

**Committee on Sanitary and Phytosanitary Measures**

**GUIDELINES TO FURTHER THE PRACTICAL IMPLEMENTATION OF ARTICLE 5.5**

At its meeting of 21-22 June 2000, the Committee adopted<sup>1</sup> the following guidelines called for in Article 5.5 of the Agreement on the Application of Sanitary and Phytosanitary Measures to further the practical implementation of that provision.

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**INTRODUCTION**

Article 5.5 of the Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement") states that:

*With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. Members shall cooperate in the Committee, in accordance with paragraphs 1, 2 and 3 of Article 12, to develop guidelines to further the practical implementation of this provision. In developing the guidelines, the Committee shall take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves.*

The following guidelines are intended to provide assistance to Members in the practical implementation of the provisions of Article 5.5 of the SPS Agreement. These guidelines do not add to nor detract from the existing rights and obligations of Members under the SPS Agreement nor any other WTO Agreement. These guidelines do not provide any legal interpretation or modification to the Agreement itself. The guidelines are without prejudice to the right of a Member to determine its appropriate level of sanitary and phytosanitary protection against risks to human life or health, or to animal and plant life or health.<sup>2</sup>

The guidelines address the two elements within Article 5.5: (1) the objective of achieving consistency in the application of the concept of the appropriate level of protection and (2) the obligation

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<sup>1</sup> At its meeting, the Committee adopted the guidelines on an ad referendum basis. Members who objected to the adoption of the guidelines were asked to make this known by 14 July 2000. No objections were raised by that date.

<sup>2</sup>"Risk" in the context of the SPS Agreement refers to the *likelihood* that an adverse event (pest or disease) will occur *and* the *magnitude of the associated potential consequences* on plant or animal life or health of the adverse event, or to the *potential for adverse effects* on human or animal life or health from food-borne risks. See paragraph 4, Annex A of the SPS Agreement.

to avoid arbitrary or unjustifiable distinctions in the levels considered appropriate if such distinctions result in discrimination or a disguised restriction on international trade. The determination of the appropriate level of protection is an element in the decision-making process which logically precedes the selection and use of one or more sanitary or phytosanitary measures. The following guidelines therefore address the application of the concept of the appropriate level of protection, and subsequently its practical implementation.

The comments accompanying the guidelines are designed to facilitate understanding of the guidelines through the provision of examples and further clarifications. These comments and examples are purely illustrative and not intended to be exclusive or complete.

The guidelines will be reviewed periodically and revised as necessary by the SPS Committee in the light of experience gained through the implementation of the SPS Agreement, the use of the guidelines themselves and any pertinent work done by the relevant international standard-setting organizations.<sup>3</sup> The Committee should undertake a first review of the guidelines within 36 months of their adoption by the Committee and thereafter as the need arises.

#### A. APPLICATION OF THE CONCEPT OF THE APPROPRIATE LEVEL OF PROTECTION

A.1. A Member should indicate the level of protection which it considers to be appropriate with respect to risks to human life or health, to animal life or health or to plant life or health in a sufficiently clear manner so as to permit examination of the extent to which any sanitary or phytosanitary measure achieves that level.

*Such an indication may be contained in a published statement or other text generally available to interested parties. The statement of the appropriate level of protection may be qualitative or quantitative, and should serve to guide its consistent implementation over time, and also to increase the transparency of the sanitary or phytosanitary regime. Examples might include government policy statements with regard to appropriate levels of protection in response to certain risks, or documents on animal health protection objectives or with respect to plant protection. The use of quantitative terms, where feasible, to describe the appropriate level of protection can facilitate the identification of arbitrary or unjustified distinctions in levels deemed appropriate in different situations.*

A.2. A Member should, when determining an appropriate level of protection, either as an overall policy objective or for a specific situation, consider:

- whether there is a difference between the level of protection under consideration and levels already determined by the Member in different situations and, if so,
- whether these differences are arbitrary or unjustifiable, and, if so,
- whether they may result in discrimination or in a disguised restriction on international trade.

*The comparison of levels of protection in different situations requires the existence of sufficient common elements to render them comparable and must be performed on a case-by-case basis. In the case of protection of plant or animal life or health from pests or disease, situations might be compared if they involve either the risk of entry,*

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<sup>3</sup> As indicated in Annex A, paragraph 3.

