

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
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Agenda Item 9

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Twenty-sixth Session, FAO Headquarters, Rome, Italy, 30 June – 7 July 2003

RISK ANALYSIS POLICIES OF THE CODEX ALIMENTARIUS COMMISSION

BACKGROUND

1. The Codex Alimentarius Commission has been discussing policies for risk analysis since its 20th Session and at its 22nd Session (Geneva, 1997), it adopted an Action Plan for Codex-wide Development and Application of Risk Analysis Principles and Guidelines¹. Elements of the Action Plan may be summarized as follows:

- a) The Codex Committee on General Principles was requested to elaborate integrated principles for risk management and risk assessment policy setting, risk communication and documentation for inclusion in the Procedural Manual;
- b) Once principles have been established, relevant Codex Committees shall prepare specific guidelines as required to aid in the uniform application of the principles. The Codex Committee on General Principles should be requested to co-ordinate this exercise and all relevant Codex Committees should be involved;²
- c) As the principles and guidelines have been established, they will 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 implementation of the principles and guidelines;

¹ Report of the 22nd Session of the Codex Alimentarius Commission, ALINORM 97/37, paragraphs 160-167.

² This would include requiring that Codex Committees involved in any aspect of risk analysis formally describe their implementation of the Codex principles and guidelines, using a standardised summary format, for publication in their respective reports and recommend that advisory bodies such as JECFA and JMPR do the same. It would also require that Codex Committees develop standards using these principles and guidelines as a checklist, and in doing so adhere closely to their documented risk assessment/risk management policies.

- d) Recognise that the judgement of equivalence of food control systems in different countries is a critical issue, and that Codex principles and guidelines associated with determination of equivalence will facilitate this process;
- e) Until such time as the principles are adopted by the Commission, request JECFA, JMPR and other advisory bodies and Codex Committees to continue evaluating and improving the application of the elements of risk assessment and risk management that they have prioritised for attention;
- f) Encourage further development of qualitative risk assessment approaches so as to achieve early improvements in elaboration of food standards.

2. The Codex Committee on General Principles has now completed the first of these tasks, and the *Draft Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* have now been submitted to the Commission for adoption³. The Committee has also submitted three new definitions for the consideration of the Commission. These definitions are contained in Appendix II.

3. The Commission may wish to note that a revised definition of *Risk Communication* was adopted in 2001 (24th Session), but has not been incorporated in the Procedural Manual. This definition is also included in Appendix II for information.

ACTION REQUESTED OF THE COMMISSION

4. The Commission is invited to take the following actions:
- a) Adopt the *Draft Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* at Step 8 of the Codex Procedure, for inclusion in the Procedural Manual;
 - b) Adopt the draft Definitions for *Risk Assessment Policy*, *Risk Profile* and *Risk Estimate* for inclusion in the Procedural Manual; and
 - c) Instruct relevant Codex Committees to prepare (or to complete) specific guidelines, as required, to aid in the uniform application of the Working Principles.

³ See also the Report of the Eighteenth Session of the Codex Committee on General Principles, Paris, 7-11 April 2003, ALINORM 03/33A, paragraphs 10-31.

APPENDIX I

**DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS FOR APPLICATION IN THE
FRAMEWORK OF THE CODEX ALIMENTARIUS**

(At Step 8 of the Procedure)

SCOPE

- 1) These principles for risk analysis are intended for application in the framework of the Codex Alimentarius.
- 2) The objective of these Working Principles is to provide guidance to the Codex Alimentarius Commission and the joint FAO/WHO expert bodies and consultations, so that food safety and health aspects of Codex standards and related texts are based on risk analysis.
- 3) Within the framework of the Codex Alimentarius Commission and its procedures, the responsibility for providing advice on risk management lies with the Commission and its subsidiary bodies (risk managers), while the responsibility for risk assessment lies primarily with the joint FAO/WHO expert bodies and consultations (risk assessors).

