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**INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES**

***GUIDELINES FOR THE DETERMINATION AND RECOGNITION OF
EQUIVALENCE OF PHYTOSANITARY MEASURES***



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INTRODUCTION

SCOPE

This standard describes the principles and requirements that apply for the determination and recognition of equivalence of phytosanitary measures. It also describes a procedure for equivalence determinations in international trade.

REFERENCES

- Agreement on the Application of Sanitary and Phytosanitary Measures*, 1994. World Trade Organization, Geneva.
- Export certification system*, 1997. ISPM No. 7, FAO Rome.
- Glossary of phytosanitary terms*, 2004. ISPM No. 5, FAO, Rome.
- Guidelines for pest risk analysis*, 1996. ISPM No. 2, FAO, Rome.
- Guidelines for regulating wood packaging material in international trade*, 2002. ISPM No. 15. FAO, Rome.
- Guidelines for the notification of non-compliance and emergency action*, 2001. ISPM No. 13, FAO, Rome.
- International Plant Protection Convention*, 1997. FAO, Rome.
- Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*, 2004. ISPM No. 11, FAO, Rome.
- Principles of plant quarantine as related to international trade*, 1995. ISPM No. 1, FAO, Rome.
- The use of integrated measures in a systems approach for pest risk management*, 2002. ISPM No. 14, FAO, Rome.

DEFINITIONS

commodity	A type of plant, plant product, or other article being moved for trade or other purpose [FAO, 1990; revised ICPM, 2001]
commodity class	A category of similar commodities that can be considered together in phytosanitary regulations [FAO, 1990]
consignment	A quantity of plants, plant products and/or other articles being moved from one country to another and covered, when required, by a single phytosanitary certificate (a consignment may be composed of one or more commodities or lots) [FAO, 1990; revised ICPM, 2001]
emergency action	A prompt phytosanitary action undertaken in a new or unexpected phytosanitary situation [ICPM, 2001]
equivalence (of phytosanitary measures)	The situation where, for a specified pest risk, different phytosanitary measures achieve a contracting party's appropriate level of protection [FAO, 1995; revised CEPM, 1999; based on the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures; revised ISPM No. 24, 2005].
fumigation	Treatment with a chemical agent that reaches the commodity wholly or primarily in a gaseous state [FAO, 1990; revised FAO, 1995]
IPPC	International Plant Protection Convention, as deposited in 1951 with FAO in Rome and as subsequently amended [FAO 1990; revised ICPM, 2001]
ISPM	International Standard for Phytosanitary Measures [CEPM, 1996; revised ICPM, 2001]

inspection	Official visual examination of plants, plant products or other regulated articles to determine if pests are present and/or to determine compliance with phytosanitary regulations [FAO, 1990; revised FAO, 1995; formerly inspect]
pest	Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products [FAO, 1990; revised FAO, 1995; IPPC, 1997]
pest risk assessment (for quarantine pests)	Evaluation of the probability of the introduction and spread of a pest and of the associated potential economic consequences [FAO, 1995; revised ISPM No 11, 2001]
phytosanitary measure (agreed interpretation)	Any legislation, regulation or official procedure having the purpose to prevent the introduction and/or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests [FAO, 1995; revised IPPC, 1997; ICPM, 2002] <i>The agreed interpretation of the term phytosanitary measure accounts for the relationship of phytosanitary measures to regulated non-quarantine pests. This relationship is not adequately reflected in the definition found in Article II of the IPPC (1997).</i>
PRA	Pest Risk Analysis [FAO, 1995; revised ICPM, 2001]
regulated pest	A quarantine pest or a regulated non-quarantine pest [IPPC, 1997]
required response	A specified level of effect for a treatment [ISPM No. 18, 2003]
surveillance	An official process which collects and records data on pest occurrence or absence by survey, monitoring or other procedures [CEPM, 1996]
systems approach(es)	The integration of different risk management measures, at least two of which act independently, and which cumulatively achieve the appropriate level of protection against regulated pests [ISPM No. 14, 2002; revised ICPM, 2005]
treatment	Official procedure for the killing, inactivation or removal of pests, or for rendering pests infertile or for devitalization [FAO, 1990, revised FAO, 1995; ISPM No. 15, 2002; ISPM No. 18, 2003; ICPM, 2005]

OUTLINE OF REQUIREMENTS

Equivalence is one of the IPPC general principles (ISPM No. 1: *Principles of plant quarantine as related to international trade*).

