



منظمة الأغذية  
والزراعة  
للأمم المتحدة

联合国  
粮食及  
农业组织

Food  
and  
Agriculture  
Organization  
of  
the  
United  
Nations

Organisation  
des  
Nations  
Unies  
pour  
l'alimentation  
et  
l'agriculture

Organización  
de las  
Naciones  
Unidas  
para la  
Agricultura  
y la  
Alimentación

## INTERIM COMMISSION ON PHYTOSANITARY MEASURES

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### Equivalence

#### I. Equivalence, the IPPC and the SPS Agreement

1. The 1997 revision of the IPPC takes into account concepts addressed by the SPS Agreement as they apply to phytosanitary measures applied to plants, plant products and other articles in international trade. Although the term equivalence is not specifically mentioned in the IPPC (1997), it is noted in several International Standards for Phytosanitary Measures (ISPMs), in particular ISPM No. 1, where it is listed as one of the general principles for plant quarantine:

“Equivalence: Countries shall recognize as being equivalent those phytosanitary measures that are not identical but which have the same effect.” (ISPM No. 1: *Principles of plant quarantine as related to international trade*, General Principle no. 7)

2. It is defined in the Glossary of Phytosanitary Terms (ISPM No. 5) as:

“Equivalence: The situation of phytosanitary measures which are not identical but have the same effect.” (ISPM No. 5: *Glossary of phytosanitary terms*)

3. Equivalence is also addressed in relation to the selection of risk management options in ISPM No. 11 (*Pest risk analysis for quarantine pests*):

“Principle of “equivalence” - If different phytosanitary measures with the same effect are identified, they should be accepted as alternatives.” (ISPM No. 11: *Pest risk analysis for quarantine pests*, section 3.4)

4. The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) affirms the right of Members to establish phytosanitary measures necessary to ensure the protection of plant life or health. Article 4 specifically addresses equivalence. The term is not defined, but the text of the Agreement states that WTO Members are required to accept as equivalent those phytosanitary measures that achieve their desired outcome (i.e. their appropriate level of protection (ALP)).

5. The SPS Committee published a Decision in October 2001 (G/SPS/19) on the implementation of Article 4 in response to developing country concerns regarding the equivalence

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of sanitary or phytosanitary measures. In this, **the SPS Committee formally encouraged the standard-setting organizations to produce guidelines on equivalence**. The SPS Secretariat noted in July 2001 that for animal and plant protection:

“... ad hoc acceptance of equivalence of specific products or of certain technical SPS aspects is widespread” (G/SPS/W/111, para. 16)

6. The SPS Committee was instructed in the Doha Ministerial Decision (WT/MIN(01)/DEC/1) of November 2001 to continue to implement equivalence provisions. A work programme (G/SPS/20), notification procedures (G/SPS/7/Rec.2/Add.1) and clarification of the Equivalence Decision (G/SPS/19/Add.1) have been adopted by the Committee.

## **II. Equivalence and the other standard-setting bodies**

7. The Codex Alimentarius Commission (CAC) adopted an advisory text on the development of equivalence agreements in 1999 (CAC/GL 34—1999). Draft guidelines on the judgement of equivalence of sanitary measures associated with food inspection and certification systems are currently being considered and may be adopted at the next CAC meeting (30 June – 5 July 2003) (ALINORM 03/30A, Appendix II).

8. The term “substantial equivalence” has been widely used for food safety assessments associated with foods derived from biotechnology (e.g. foods derived from genetically modified plants) (see Schauzu (2000) AgBiotechNet Vol. 2 April ABN 044, available at: <http://binas.unido.org/binas/reviews/Schauzu.pdf>). This terminology expresses the idea that existing products used as foods can serve as a basis for comparison when assessing the safety or nutritional value of a food or food ingredient that has been modified or is new. If a novel food is found to be “substantially equivalent” to an existing food, then it can be treated in the same manner with respect to safety. The concept of substantial equivalence has therefore assumed a specific understanding as it applies to the safety assessment of foods derived from genetically modified organisms. As a result, its use in relation to the equivalence of phytosanitary measures may not be appropriate.

9. The Office International des Epizooties (OIE) submitted draft guidelines to the SPS Committee in March 2002 explaining procedures for reaching a judgement on the equivalence of sanitary measures (G/SPS/W/119). It is anticipated that a revised draft will be submitted for adoption at the next general session of the OIE in May 2003.

## **III. Action by the ICPM regarding the SPS Committee’s request for the guidance on equivalence**

10. The Fourth Session of the Interim Commission on Phytosanitary Measures (ICPM) in March 2002 decided that developing guidance on the concept of the efficacy of phytosanitary measures was prerequisite to developing guidance on equivalence (Report of the Fourth Session of the ICPM, para. 91). This decision was conveyed to the SPS Committee in June 2002 (G/SPS/R/27, para. 89).