RISK ANALYSIS - GENERAL ASPECTS

- 4) The risk analysis used in Codex should be:
 - applied consistently;
 - open, transparent and documented;
 - conducted in accordance with both the *Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken into Account* and the *Statements of Principle Relating to the Role of Food Safety Risk Assessment*; and
 - evaluated and reviewed as appropriate in the light of newly generated scientific data.
- 5) The risk analysis should follow a structured approach comprising the three distinct but closely linked components of risk analysis (risk assessment, risk management and risk communication) as defined by the Codex Alimentarius Commission¹, each component being integral to the overall risk analysis.
- 6) The three components of risk analysis should be documented fully and systematically in a transparent manner. While respecting legitimate concerns to preserve confidentiality, documentation should be accessible to all interested parties².
- 7) Effective communication and consultation with all interested parties should be ensured throughout the risk analysis.
- 8) The three components of risk analysis should be applied within an overarching framework for management of food related risks to human health.
- 9) There should be a functional separation of risk assessment and risk management, in order to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers and to reduce any conflict of interest. However, it is recognized that risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential for practical application.

¹ For the definition of terms used through these Working Principles, see *Definitions of Risk Analysis Terms Related to Food Safety*, Procedural Manual of the Codex Alimentarius Commission, 13th Edition, FAO/WHO, Rome, in preparation.

² For the purpose of the present document, the term “interested parties” refers to “risk assessors, risk managers, consumers, industry, the academic community and, as appropriate, other relevant parties and their representative organizations”.

10) When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Codex Alimentarius Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence.³

11) Precaution is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis. Where there is sufficient scientific evidence to allow Codex to proceed to elaborate a standard or related text, the assumptions used for the risk assessment and the risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard.

12) The needs and situations of developing countries should be specifically identified and taken into account by the responsible bodies in the different stages of the risk analysis.

RISK ASSESSMENT POLICY

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

14) Risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties. This procedure aims at ensuring that the risk assessment is systematic, complete, unbiased and transparent.

15) The mandate given by risk managers to risk assessors should be as clear as possible.

16) Where necessary, risk managers should ask risk assessors to evaluate the potential changes in risk resulting from different risk management options.

RISK ASSESSMENT⁴

17) The scope and purpose of the particular risk assessment being carried out should be clearly stated and in accordance with risk assessment policy. The output form and possible alternative outputs of the risk assessment should be defined

18) Experts responsible for risk assessment should be selected in a transparent manner on the basis of their expertise, experience, and independence with regard to the interests involved. The procedures used to select these experts should be documented including a public declaration of any potential conflict of interest. This declaration should also identify and detail their individual expertise, experience and independence. Expert bodies and consultations should ensure effective participation of experts from different parts of the world, including experts from developing countries.

19) Risk assessment should be conducted in accordance with the *Statements of Principle Relating to the Role of Food Safety Risk Assessment* and should incorporate the four steps of the risk assessment, i.e. hazard identification, hazard characterization, exposure assessment and risk characterization.

20) Risk assessment should be based on all available scientific data. It should use available quantitative information to the greatest extent possible. Risk assessment may also take into account qualitative information.

21) Risk assessment should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection and the prevalence of specific adverse health effects.

22) Risk assessment should seek and incorporate relevant data from different parts of the world, including that from developing countries. These data should particularly include epidemiological surveillance data, analytical and exposure data. Where relevant data are not available from developing countries, the Commission should request that FAO/WHO initiate time-bound studies for this purpose. The conduct of the risk assessment

³ Statement adopted by the 24th Session of the Commission (ALINORM 01/41, paras. 81-83)

⁴ Reference is made to the *Statements of Principle Relating to the Role of Food Safety Risk Assessment*, Procedural Manual of the Codex Alimentarius Commission, 13th ed., Appendix, FAO/WHO, Rome, in preparation.

should not be inappropriately delayed pending receipt of these data; however, the risk assessment should be reconsidered when such data are available.

23) Constraints, uncertainties and assumptions having an impact on the risk assessment should be explicitly considered at each step in the risk assessment and documented in a transparent manner. Expression of uncertainty or variability in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable.

24) Risk assessments should be based on realistic exposure scenarios, with consideration of different situations being defined by risk assessment policy. They should include consideration of susceptible and high-risk population groups. Acute, chronic (including long-term), cumulative and/or combined adverse health effects should be taken into account in carrying out risk assessment, where relevant.