Equivalence generally applies to cases where phytosanitary measures already exist for a specific pest associated with trade in a commodity or commodity class. Equivalence determinations are based on the specified pest risk and equivalence may apply to individual measures, a combination of measures, or integrated measures in a systems approach.

A determination of equivalence requires an assessment of phytosanitary measures to determine their effectiveness in mitigating a specified pest risk. The determination of equivalence of measures may also include an evaluation of the exporting contracting party's phytosanitary systems or programs that support implementation of those measures. Normally, the determination involves a sequential process of information exchange and evaluation, and is generally an agreed procedure between importing and exporting contracting parties. Information is provided in a form that allows the evaluation of existing and proposed measures for their ability to meet the importing contracting party's appropriate level of protection¹.

The exporting contracting party may request information from the importing contracting party on the contribution that its existing measures make to meeting its appropriate level of protection. The exporting contracting party may propose an alternative measure, indicating how this measure achieves the required level of protection, and this is evaluated by the importing contracting party. In some cases, such as where technical assistance is provided, importing contracting parties may make proposals for alternative phytosanitary measures. Contracting parties should endeavour to undertake equivalence determinations and to resolve any differences without undue delays.

¹ This term is defined in the *Agreement on the Application of Sanitary and Phytosanitary Measures* of the World Trade Organization (WTO-SPS Agreement). Many WTO members otherwise refer to this concept as the "acceptable level of risk".

REQUIREMENTS

1. General Considerations

Equivalence is described as general principle No. 7 in ISPM No. 1 (*Principles of plant quarantine as related to international trade*, 1993): "Equivalence: Countries shall recognize as being equivalent those phytosanitary measures that are not identical but which have the same effect". Furthermore, the concept of equivalence and the obligation of contracting parties to observe the principle of equivalence is an integral element in other existing ISPMs. In addition, equivalence is described in Article 4 of the WTO-SPS Agreement.

The process of recognizing equivalence is the objective examination of alternative phytosanitary measures proposed to determine if they achieve the appropriate level of protection of an importing country as indicated by existing measures of that country.

Contracting parties recognize that alternative phytosanitary measures can achieve their appropriate level of protection. Therefore, while not formalized under the title of "equivalence", there is widespread application of equivalence in current phytosanitary practices.

To manage a specified pest risk and achieve a contracting party's appropriate level of protection, equivalence may be applied to:

- an individual measure,
- a combination of measures, or
- integrated measures in a systems approach.

In the case of a systems approach, alternative measures may be proposed as equivalent to one or more of the integrated measures, rather than changing the entire systems approach. Equivalence arrangements are applicable for commodities rather than for individual consignments.

The evaluation for equivalence of phytosanitary measures may not be limited to an assessment of the measures alone, but may also involve consideration of aspects of the export certification system or other factors associated with the implementation of pest risk management measures.

This standard provides guidelines for situations where an importing contracting party has a phytosanitary measure in place, or is proposing a new measure, and an exporting contracting party proposes an alternative measure to achieve the importing contracting party's appropriate level of protection. The alternative measure is then evaluated for equivalence.

In some cases importing contracting parties list a number of phytosanitary measures that are considered to achieve their appropriate level of protection. Contracting parties are encouraged to include two or more equivalent measures for regulated articles as part of their import regulations. This allows for taking into account different or changing phytosanitary situations in exporting countries. These measures may differ in the extent to which they achieve or exceed the contracting party's appropriate level of protection. The evaluation of the equivalence of such measures listed by an importing contracting party is not the primary subject of this standard.