*establishment or spread of the same or a similar disease, or the risk of the same or similar associated potential biological and economic consequences. In the case of protection of human life or health from specific risks, i.e. food-borne risks, or of animal life or health from risks arising from feedstuffs, situations involving the same type of substance or pathogen, and/or the same type of adverse health effect, could be compared to one another.*

*The determination of whether differences in appropriate levels of protection are arbitrary or unjustifiable depends on the particular case and has to be determined on a case-by-case basis. The establishment of different levels of protection in the face of similar risks in different situations may raise the question as to whether the differences in the levels of protection are arbitrary or unjustifiable.*

*The determination of whether arbitrary or unjustifiable differences in levels of protection established by a Member in different situations do in fact result in discrimination or a disguised restriction on trade should be examined in the context of the circumstances of each case, including the potential effects on international trade. Although no precise definition of "discrimination or a disguised restriction on international trade" currently exists, cumulative occurrence of the following "warning signals" could indicate the existence of discrimination or a disguised restriction on trade:*

- *substantial differences in the levels of protection considered to be appropriate in different situations;*
- *the existence of arbitrary or unjustifiable differences in the levels of protection considered by a Member as appropriate in different situations;*
- *the absence of a scientific justification for a sanitary or phytosanitary measure applied allegedly to achieve the appropriate level of protection, or the fact that a measure is not based on a risk assessment as appropriate to the circumstances (either because there is no risk assessment or because there is an insufficient risk assessment).*

A.3. A Member should establish clear and effective communication and information flows within and between the authorities responsible for the determination of appropriate levels of protection.

*An important element in seeking to ensure that decisions on an appropriate level of protection meet the provisions of Article 5.5 is information and communication. The authorities responsible for the preparation and implementation of such decisions should be aware of relevant decisions taken by that Member in other cases, and particularly in situations comparable to the one at hand.*

A.4. To avoid arbitrary or unjustifiable differences in the level of protection a Member considers to be appropriate in different situations, a Member should compare any proposed decision on the level of protection in a particular situation with the level it has previously considered or is considering to be appropriate in situations which contain sufficient common elements so as to render them comparable with regard to human life or health, to animal life or health, or to plant life or health.

*It can be useful to compare a proposed appropriate level of protection with previous decisions, including those that might have been taken in an ad hoc fashion, to ensure that any differences in levels of protection applied in a similar situation are justifiable*

*and would not result in discrimination or a disguised restriction on international trade. If differences are observed in comparable situations, either the proposed level may need to be modified, or the level of protection previously determined may need to be revised in light of the Member's current views on its appropriate level of protection, or a combination of the two.*

*What a Member is comparing are the levels of protection against the risks posed by potential hazards to human, animal or plant life or health. Risk in the context of the SPS Agreement refers to the likelihood that an adverse event (pest or disease) will occur **and** the magnitude of the associated potential consequences on plant or animal life or health of the adverse event, or to the potential for adverse effects on human or animal life or health from food-borne risks. (See paragraph 4, Annex A of the SPS Agreement.) Accordingly, categorizing risks as "similar" must include a comparison of both the relevant likelihood and the corresponding consequences. To facilitate comparison of levels of protection considered appropriate in different situations, Members may wish to categorize the various risks they are examining into groups of what they consider to be similar. (See also the first comment to guideline A2.)*

*The comparison of the levels of protection considered appropriate in one situation with those considered appropriate in another situation can be facilitated if the potential damage is expressed in common terms, whether qualitative or quantitative. Where feasible, use of quantitative terms and/or common units can facilitate comparisons.*

A.5. In determining a new or modified appropriate level of protection, a Member should review its previous decisions regarding appropriate levels of protection in the light of the objectives and obligations of Article 5.5, taking into account current decisions and developments.

*In undertaking this review, a Member may wish to give priority to the review and revision, as necessary, of those decisions which most substantially deviate from the objectives and obligations of Article 5.5 and which may have the most negative impact on international trade.*

*Unless changes are made at the same time to all its comparable decisions on appropriate levels of protection, a Member may find it difficult to avoid (at least temporary) unjustifiable differences in levels of protection.*

*A Member should review its previous decisions on appropriate levels of protection at suitable intervals.*

A.6. In determining a new or modified appropriate level of protection a Member may find it helpful to examine any relevant international standards, guidelines or recommendations, or decisions taken by other Members facing similar risks and situations.

*Notwithstanding that it is the right of each Member to determine its appropriate level of protection and that there is no obligation for a Member to harmonize its level of protection with that of other Members, comparisons with the level of protection other Members have considered appropriate when addressing similar risks and situations may assist a Member in making its own decision.*

*Likewise, significant differences between the level of protection which would result from the application of the relevant international standard, guideline or recommendation*

*and the level of protection which a Member is considering may prompt the Member to re-consider its proposed level of protection.*

A.7. A Member may consider seeking expert advice to contribute to its decision-making process with regard to the determination of a new or modified appropriate level of protection.

*Advice may be sought from recognized, qualified experts, and could include commenting on any unjustifiable distinctions in levels of protection, potential discriminatory trade effects or other aspects related to consistency in the application of its appropriate level of protection. A Member may seek assistance from the relevant international standard-setting organizations in identifying appropriate experts.*

A.8. A Member should clearly identify those situations which it considers justify its acceptance exceptionally of a lower level of protection for human health specifically with respect to risks to which people voluntarily expose themselves.

