of the equivalence of its measures, normally within a six-month period of time.
4. The exporting Member shall provide appropriate science-based and technical information to support its objective demonstration that its measure achieves the appropriate level of protection identified by the importing Member. This information may include, *inter alia*, reference to relevant international standards, or to relevant risk assessments undertaken by the importing Member or by another Member. In addition, the exporting Member shall provide reasonable access, upon request, to the importing Member for inspection, testing and other relevant procedures for the recognition of equivalence.
5. The importing Member should accelerate its procedure for determining equivalence in respect of those products which it has historically imported from the exporting Member.

The Committee agrees that historic trade provides an opportunity for an importing Member to become familiar with the infrastructure and measures of an exporting

² Product-related infrastructure and programmes is in reference to testing, inspection and other relevant requirements specific to product safety.

³ In doing so, Members should take into account the *Guidelines to Further the Practical Implementation of Article 5.5* adopted by the Committee on Sanitary and Phytosanitary Measures at its meeting of 21-22 June 2000 (document G/SPS/15, dated 18 July 2000).

Member, and to develop confidence in the regulatory procedures of that Member. This information and experience, if directly relevant to the product and measure under consideration, should be taken into account in the recognition of equivalence of measures proposed by the exporting Member. In particular, information already available to the importing Member should not be sought again with respect to procedures to determine the equivalence of measures proposed by the exporting Member.

An importing Member should consider the relevant information and experience that the sanitary and phytosanitary services have on the measure(s) for which recognition of equivalence is requested as applied to the product for which that request relates.

This information and experience refers to:

- (i) The historic knowledge and confidence that the competent authority of the importing Member has of the competent authority of the exporting Member.*
- (ii) The existence of an evaluation and recognition of the products-related system of inspection and certification of the exporting Member by the importing Member.*
- (iii) The available scientific information supporting the request for the recognition of equivalence.*

The more such relevant information and experience is available to the importing Member, the more rapid should be the procedure for recognition of equivalence by that Member.

A Member should consider the existence of information between competent authorities related to sanitary and phytosanitary measures of other products (different from the one for which equivalence is requested) when this information is useful.

A Member should consider the risk of the product to which the sanitary and phytosanitary measures are applied, in order to reduce requirements and accelerate the procedure in cases of low risk.

The importing Member should not seek again information already available with respect to the determination of the equivalence of sanitary and phytosanitary measures proposed by the exporting Member, unless this information needs to be updated.

For accelerated procedures, the importing Member should estimate the steps that the demonstration of equivalence will require, and inform the exporting Member, when it is possible, of an estimated time schedule for the whole process. These steps should be considered between the exporting and importing Members, on an issue-by-issue basis, in order to give predictability to the process of determination of equivalence.

When more than one agency is involved, the relevant requirements of all of these agencies must be taken into account and included in the steps and timetable identified above.

The Committee notes that the importance of this knowledge based on historic trade has been fully recognized in the draft FAO/WHO Joint Codex Alimentarius Commission Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems.⁴ The Committee further notes that the importance of such prior experience is also recognized in the draft paper of the World Organization for Animal Health (OIE) on the Judgement of Equivalence of Sanitary Measures relating to International Trade in Animals and Animal Products.⁵ The Committee encourages that further elaboration of specific guidance by these organizations should ensure that such recognition is maintained.

The Committee draws the attention of the Interim Commission on Phytosanitary Measures (ICPM) to the Decision on Equivalence (G/SPS/19), and to the above clarification with respect to Paragraph 5 of the Decision. The Committee requests that the ICPM take into consideration the Decision and this clarification in its future work on judgement of equivalence with regard to sanitary measures to address plant pests and diseases.⁶

6. The consideration by an importing Member of a request by an exporting Member for recognition of the equivalence of its measures with regard to a specific product shall not be in itself a reason to disrupt or suspend on-going imports from that Member of the product in question.

The Committee agrees that since a request for recognition of equivalence does not in itself alter the way in which trade is occurring, there is no justification for disruption or suspension of trade. If an importing Member were to disrupt or suspend trade solely because it had received a request for an equivalence determination, it would be in apparent violation of its obligations under the SPS Agreement (e.g. under Article 2).

At the same time, a request for recognition of equivalence does not impede the right of an importing Member to take any measure it may decide is necessary to achieve its appropriate level of protection, including in response to an emergency situation. However, if the decision to impose some additional control measure were to coincide with consideration by the same Member of a request for recognition of equivalence, this might lead an exporting Member whose trade is affected to suspect that the two events were linked. To avoid any misinterpretation of this kind, the Committee recommends that the importing Member should give an immediate and comprehensive explanation of the reasons for its action in restricting trade to any other Members affected, and that it should also follow the normal or emergency notification procedures established under the SPS Agreement.

The Committee notes that this issue has been addressed also in the draft Codex Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems⁴, and should encourage the maintenance of such a provision in the further elaboration of specific guidance by the Codex. The

⁴ The Codex Alimentarius Commission adopted the Guidelines for the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems at its 26th Session held in Rome, Italy, from 30 June to 7 July 2003.

⁵ The International Committee of the OIE adopted the Guidelines for Reaching a Judgement on Equivalence of Sanitary Measures at its 71st General Session held in Paris, France, from 18 to 23 May 2003.

⁶ The Interim Commission on Phytosanitary Measures (ICPM) noted the request of the SPS Committee at its 5th Session held in Rome, Italy, from 7 to 11 April 2003. The ICPM agreed to include Equivalence and Efficacy of Measures, considered a pre-requisite to an ISPM on Equivalence, as priorities in its work programme. Work on these two issues is currently underway.