## **IV. Issues for consideration in relation to equivalence and the IPPC**

### **A. LACK OF COMMON UNDERSTANDING OF THE TERM EQUIVALENCE**

11. The SPS Committee noted the lack of understanding of the term equivalence (G/SPS/W/111, para. 4) and stated:

“the concept of equivalence is **not about “duplication” or “sameness of measures”** ... equivalence may take many different forms, ranging from the acceptance of the equivalence of particular sanitary and phytosanitary measures to protect against specific

risks in a specific product, to formal systems-wide or broad-ranging agreements on equivalence.” (G/SPS/W/111, para 8)

12. Exporting countries should not be required to duplicate the same measures as those that are used by an importing country. Measures that achieve the appropriate level of phytosanitary protection may be considered equivalent.

#### **B. EQUIVALENCE ALREADY APPLIES IN THE PHYTOSANITARY FIELD, BUT FORMAL AGREEMENTS ARE RARE**

13. The SPS Committee has acknowledged that the principle of equivalence operates in the phytosanitary field (the “ad hoc” acceptance of the equivalence of measures). It is noted however that formal equivalence agreements are resource-intensive, time-consuming, and often create substantial administrative burdens. As a result, such agreements are relatively rare in the phytosanitary area. Examples relate to specific products or commodities (e.g. equivalence of seed potatoes from Switzerland, 95/513/EC, not currently in force).

#### **C. THE ELABORATION OF SPECIFIC GUIDANCE ON THE CONCEPT OF EQUIVALENCE OF PHYTOSANITARY MEASURES**

14. Although equivalence may already be operating to some extent at the technical level, there are opportunities to provide guidance and encourage harmonization regarding the application of the concept of equivalence in the phytosanitary area. As equivalence is one of the general principles of the IPPC, the ICPM may wish to consider producing a supplement to either ISPM No. 5 or ISPM No. 1 dealing specifically with equivalence.

15. The CAC and OIE draft documents could form useful input papers/background documents. They include sections on:

- the context of an equivalence determination/prerequisite considerations in a judgement of equivalence;
- general principles for the determination/judgement of equivalence;
- objective basis of comparison; and
- sequence of steps/procedure (plus flow chart) for the determination of equivalence.

16. The ICPM may also wish to consider whether additional specific guidance or reference to the determination of equivalence of phytosanitary measures is/will be required in new ISPMs or when existing ISPMs are revised.

#### **D. LEVELS OF APPLICATION IN PRACTICE**

17. The equivalence of phytosanitary measures may be approached at various levels, including:

- the specific measure,
- a specific commodity programme; or
- in relation to broad areas or the entire phytosanitary system.

18. The concept of equivalence may be more often and more easily applied, at least initially and/or where data are limited, to specific measures or at a commodity programme level, rather than in relation to a whole phytosanitary system. Equivalence agreements/negotiations at the system level may be lengthy, time-consuming (see para. 13) and require substantial data inputs as well as experience. For this reason, they are not considered further in this paper.

##### *Equivalence at the individual measure level*

19. An ICPM expert working group is in the process of formulating a standard on the efficacy of phytosanitary measures. The standard will include a consideration of the factors to be taken into account in determining the equivalence of phytosanitary measures.

20. The determination of equivalence of a measure or measures may be to assess whether:

- they achieve the same end point<sup>1</sup> and are therefore considered interchangeable, or
- they meet a particular pest management threshold.

**a) Measures achieving the same end point (interchangeability: “as good as”/same/duplicate effect)**

21. Phytosanitary treatments can be compared for their efficacy according to strict criteria, for example percentage of pest mortality under defined environmental conditions and initial pest populations with defined confidence limits (e.g. probit 9 level). There are many examples of treatment protocols achieving probit 9 mortality of insect pests, particularly fruit flies (e.g. high temperature forced air, vapour heat and cold treatments).

22. Based on research data, it is possible to establish whether such phytosanitary measures can be used interchangeably without a significant effect on the outcome. This can be done by determining their “closeness of efficiencies” or “range of equivalence” (see *Determination of efficacy product evaluation*, American Dental Association on Scientific Affairs, 1999, available at: <http://www.ada.org/prof/prac/stands/efficacyguidelines.pdf>; referred to in Sgrillo 2002, input paper for the efficacy of measures working group). Treatments achieving the same efficacy should be considered interchangeable as phytosanitary measures. However, the final choice of measure will also depend on other factors such as availability/approval of the technology, the feasibility of the measure, and phytotoxicity.

