

Committee on Sanitary and Phytosanitary Measures

CONSISTENCY IN RISK MANAGEMENT DECISIONS

Note by the Secretariat

Introduction

1. Article 5, paragraph 5 of the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) states

"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. ..."

The Committee is charged to develop guidelines "to further the practical implementation of this provision." To assist the Committee in this task, the Secretariat has prepared this background paper which reviews the negotiating history and previous discussions regarding the inclusion of this provision in the Agreement.

2. For the purposes of this paper, "risk management decisions" refers to the decisions taken by governments regarding the need for and type of measures to be taken to ensure that food and beverages are safe for human consumption and feedstuffs safe for animal consumption; that humans are adequately protected from animal- and plant-carried diseases; that animals and plants are adequately protected from pests and diseases; and that the national territory is protected against the spread of pests. Decisions as to whether any action or measure is needed, as well as what type of action to take, are encompassed by the term "risk management".

3. The basis on which those risk management decisions are made and the manner in which they are taken is not at issue here; regardless of what basis is used for their decisions, governments have long been in the business of deciding that certain foodstuffs (or elements in foodstuffs) should be restricted or prohibited and that the spread of certain animal diseases or plant pests should be limited -- in other words, taking decisions in order to manage risks to health. What is at issue here is to ensure that these decisions are not arbitrary or discriminatory.

4. As the following review of the drafting history of the SPS Agreement makes clear, it was agreed at a very early stage in the negotiations that sanitary and phytosanitary measures should not be applied in an arbitrary or unjustifiably discriminatory manner. It was also agreed that sanitary and phytosanitary measures should primarily be based on risk assessment and analysis, and subsequently that each government was responsible for the determination of what it considered to be its acceptable level of risk (appropriate level of sanitary or phytosanitary protection). From this it followed that to ensure that such governmental decisions did not result in arbitrary or unjustifiable discrimination in

the application of sanitary or phytosanitary measures, there must be some consistency in the decisions taken.

Non discrimination

5. The underlying objective of the negotiation of an agreement on the application of sanitary and phytosanitary measures was to ensure that sanitary and phytosanitary measures which result in restrictions on international trade are justified on the basis of a scientifically demonstrated need to protect health. The concern to ensure that measures not be arbitrary or unjustifiably discriminatory was introduced early in the negotiations, and appeared to be broadly accepted. For example, early in October 1989 the Cairns Group proposed that:

"SPS measures shall only be applied to the extent necessary to protect human, animal or plant life or health and shall be based on verifiable scientific evidence. They shall not be applied in a manner which creates arbitrary, disguised or unjustifiable obstacles to international trade." (MTN.GNG/NG5/W/112).

The December 1989 proposal of the European Communities echoed some of these views:

"Such a framework [of rules] will be helpful in defining more precisely under which conditions the exception of Article XX(b) shall be applied to ensure the absence of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or disguised restrictions on trade." (MTN.GNG/NG5/W/146).

The Nordic proposal of February 1990 stated that:

"The objective of an SPS discipline should be to ensure that, consistent with well-established scientific evidence, where available, SPS measures are only applied to the extent necessary to protect human, animal or plant life or health, and that they are not applied in a manner that creates arbitrary, disguised or unjustifiable obstacles to international trade." (MTN:GNG/NG5/WGSP/W/10)

Use of risk assessment

6. The use of risk assessment methodology to ensure that there was a scientifically demonstrated need to protect human, animal or plant health, and to what extent, was also introduced early in the negotiation of the Agreement. At about the same time, the argument was made that it was the sovereign right of governments to decide what level of risk was acceptable, or, in the terms adopted for the Agreement, on the acceptable level of sanitary and phytosanitary protection. For example, in its Informal Discussion Paper on Risk Assessment submitted to the Working Group on Sanitary and Phytosanitary Regulations and Barriers in April 1990, the United States noted:

"The relevant international standards-setting organizations should provide risk assessment guidelines for national sanitary and phytosanitary measures, and these guidelines may be used to evaluate the legitimacy of a measure which is perceived as unjustified by another country. However, it is not the role of these international organizations to do the risk assessment for any individual country."