Although equivalence is generally a bilateral process between importing and exporting contracting parties, multilateral arrangements for comparing alternative measures take place as part of the standard setting process of the IPPC. For example, there are alternative measures approved in ISPM No 15: *Guidelines for regulating wood packaging material in international trade*.

2. General Principles and Requirements

2.1 Sovereign authority

Contracting parties have sovereign authority, in accordance with applicable international agreements, to apply phytosanitary measures to protect plant health within their territories and to determine their appropriate level of protection to plant health. A contracting party has sovereign authority to regulate the entry of plants, plant products and other regulated articles

(Article VII.1 of the IPPC, 1997). Therefore a contracting party has the right to make decisions relating to determinations of equivalence. In order to promote cooperation, an importing contracting party evaluates the equivalence of phytosanitary measures.

2.2 Other relevant principles of the IPPC

In equivalence evaluations, contracting parties should take into account the following principles:

- minimal impact (Article VII.2g of the IPPC, 1997)
- modification (Article VII.2h of the IPPC, 1997)
- transparency (Articles VII.2b, 2c, 2i and VIII.1a of the IPPC, 1997)
- harmonization (Article X.4 of the IPPC, 1997)
- risk analysis (Articles II and VI.1b of the IPPC, 1997)
- managed risk (Article VII.2a and 2g of the IPPC, 1997)
- non-discrimination (Article VI.1a of the IPPC, 1997).

2.3 Technical justification for equivalence

Assessments of equivalence should be risk-based, using an evaluation of available scientific information, either through PRA or by evaluation of the existing measures and the proposed measures. The exporting contracting party has the responsibility for providing the technical information to demonstrate that the alternative measures reduce the specified pest risk and that they achieve the appropriate level of protection of the importing contracting party. In some cases (e.g. as described in section 3.2), however, importing contracting parties may propose alternative measures for the exporting contracting party to consider. This information may be qualitative and/or quantitative as long as comparison is possible.

Although the alternative measures need to be examined, a new complete pest risk assessment may not necessarily be required since, as trade in the commodity or commodity class is already regulated, the importing country should have at least some PRA-related data.

2.4 Non-discrimination in the application of the equivalence of phytosanitary measures

The principle of non-discrimination requires that when equivalence of phytosanitary measures is granted for one exporting contracting party, this should also apply to contracting parties with the same phytosanitary status and similar conditions for the same commodity or commodity class and/or pest. Therefore, an importing contracting party which recognizes the equivalence of alternative phytosanitary measures of an exporting contracting party should ensure that it acts in a non-discriminatory manner. This applies both to applications from third countries for recognition of the equivalence of the same or similar measures, and to the equivalence of any domestic measures.

It should be recognized that equivalence of phytosanitary measures does not, however, mean that when a specific measure is granted equivalence for one exporting contracting party, this applies automatically to another contracting party for the same commodity or commodity class or pest. Phytosanitary measures should always be considered in the context of the pest status and phytosanitary regulatory system of the exporting contracting party, including the policies and procedures.

2.5 Information exchange

Contracting parties have obligations under the IPPC to provide and exchange information, which should be made available for equivalence determinations. This includes making available, on request, the rationale for phytosanitary requirements (Article VII.2c of the IPPC, 1997) and cooperating to the extent practicable in providing technical and biological information necessary for pest risk analysis (Article VIII of the IPPC, 1997). Contracting parties should aim to limit any data requests associated with an evaluation of equivalence to those which are necessary for this evaluation.

To facilitate discussions on equivalence the importing contracting party should, on request, provide information describing how its existing measures reduce the risk of the specified pest and how they achieve its appropriate level of protection. This information may be provided in either quantitative or qualitative terms. Such information should assist the exporting contracting party in understanding the existing measures. It may also help the exporting contracting party to explain how its proposed alternative measures reduce the pest risk and achieve the importing contracting party's appropriate level of protection.

2.6 Technical assistance

In accordance with Article XX of the IPPC (1997), contracting parties are encouraged to consider providing technical assistance for the development of measures based on equivalence if requested by another contracting party.