**b) Measures achieving a pest management threshold (e.g. at a critical control point)**

23. Where quantitative assessments of the risks associated with different components of a plant/commodity production process is possible, risk analysis may identify that a desired level of control is required at a certain critical point. This may be illustrated by two examples:

**Example 1:**

An NPPO has identified a threshold rate of pest infestation for a consignment, i.e. pest infestation rates higher than this level would result in an unacceptable risk. This is the ALP for this control point. A number of pest management options may be available to lower the pest level to the required level, e.g. measures at the production site, production in an area of low pest prevalence, treatment of the consignment etc. Provided these measures result in a pest infestation level below the required threshold, they would be acceptable measures and would be considered **equivalent** in meeting the ALP. A single measure may not be the only option that results in achieving the ALP. Two or more measures, each achieving less than the required level of control, may result in the desired ALP when used in combination as in a systems approach.

**Example 2:**

Assume that a pest population has a specific, known infestation rate and that 95% mortality is required for  $x$  number of consignments to meet the ALP. A number of treatments or management options could be available with different efficacies e.g. pest mortality from 95% to 99.9968% (probit 9). All the options meeting the desired efficacy of 95% mortality could then be considered **equivalent phytosanitary measures**, as they all meet the ALP.

24. In all cases, the choice of phytosanitary measure depends on a number of factors, but should also take into account the principles of necessity, minimal impact and non-discrimination.

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<sup>1</sup> This is the same as “required response” in the draft ISPM: Guidelines for the use of irradiation as a phytosanitary measure (ICPM03/9-4).

*Equivalence at the programme level*

25. ISPM No. 14: *The use of integrated measures in a systems approach for pest risk management* (FAO, 2002) contains guidance on evaluating the efficacy of measures and on evaluating systems approaches for pest risk management. This guidance is relevant for assessing the equivalence of measures within different programmes to achieve the appropriate level of protection. Where quantitative data are available, a quantitative determination of the overall ALP for a programme may be made. For a quarantine pest this could be expressed in terms of the “probable number of establishments” (see the box below).

**E. DETERMINING THE ALP - QUANTIFICATION AND EQUIVALENCE ASSESSMENTS (END POINTS AND UNITS)**

26. Where the end points of phytosanitary measures are not directly comparable, it will be essential to determine the ALP. Article 5 of the SPS Agreement describes the requirement for risk assessment in determining the measure to be applied to achieve the ALP.

27. A major issue associated with the determination of an ALP is consistency. The SPS Committee adopted guidelines in July 2000 (G/SPS/15) to further the practical implementation of the concept. The definition is:

“Appropriate level of sanitary or phytosanitary protection: The level of protection deemed appropriate by the member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.”

Note: Many Members otherwise refer to this concept as the “acceptable level of risk.” (SPS Agreement Annex A, para. 5).

The SPS Committee has noted that there have been difficulties with identifying the ALP of importing countries (G/SPS/W/111, para. 10).

28. According the SPS Committee, an ALP should be published but does not have to be quantitatively defined. It should be accompanied by a risk assessment or technical justification based on a relevant international standard, guideline or recommendation (G/SPS/19). An ALP may be defined in relation to past requirements, but this, again, is not necessarily quantitative. Guidance on the determination of ALPs in the phytosanitary field may therefore be helpful in addressing this issue (see box for an example of a quantitative approach).

### **Quantitative analysis of an ALP and determination of equivalence of measures**

(based on Sgrillo, 2002)

Quantitative analysis of the components of a plant/commodity production system can be used to identify the ALP for that system. For example, for a quarantine pest the ALP can be expressed in terms of rate of establishment using the following equation:

$$ALP \text{ (Probable number of establishments)} = \text{pest prevalence} \times \text{the total probability of establishment}$$

(Pest prevalence = rate of infection/infestation x number or size of consignments; and the total probability of establishment = multiplication of each specific probability or probability distribution)

Pest prevalence takes into account the elements of probability relating to pest prevalence in the imported consignment (initial pest population, efficacy of treatment, probability of survival). The total probability of establishment takes into account the probability of there being gravid females (invertebrate pests) or finding a mate, finding suitable hosts and finding suitable environmental conditions.

An evaluation of the equivalence of the available phytosanitary measures is possible where relevant data are available. Phytosanitary measures may be used to decrease the pest prevalence and/or decrease the probability of establishment. Measures may also be used to detect infested consignments. The equivalence of phytosanitary measures can be determined in relation to individual elements of the system or the system as a whole. Measures or combinations that result in the same rate of establishment i.e. meet(s) the desired ALP would be considered to be equivalent.

29. The ICPM is invited to:

1. *Consider* producing a guidance standard on the concept of equivalence of phytosanitary measures. This may be best achieved as a supplement to ISPM No. 1 or ISPM No. 5.
2. *Endorse* the inclusion of specific guidance on the determination of equivalence of phytosanitary measures in the forthcoming ISPM on efficacy of measures and consider whether additional guidance on equivalence should be included in new ISPMs (e.g. import regulatory systems) or when existing ISPMs are revised.
3. *Note* the specific use of the term “substantial equivalence” and recognize that it would not be appropriate for adoption as phytosanitary terminology.