The proposal by the Cairns Group, also in April of 1990, made it clear that:

"The onus of justifying the acceptable level of risk established by an importing country rests with that country." (MTN.GNG/NG5/W/164)

An earlier Nordic proposal (November 1988) provided some arguments as to why the decision of an acceptable level of risk should rest with the government:

"Local and regional considerations, including consumption patterns, cannot be separated from the concept of sound and verifiable evidence. ... In some cases, however the scientific evidence is relative in nature: the greater the concentration of a certain substance, the higher the risk for health. In such cases governments must have the right to individually assess the acceptable risk level for their country." (MTN.GNG/NG5/88)

Consistency in risk management

7. Once the concept of governments deciding what was an acceptable level of risk on the basis of an analysis of the actual risks involved was adopted as a basic element of the emerging SPS Agreement, it was recognized that disciplines were needed to ensure that this right to take a sovereign decision not be used to circumvent the obligations of non-arbitrariness or unjustifiable discrimination. Although the disciplines under discussion regarding the use of international standards and the assessment of risks could reduce the scope for arbitrariness and unjustifiable discrimination in the identification and measurement of risks, it was noted that there was still ample scope for governments to succumb to political pressures to protect certain domestic industries from foreign competition through their decisions regarding acceptable levels of risk/sanitary and phytosanitary protection. The proposal tabled by the Cairns Group on 18 April 1990 suggested addressing this concern in the following manner:

"Risk assessment principles and procedures should be applied in a uniform way. The acceptable level of risk used by an importing country should not be different for the same commodity from different origins or between locally produced and imported commodities." (MTN.GNG/NG5/W/164)

8. This concern was reflected in the first draft text of an Agreement put forward for consideration in July 1990:

"18. [Contracting parties shall, as far as possible, ensure that their sanitary or phytosanitary measures reflect an acceptable level of sanitary or phytosanitary protection which is consistent with respect to other internal measures taken to protect human, animal or plant life or health.] " (MTN.GNG/NG5/W/170, Annex II)

9. Detailed, informal discussions were subsequently held regarding this proposed text. Three separate areas of concern were raised in the course of those discussions and addressed in subsequent proposed text. These were (1) how this provision could be applied in practice; (2) whether consistency between decisions regarding human health with animal and/or plant health concerns was desirable or politically acceptable; and (3) to what extent was consistency applicable in the face of voluntary human consumption of high risk foods and beverages.

10. With respect to the application of this provision, it was noted that most risk assessment methodologies resulted in information regarding both the probability of occurrence (of food poisoning, for example, or of the entry and spread of a plant pest or animal disease) and the extent or costs of

the damage that could occur. When risk assessments for different products or situations resulted in similar probability/value assessments, they should uniformly be judged to be acceptable risks or not, irrespective of the products (or countries) involved. However, as there was not sufficient time in the course of the negotiation to further elaborate how a government could ensure such consistency in its decision-making, it was agreed that the Committee should be given the task to develop guidelines in this regard.

11. The next concern was that what were considered as acceptable levels of risk with regard to animal or plant health could not necessarily be considered as (politically) acceptable levels of risk in matters regarding human health, or vice-versa. That is, consistency might be desirable and achievable among decisions regarding animal health, or even between plant and animal health issues, however an across-the-board consistency between decisions regarding human, animal and plant health risks was not acceptable. The text was therefore modified to separate the requirement for consistency among decisions regarding human health from consistency among animal and plant health decisions.

12. The final concern raised in the negotiation of this provision was that humans at times willingly consumed products which pose relatively high health risks (such as alcoholic beverages, smoked meats or poisonous fish), yet such high risks could not be considered as generally acceptable with regard to food and beverages. Consistency should not be required, for example, between decisions on acceptable risks from pesticide residues in baby foods and accepted health risks from whisky or vodka. The Committee is thus tasked to take this factor into account when it develops the guidelines for the implementation of the provision.

13. The proposed text of the Agreement tabled in November 1990 addressed these concerns:

"19. With the objective of achieving consistency in the application of the concept of appropriate level of sanitary and phytosanitary protection against risks to human life or health, or to animal and plant life or health, each contracting party 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.

"20. Contracting parties shall co-operate in the Committee on Sanitary and Phytosanitary Measures in accordance with paragraphs 40 and 41 of this decision, 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." (MTN.GNG/NG5/WGSP/7)

Subsequent to November 1990, there was no further discussion or substantive revision of this provision. It was not identified as an area of contention or disagreement at the meeting in Brussels in December 1990 nor when it appeared in subsequent drafts of the Agreement. The provision was thus considered to have been generally accepted as of the end of 1990. For the final version of the Agreement, the two paragraphs above were combined into a single paragraph, and only editorial changes (substituting "Members" for "Contracting Parties", etc.) were made.

14. As the drafting history demonstrates, the purpose of this provision is to ensure that government decisions as to what levels of risk are acceptable in various situations are not taken in such a manner as to result in discrimination or disguised restrictions on trade. It has been agreed that the mechanism for ensuring that governments avoid arbitrary or unjustifiable distinctions in the levels of risk they accept is to require governments to be consistent in their risk management decisions.