2.7 Timeliness

Contracting parties should endeavour to determine the equivalence of phytosanitary measures and to resolve any differences without undue delays.

3. Specific Requirements for the Application of Equivalence

3.1 Specific pests and commodities

The process of comparing alternative phytosanitary measures for the purpose of determining their equivalence usually relates to a specified export commodity and specified regulated pests identified through pest risk analysis.

3.2 Existing measures

Equivalence generally applies to cases where the importing contracting party has already existing measures for the current trade concerned. However, it may also apply where new measures are proposed by the importing contracting party. Usually an exporting contracting party presents an alternative measure that is intended to achieve the importing contracting party's appropriate level of protection. In some cases, such as where technical assistance is being provided, contracting parties may propose alternative measures for the consideration of other contracting parties.

Where new commodities or commodity classes are presented for importation and no measures exist, contracting parties should refer to ISPM No. 11 (*Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*, 2004) and ISPM No. 21 (*Pest risk analysis for regulated non-quarantine pests*) for the normal PRA procedure.

3.3 Entry into consultation

When requested, contracting parties are encouraged to enter into consultations with the aim of facilitating a determination of equivalence.

3.4 Agreed procedure

Contracting parties should agree on a procedure to determine equivalence. This may be based on the procedure recommended in Annex 1 of this standard or another bilaterally agreed procedure.

3.5 Factors considered in determining equivalence

The determination of the equivalence of phytosanitary measures depends on a number of factors. These may include:

- the effect of the measure as demonstrated in laboratory or field conditions
- the examination of relevant literature on the effect of the measure
- the results of experience in the practical application of the measure
- the factors affecting the implementation of the measure (e.g. the policies and procedures of the contracting party).

The effect of phytosanitary measures implemented in a third country may be considered as reference. Information on the measure is used by the importing contracting party to assess the contribution of the alternative measure in reducing the pest risk to a level that provides the appropriate level of protection.

When comparing existing measures and measures proposed as equivalent, importing and exporting contracting parties should assess the ability of the measures to reduce a specified pest risk. The proposed measures should be assessed for their ability to achieve the importing contracting party's appropriate level of protection. In cases where the effects of both the existing measures and the proposed measures are expressed in the same way (i.e. the same type of required response), the effects may be compared directly for their ability to reduce the pest risk. For example, a fumigation treatment and a cold treatment may be compared for their effects based on mortality.

Where measures are expressed differently, they may be difficult to compare directly. In such cases, the proposed measures should be assessed for their ability to achieve the importing contracting party's appropriate level of protection. This may require data to be converted or extrapolated so that common units are used before comparison is possible. For example, effects such as mortality and an area of low pest prevalence may be compared if considered in relation to pest freedom at an agreed level of confidence (for example per consignment or per year).

When determining equivalence, a comparison of specific technical requirements of the existing and proposed measures may suffice. In some circumstances, however, the determination of whether a proposed measure achieves the appropriate level of protection may need to be considered in relation to the capacity of the exporting country to apply this measure. In the cases where trade is already established between contracting parties, this provides knowledge about and experience with the exporting contracting party's phytosanitary regulatory systems (e.g. legal, surveillance, inspection, certification, etc.) This knowledge and experience should strengthen confidence between parties and assist, if necessary, with the evaluation of an equivalence proposal. In relation to such information, an importing contracting party may require updated information, when technically justified, of procedures of the exporting contracting party related specifically to the implementation of the phytosanitary measures proposed as equivalent.

The final acceptance of a proposed measure may depend on practical considerations such as availability/approval of the technology, unintended effects of the proposed measure (e.g. phytotoxicity), and operational and economic feasibility.

3.6 Non-disruption of trade

A submission of a request for recognition of equivalence should not in itself alter the way in which trade occurs; it is not a justification for disruption or suspension of existing trade or existing phytosanitary import requirements.

3.7 Provision of access

In order to support an importing contracting party's consideration of an equivalence request, the exporting contracting party should facilitate access by the importing contracting party to relevant sites to conduct any reviews, inspections or verifications for an equivalence determination when technically justified.