*Reasons for a significant difference in a proposed or accepted level of protection for human health may, in exceptional circumstances, include a risk which humans voluntarily accept. Such circumstances might arise with respect to traditional foods or some other products for which consumers knowingly accept a higher risk than that generally considered to be appropriate for food products.<sup>4</sup>*

## B. PRACTICAL IMPLEMENTATION OF THE CONCEPT OF AN APPROPRIATE LEVEL OF PROTECTION

The SPS Agreement does not contain explicit provisions which oblige a Member to determine its appropriate level of protection, although there is an implicit obligation to do so. In practice, and for various reasons, Members are not always able to indicate precisely their appropriate level of protection. In such cases, the appropriate level of protection may be determined on the basis of the level of protection reflected in the sanitary or phytosanitary measures in place. Therefore, to further the practical implementation of this provision, the following guidelines address the selection and use of measures. This is without prejudice to the other provisions of the SPS Agreement which relate to measures, which the Committee may decide to address separately.

B.1. A Member should establish clear and effective communication and information flows within and between the authorities responsible for the determination of appropriate levels of protection, and those responsible for the selection and implementation of sanitary or phytosanitary measures designed to achieve the appropriate level of protection.

*Since the concept of appropriate level of protection is applied in practice through sanitary or phytosanitary measures, communication and transparency between the government authorities responsible for the selection and implementation of sanitary or phytosanitary measures and those responsible for the determination of the appropriate level of protection is an important element in enhancing consistency.*

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<sup>4</sup> Examples which were identified during the negotiation of this provision include the consumption of alcoholic beverages, or substantial consumption of some traditional foods such as smoked fish, or of varieties of fish known to be toxic.

B.2. A Member should establish common approaches or consistent procedures for use by the authorities assessing risks and evaluating the measures which might be applied to achieve the desired levels of protection. In particular, a common approach should be developed with respect to risks affecting human life or health, a common approach for consideration of risks to animal life or health, and a common approach for risks to plant life or health.

*Clearly identified, comprehensive and consistent procedures for assessing risks and for evaluating measures to reduce risk to acceptable levels will assist a Member to be more consistent in the application of its appropriate level of protection.*

*What a Member is comparing are the measures against the risks posed by potential hazards to human, animal or plant life or health. Risk in the context of the SPS Agreement refers to the likelihood that an adverse event (pest or disease) will occur **and** the magnitude of the associated potential consequences on plant or animal life or health of the adverse event, or to the potential for adverse effects on human or animal life or health from food-borne risks. (See paragraph 4, Annex A of the SPS Agreement.) Accordingly, categorizing risks as "similar" must include a comparison of both the relevant likelihoods and the corresponding consequence. To facilitate comparison of levels of protection considered appropriate in different situations, Members may wish to categorize the various hazards they are examining into groups of what they consider to be similar.*

*To the extent possible, risk should be assessed using the principles and procedures developed by the relevant international standard-setting organizations, taking into account the nature of the hazards in question.*

B.3. A Member should compare any proposed measure intended to achieve the appropriate level of protection in a particular situation with other sanitary or phytosanitary measures it has taken, or is considering, with regard to human life or health, to animal life or health, and plant life or health in situations which present sufficient common elements so as to render them comparable.

*Since the concept of an appropriate level of protection is applied through the selection and implementation of a sanitary or phytosanitary measure (or measures), such a comparison can be useful to ensure the consistency of the proposed measure with any previous measures designed to achieve the same level of protection in situations which present sufficient common elements so as to render them comparable.*

B.4. A Member should routinely review existing measures applied to achieve its appropriate level of protection in accordance with the objectives of guideline A.5, taking also into account current decisions and developments.

*In undertaking this review, a Member may wish to give priority to the review and revision, as necessary, of the measures applied to achieve the appropriate levels of protection reviewed in accordance with guideline A.5.*

B.5. In considering a measure to achieve an appropriate level of protection in a particular situation, a Member should determine whether a relevant international standard, guideline or recommendation exists, and if it does, whether adoption of it would achieve the Member's appropriate level of protection.

*Comparisons with the manner in which an international standard, guideline or recommendation would address a particular risk may assist a Member in clarifying its own decision. Significant differences in the measure applied by a Member to address assessed risk compared to the measures that would result from the application of a relevant international standard, guideline or recommendation, may encourage the Member to reconsider whether it is acting in accordance with its obligations under the SPS Agreement.*

B.6. In considering a proposed measure to achieve its appropriate level of protection in a particular situation, a Member may find it helpful to examine measures applied by other Members facing similar risks and situations.

*Notwithstanding that there is no obligation for a Member to harmonize its measures with those of other Members, significant differences in the measures applied by a Member in order to address a particular risk compared to the measures applied by other Members facing similar risks and situations, and in particular measures which are less restrictive of trade, may prompt the Member to reconsider whether it is acting consistently with its obligations under the SPS Agreement. The Member should in particular compare its proposed measure with those applied by other Members seeking a similar level of protection from risks.*

B.7. A Member may consider seeking expert advice on the selection and implementation of sanitary and phytosanitary measures to achieve its appropriate level of protection.

*Advice may be sought from recognized, qualified experts, and could include commenting on any potential discriminatory trade effects arising from specific sanitary and phytosanitary measures. A Member may seek assistance from the relevant international standard-setting organizations in identifying appropriate experts.*

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