Committee draws the attention of the World Organization for Animal Health (OIE) and the Interim Commission on Phytosanitary Measures (ICPM) to the above clarification with respect to Paragraph 6 of the Decision on Equivalence, and requests that the OIE and the ICPM take this clarification into consideration in their future work on equivalence with regard to sanitary or phytosanitary measures.^{5,6}

7. When considering a request for recognition of equivalence, the importing Member should analyze the science-based and technical information provided by the exporting Member on its sanitary or phytosanitary measures with a view to determining whether these measures achieve the level of protection provided by its own relevant sanitary or phytosanitary measures.

The Committee notes that conscientious implementation of the Guidelines to Further the Practical Implementation of Article 5.5 (G/SPS/15) will assist Members in determining equivalence.

The Committee further notes that the relationship between the level of protection provided by the importing Member's own measures and what it requires from imported products has been explicitly addressed in the draft Codex Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems.^{4,7} The Committee notes that the OIE Guidelines for Reaching a Judgement of Equivalence of Sanitary Measures also recognizes the importance of facilitating comparison of the exporting and importing Members' measures. The Committee agrees that Members should consider the Codex approach of establishing an objective basis for comparison or the similar OIE approach when determining the equivalence of sanitary measures.

The Committee encourages the FAO/WHO Codex Alimentarius Commission and the World Organization for Animal Health to ensure that the recognition of the importance of facilitating comparison of the exporting and importing Members' measures is maintained in any elaboration of guidance by these organizations.

The Committee requests that the Interim Commission on Phytosanitary Measures (ICPM) take into consideration the Decision on Equivalence and this clarification in its future work on judgement of equivalence with regard to measures to address plant pests and diseases.

The Committee agrees that where the objective basis for comparison, or a similar approach established by a relevant international organization, demonstrates that the level of protection achieved by the importing Member's sanitary or phytosanitary measure differs from its appropriate level of protection, the importing Member should resolve this difference independently of the procedure for determination of equivalence.

If the exporting Member demonstrates by way of an objective basis of comparison or similar approach established by a relevant international organization that its measure has the same effect in achieving the objective as the importing Member's measure, the importing Member should recognize both measures as equivalent.

⁷ The Committee recognizes that the Codex Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems are also relevant in this regard.

8. In accordance with Article 9 of the Agreement on the Application of Sanitary and Phytosanitary Measures, a Member shall give full consideration to requests by another Member, especially a developing country Member, for appropriate technical assistance to facilitate the implementation of Article 4. This assistance may, *inter alia*, be to help an exporting Member identify and implement measures which can be recognized as equivalent, or to otherwise enhance market access opportunities. Such assistance may also be with regard to the development and provision of the appropriate science-based and technical information referred to in paragraph 4, above.

9. Members should actively participate in the ongoing work in the Codex Alimentarius Commission on the issue of equivalence, and in any work related to equivalence undertaken by the World Organization for Animal Health and in the framework of the International Plant Protection Convention. Bearing in mind the difficulties faced by developing country Members to participate in the work of these bodies, Members should consider providing assistance to facilitate their participation.

10. The Committee on Sanitary and Phytosanitary Measures recognizes the urgency for the development of guidance on the judgement of equivalence and shall formally encourage the Codex Alimentarius Commission to complete its work with regard to equivalence as expeditiously as possible.⁴ The Committee on Sanitary and Phytosanitary Measures shall also formally encourage the World Organization for Animal Health and the Interim Commission on Phytosanitary Measures to elaborate guidelines, as appropriate, on equivalence of sanitary and phytosanitary measures and equivalence agreements in the animal health and plant protection areas.^{5,6} The Codex Alimentarius Commission, the World Organization for Animal Health and the Interim Commission on Phytosanitary Measures shall be invited to keep the Committee on Sanitary and Phytosanitary Measures regularly informed regarding their activities relating to equivalence.

11. The Committee on Sanitary and Phytosanitary Measures shall revise its recommended notification procedures to provide for the notification of the conclusion of agreements between Members which recognize the equivalence of sanitary and phytosanitary measures.⁸ Furthermore, the procedures shall reinforce the existing obligation in paragraph 3(d) of Annex B of the Agreement on the Application of Sanitary and Phytosanitary Measures for national Enquiry Points to provide information, upon request, on the participation in any bilateral or multilateral equivalence agreements of the Member concerned.

12. Members should regularly provide to the Committee on Sanitary and Phytosanitary Measures information on their experience regarding the implementation of Article 4 of the Agreement on the Application of Sanitary and Phytosanitary Measures. In particular, Members are encouraged to inform the Committee on Sanitary and Phytosanitary Measures of the successful conclusion of any bilateral equivalence agreement or arrangement. The Committee on Sanitary and Phytosanitary Measures shall consider establishing a standing agenda item for its regular meetings for this purpose.

13. The Committee on Sanitary and Phytosanitary Measures shall develop a specific programme to further the implementation of Article 4, with particular consideration of the problems encountered by developing country Members.⁹ In this respect, the Committee on Sanitary and Phytosanitary Measures shall review this decision in light of the relevant work undertaken by the Codex

⁸ G/SPS/7/Rev.2 and Rev.2/Add.1.

⁹ In the light of this paragraph and the decision at the Fourth Ministerial Conference regarding implementation-related issues and concerns (WT/MIN(01)17, paragraph 3.3), the SPS Committee adopted a programme for further work on equivalence at its meeting of 19-21 March 2002 (G/SPS/20). The Committee completed this work programme in March 2004 but agreed that equivalence would be a standing agenda item for its regular meetings.

Alimentarius Commission, the World Organization for Animal Health and the Interim Commission on Phytosanitary Measures, as well as the experience of Members.

14. The Committee on Sanitary and Phytosanitary Measures requests that the General Council take note of this decision.
