

Committee on Sanitary and Phytosanitary Measures

RISK ANALYSIS

Note by the Secretariat

Introduction

1. Article 5:5 of the Agreement on Sanitary and Phytosanitary Measures (the "SPS Agreement") states, in part, 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. "

The Article also indicates that the Committee shall develop guidelines to further the practical implementation of this provision.

2. In order to put this task into perspective, this note (i) briefly summarizes the work on risk analysis undertaken by the Office international des épizooties (OIE), the FAO/WHO Codex Alimentarius Commission (Codex) and the International Plant Protection Convention (IPPC); and (ii) highlights the relevant provisions of the SPS Agreement. This note is intended to provide background information to facilitate the task of the Committee. It is not intended to provide a legal interpretation of the Agreement.

Risk Analysis Work by OIE, Codex and IPPC

3. Since the drafting and entry into force of the SPS Agreement, a substantial amount of work has been undertaken in the area of risk analysis by the three international organizations referred to in the Agreement, OIE, Codex and IPPC.

4. The following table briefly summarizes for each of these organizations what they have identified to be the steps of risk analysis; their definitions of risk assessment, risk management and risk communication; and the elements of risk management which they have identified. Although the definitions used by each of these organizations is specific to their field of operation, there is considerable commonality of views regarding the processes involved in risk analyses for sanitary and phytosanitary measures.

	OIE	Codex	IPPC
Summary of work	In May 1993, the OIE International Committee adopted recommendations on import risk analysis, which were then included in the <i>International Animal Health Code</i> (as Section 1.4). Similar provisions were adopted in the International Aquatic Animal Health Code in May 1995.	General principles for risk assessment and definitions were considered by the Codex Committee on General Principles in November 1996, and have been proposed for inclusion in the Codex Procedural Manual. A decision on this proposal is expected to be taken by the Codex Commission when it meets in June 1997. More recently, principles on risk management have been drafted and will be considered by Codex member governments and the Codex Commission.	The IPPC guidelines for pest risk analysis was approved by the FAO Conference in October 1995. The IPPC standard includes definitions and descriptions of the processes to be followed.
Elements of risk analysis	risk assessment, which may be followed by risk management and risk communication - evaluation of Veterinary Services - zoning and regionalization of countries - surveillance and monitoring of animal health.	risk assessment - risk management - risk communication	initiating the process for analyzing risk - assessing pest risk - and managing pest risk
Definitions and/or descriptions risk assessment	The processes of identifying and estimating the risks associated with the importation of a commodity and evaluating the consequences of taking those risks.	A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment and (iv) risk characterization.	Initiating the process involves identification of pests or pathways for which the pest risk assessment is needed. Pest risk assessment determines whether each pest identified as such, or associated with the pathway, is a quarantine pest, characterized in terms of likelihood of entry, establishment, spread and economic importance.

	OIE	Codex	IPPC
risk management	The identification, documentation, and implementation of the measures that can be applied to reduce the risks and their consequences.	The process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures.	The decision-making process of reducing the risk of introduction of a quarantine pest. Pest risk management involves developing, evaluating, comparing and selecting options for reducing the risk.
risk communication	The processes of communicating the risk assessment results to the regulators of the import programmes, and to other interested parties such as industry and public.	The interactive exchange of information and opinions concerning risk among risk assessors, risk managers, consumers and other interested parties.	
Elements of risk management	identify options assess options select most appropriate option implement selected option document and monitor	risk evaluation risk management option evaluation implementation of management decision monitoring and evaluation	generate, evaluate and compare management options select option monitor and evaluate after implementation

Risk Analysis in the SPS Agreement Context

5. Although the term "risk analysis" is not used, per se, in the SPS Agreement, the Agreement clearly addresses at least some aspects of this multi-step process as defined by the three international organizations. Risk assessment is explicitly addressed in Articles 5:1, 5:2 and 5:3. Furthermore, the Agreement provides a definition of risk assessment that addresses concerns relating to food safety, animal or plant health protection¹.

Risk Assessment

6. The SPS Agreement requires Members to base their sanitary and phytosanitary measures on an assessment of the risk to human, animal or plant health. However, the current situation is that the use of formal risk assessment procedures, and much less quantitative risk assessment, is not yet a common practice of many Members. Its use is evolving rapidly, but is not yet systematically widespread. Nonetheless, Members are faced almost daily with the prospect of imports which potentially may pose sanitary or phytosanitary risks, and Members do, in practice, in one manner or another evaluate these potential risks.

7. It is clear from the definitions developed by the three international organizations that risk assessment is primarily a scientific procedure to identify the existence and severity of possible risks. What is done with the information resulting from a risk assessment is risk management (and sometime risk communication).

Risk Management

8. Risk management involves a number of steps. These include, *inter alia*, decisions regarding the acceptable level of risk; identification of possible options to reduce or eliminate the identified risk; evaluation and selection among these options; implementation of the selected measures, as appropriate; and monitoring and control of the effectiveness of the selected measure.

9. Risk management, or at least several elements of it, are addressed, *inter alia*, in Articles 5:4, 5:5, and 5:6. These provisions address the decisions to be taken on what level of risk is acceptable, as well as what measure is applied to ensure the selected level of protection. The Agreement also provides a definition on the appropriate level of sanitary or phytosanitary protection, also known as the acceptable level of risk.²

10. Although the situation of Members may differ in terms of their current use of formalized risk assessment procedures, their resources and the technical expertise they have in this regard, each and

¹Annex 1, definition 4 defines risk assessment as: "The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs."

²Annex 1, definition 5 defines the appropriate level of sanitary or phytosanitary protection as: "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".

every Member nonetheless regularly makes decisions as to whether to permit the imports in question without further restriction, or whether to require some particular treatment to reduce the potential risks, or whether to ban altogether the importation of the product concerned. This decision, however unsophisticated methods it may be based on, represents a management of the risks at hand and reflects an inherent decision of what level of risk the Member considers to be acceptable in that particular situation.

11. It is this part of the decision-making element of risk management, i.e., the determination of the level of sanitary or phytosanitary risk which a Member determines to be acceptable in any particular situation, which is the subject of Article 5:5. The objective of the proposed guidelines is to assist each Member to enhance the consistency of its decisions in this respect.

Risk Communication

12. Some elements related to risk communication are also addressed in the Agreement, through (i) its transparency requirements, including those of publication and notification of measures, the provision of information through Enquiry Points, and the explanation of measures upon request; and (ii) the technical assistance provisions..