3.8 Review and monitoring

After the recognition of equivalence, and to provide continued confidence in the equivalence arrangements, contracting parties should implement the same review and monitoring procedures as for similar phytosanitary measures. These may include assurance procedures such as audits, periodic checks, reporting of non-compliances (see also ISPM No. 13:

Guidelines for the notification of non-compliance and emergency action) or other forms of verification.

3.9 Implementation and transparency

To achieve the required transparency, amendment of regulations and related procedures should also be made available to other interested contracting parties.

ANNEX 1

Procedure for the determination of equivalence

The interactive procedure described below is recommended for assessing phytosanitary measures in order to make a determination as to their equivalence. However, the procedure that trading partners utilise to determine equivalence may vary depending on the circumstances. .

Recommended steps are:

1. The exporting contracting party communicates its interest in an equivalence determination to its trading partner, indicating the specified commodity, the regulated pest of concern and the existing and proposed alternative measures, including relevant data. At the same time it may request from the importing contracting party the technical justification for the existing measures. In discussions on the determination of equivalence, an agreement including an outline of the steps involved, an agenda and a possible timetable may be established.

2. The importing contracting party describes its existing measures in terms that will help to facilitate a comparison with alternative phytosanitary measures. To the best of its ability, the information provided by the importing contracting party should include the following:

- a) the purpose of the phytosanitary measures, including identification of the specific pest risk that these measures are being used to mitigate
- b) to the extent possible, how the existing phytosanitary measures achieve the importing contracting party's appropriate level of protection
- c) the technical justification for the existing phytosanitary measures, including the PRA where appropriate
- d) any additional information that may assist the exporting contracting party in demonstrating that the proposed measures achieve the importing contracting party's appropriate level of protection.

3. The exporting contracting party provides the technical information that it believes demonstrates equivalence of phytosanitary measures, and makes a request for equivalence. This information should be in a form suitable for comparison with the information provided by the importing contracting party and which therefore facilitates the necessary evaluation by the importing contracting party. This should include the following elements:

- a) the description of the proposed alternative measures
- b) the effectiveness of the measures
- c) to the extent possible, the contribution of the proposed alternative measures in achieving the importing contracting party's appropriate level of protection
- d) information on how the measures were evaluated (e.g. laboratory testing, statistical analysis, practical operational experience), and the performance of the measures in practice
- e) a comparison between the proposed alternative measures and the importing contracting party's existing measures for same pest risk
- f) information on technical and operational feasibility of the proposed alternative measures.

4. The importing contracting party receives and evaluates the proposed alternative phytosanitary measures, taking into account, but not being limited to the following:

- a) the submission from the exporting contracting party, including supporting information regarding the effectiveness of the proposed alternative measures
- b) the degree to which the alternative phytosanitary measures achieve the appropriate level of protection, either on the basis of qualitative or quantitative information
- c) information regarding the method, action and operation of the proposed alternative phytosanitary measures in preventing or reducing the specified pest risk
- d) the operational and economic feasibility of adopting the proposed alternative phytosanitary measures.

During the evaluation further clarification may be required. Additional information and/or access to operational procedures may be requested by the importing contracting party in order to complete the assessment. The exporting contracting party should respond to any technical concerns raised by the importing contracting party by providing relevant information and/or providing access to relevant information or sites to facilitate reviews, inspections or other verifications necessary for making an equivalence determination.

5. The importing contracting party notifies the exporting contracting party of its decision and provides, upon request, an explanation and technical justification for its determination as quickly as possible.

6. In the event of a rejection of the request for equivalence, efforts should be made to resolve differences of opinion through bilateral dialogue.

7. If equivalence is recognized by the importing contracting party, implementation should be achieved by the prompt amendment of the import regulations and any associated procedures of the importing contracting party. The amendments should be communicated in accordance with Article VII.2b of the IPPC (1997).

8. An audit and monitoring procedure may be established and included in the plan or arrangement which implements any recognized equivalence measures or programmes.