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FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD HEALTH
ORGANIZATION

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Agenda Item 3

CX/GP 99/4

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON GENERAL PRINCIPLES

Fourteenth Session

Paris, France, 19 – 23 April 1999

RISK ANALYSIS

2) WORKING PRINCIPLES FOR RISK ANALYSIS

The 22nd Session of the Codex Alimentarius Commission considered the application of risk analysis principles in Codex, in the light of the recommendations of the Joint FAO/WHO Expert Consultation on Risk Management and Food Safety. The Commission discussed a document which had been prepared with the objective of developing an action plan to apply risk analysis more consistently and uniformly throughout Codex, with a particular emphasis on risk management. On this basis the Commission agreed on an Action Plan for Codex-wide Development and Application of Risk Analysis Principles and Guidelines.

The Commission requested the Committee on General Principles to elaborate integrated principles for risk management and risk assessment policy setting, risk communication and documentation for inclusion in the Procedural Manual. Once principles have been established, specific guidelines should be prepared as required to aid in the uniform application of the principles. The CCGP should coordinate this exercise and all relevant Codex Committees should be involved. The principles and guidelines should be included in the Procedural Manual, with the addition of an introductory narrative on risk analysis in the Codex system and identification of the responsibilities of Committees in the implementation of the principles and guidelines.

The Commission also agreed that the Working Principles should be developed through the Step Procedure and that steps could be omitted if the CCGP so recommended. The 13th Session of the CCGP considered the Proposed Draft Working Principles in general terms and noted several proposals for amendemnt but did not reach consensus on the elements which should be included. The Committee agreed that the document should be redrafted in the light of the discussion. The redrafted Principles contained in the Annex have been revised taking into account the written comments presented to the Committee and the proposals made during the session (ALINORM 99/33, paras 18-23).

During the discussion, some delegations and the Observer from Consumers International proposed the inclusion of a reference to the precautionary principle. This proposal was also included in the comments from the European Community. Other delegations stated that the inclusion of such a reference would need to be based on as agreed definition of the precautionary principle, and understanding of its scope of application. Although no recognized definition exists and there is no consensus on its application at this stage, a reference to this principle has been included under “Risk Management” in order to ask for comments and facilitate the discussion on this issue, with a view to its further clarification.

Governments and international organizations wishing to submit comments on the Proposed Draft Principles (at Step 3) should do so in writing to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, via delle Terme di Caracalla, 00100 Rome, Italy, **before 20 March 1999**.

PROPOSED DRAFT CODEX WORKING PRINCIPLES FOR RISK ANALYSIS

(At Step 3 of the Procedure)

Principles of risk analysis for Codex-wide application can be aggregated from formal Codex activities, current responses by Codex Committees, other sources, and a general consideration of the practical implications for the Codex system. The three principles denoted in **bold face** have been included in the 10th edition of the Procedural Manual (page 147). A number of recommendations in the earlier Codex reports on risk analysis have been subsumed by the recent establishment of a list of Codex definitions and by general principles presented in this report.

The changes to the document considered by the CCGP in 1998 (CX/GP 98/4) are shown in italics.

RISK ANALYSIS

Health and safety aspects of Codex decisions and recommendations should be based on a risk assessment, as appropriate to the circumstances.

Risk analysis consists of three components: risk assessment, risk management and risk communication

Risk analysis should be based on sound science, should incorporate the four steps of the risk assessment process and should be documented in a transparent manner. There should be a general undertaking to identify *separately* and systematically document the elements of risk assessment, *risk management and risk communication* that are incorporated in the elaboration of Codex standards.

Risk analysis procedures used by Codex should be harmonized with those of other bodies and national governments to the greatest extent possible.

The risk analysis needs of developing countries should be specifically identified and addressed. Adequate flexibility should be provided where appropriate to meet any special needs of developing countries.

The risk analysis process should be as open and transparent as possible.

RISK ASSESSMENT

Risk assessments should use available quantitative information to the greatest extent possible and risk characterisations should be presented in a readily understandable and useful form.

Risk assessments should be based on realistic exposure scenarios, with consideration of “worst-case” situations being defined by risk assessment policy. *They should be applicable to susceptible and high risk population groups. Risk assessment should take into account all available scientific data and relevant production processes, methods of sampling and inspection and the prevalence of specific diseases. Long term effects and synergic effects should be taken into account in worst case studies.*

Risk assessments should be transparent, documented and accessible to interested parties.

Risk estimates should wherever possible include a numerical expression of uncertainty, and this should be conveyed to risk managers in a readily understandable form *Risk assessment should take into account uncertainty in exposure estimates and, if necessary, in the assessment of dose-effect toxicity.* The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessor.

Risk assessment may include non-measurable, qualitative data.

There should be increased recognition of differences between acute and chronic (*including long-term*) adverse health effects in carrying out risk assessments and establishing food standards.

There should be a functional separation of risk assessment and risk management, while recognising that some interactions are essential for a pragmatic approach.

RISK ASSESSMENT POLICY

Determination of risk assessment policy should be included as a specific component of risk management.

RISK MANAGEMENT

Risk management should follow a structured approach.

Protection of human health should be the primary consideration in risk management decisions.

Risk management should be focused on agreed outcomes rather than on processes.

Risk management policies should be documented, and where appropriate *clearly* acknowledged in individual Codex standards so as to foster a wider understanding of risk management concepts, and the particular risk policy used in the elaboration of individual Codex standards.

Guidelines should be available for the inclusion in risk management decisions of “other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade”.

If economic *analyses have to be* used in support of risk management decisions, the process should be subject to consistent and transparent decision-making criteria *and should be consistent with fair trade practices*.

Where risk management involves selection of options other than (or in addition to) quantitative food standards for the prevention, elimination or control of hazards, each available option should be evaluated according to a relevant risk management framework.

“Horizontal” issues¹, , in the elaboration of food standards and related texts according to risk analysis principles should be clearly identified and consistently addressed.

Risk management decisions should take into account conditions prevailing in all countries, where possible, without affecting the agreed outcome.

The situations where scientific evidence is insufficient or negative effects are difficult to evaluate should be clearly identified. In such situations, it should be possible to apply the precautionary principle. It will be necessary to elaborate guidelines on the use of this principle in risk management decisions.

RISK COMMUNICATION²

Risk analysis should include clear, interactive communication, *exchange of information and opinions on risk and related factors, between risk assessors and risk managers*, and communication with consumers and other interested parties in all aspects of the process.

A risk communication strategy should be proactive and include a plan specifying how information is to be communicated.

Risk managers should include an assessment of uncertainty in risk estimates in their communication with the public.

DOCUMENTATION

Risk assessment and risk management should be fully documented in a transparent manner. Risk management should be transparent, flexible, objective and repeatable and this requires full documentation.

¹ *Issues of a general nature which affect all standards in relation to food safety*

² Risk communication has yet to be formally addressed by Codex, but the following working principles introduce relevant issues. A major function of risk communication is establishing a process whereby information and opinion essential to effective risk management is made available. All parties interested in the risk management decisions of the CAC should be involved to the extent that is practical and reasonable.

Risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions. Food standards must be consistent with new scientific knowledge and other information relevant to risk analysis.