25) The report of the risk assessment should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment. Minority opinions should also be recorded. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors.

26) The conclusion of the risk assessment including a risk estimate, if available, should be presented in a readily understandable and useful form to risk managers and made available to other risk assessors and interested parties so that they can review the assessment.

RISK MANAGEMENT

30) While recognizing the dual purposes of the Codex Alimentarius are protecting the health of consumers and ensuring fair practices in the food trade, Codex decisions and recommendations on risk management should have their primary objective the protection of the health of consumers. Unjustified differences in the level of consumer health protection to address similar risks in different situations should be avoided.

31) Risk management should follow a structured approach including preliminary risk management activities⁵, assessment of risk management options, monitoring and review of the decision taken. The decisions should be based on risk assessment, and taking into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade, in accordance with the *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principle*⁶.

32) The Codex Alimentarius Commission and its subsidiary bodies, acting as risk managers in the context of these Working Principles, should ensure that the conclusion of the risk assessment is presented before making final proposals or decisions on the available risk management options, in particular in the setting of standards or maximum levels, bearing in mind of the guidance given in paragraph 10.

33) In achieving agreed outcomes, risk management should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection, feasibility of enforcement and compliance, and the prevalence of specific adverse health effects.

34) The risk management process should be transparent, consistent and fully documented. Codex decisions and recommendations on risk management should be documented, and where appropriate clearly identified in individual Codex standards and related texts so as to facilitate a wider understanding of the risk management process by all interested parties.

35) The outcome of the preliminary risk management activities and the risk assessment should be combined with the evaluation of available risk management options in order to reach a decision on management of the risk.

⁵ For the purpose of these Principles, preliminary risk management activities are taken to include: identification of a food safety problem; establishment of a risk profile; ranking of the hazard for risk assessment and risk management priority; establishment of risk assessment policy for the conduct of the risk assessment; commissioning of the risk assessment; and consideration of the result of the risk assessment.

⁶ These criteria have been adopted by the 24th Session of the Commission (see Procedural Manual of the Codex Alimentarius Commission, 13th Edition, Appendix, FAO/WHO, Rome, in preparation).

36) Risk management options should be assessed in terms of the scope and purpose of risk analysis and the level of consumer health protection they achieve. The option of not taking any action should also be considered.

37) In order to avoid unjustified trade barriers, risk management should ensure transparency and consistency in the decision-making process in all cases. Examination of the full range of risk management options should, as far as possible, take into account an assessment of their potential advantages and disadvantages. When making a choice among different risk management options, which are equally effective in protecting the health of the consumer, the Commission and its subsidiary bodies should seek and take into consideration the potential impact of such measures on trade among its Member countries and select measures that are no more trade-restrictive than necessary.

38) Risk management should take into account the economic consequences and the feasibility of risk management options. Risk management should also recognize the need for alternative options in the establishment of standards, guidelines and other recommendations, consistent with the protection of consumers' health. In taking these elements into consideration, the Commission and its subsidiary bodies should give particular attention to the circumstances of developing countries.

39) 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 and related texts should be reviewed regularly and updated as necessary to reflect new scientific knowledge and other information relevant to risk analysis.

RISK COMMUNICATION

40) Risk communication should :

- i) promote awareness and understanding of the specific issues under consideration during the risk analysis;
- ii) promote consistency and transparency in formulating risk management options/recommendations;
- iii) provide a sound basis for understanding the risk management decisions proposed;
- iv) improve the overall effectiveness and efficiency of the risk analysis ;
- v) strengthen the working relationships among participants;
- vi) foster public understanding of the process, so as to enhance trust and confidence in the safety of the food supply;
- vii) promote the appropriate involvement of all interested parties²; and
- viii) exchange information in relation to the concerns of interested parties⁴ about the risks associated with food.

41) Risk analysis should include clear, interactive and documented communication, amongst risk assessors (Joint FAO/WHO expert bodies and consultations) and risk managers (Codex Alimentarius Commission and its subsidiary bodies), and reciprocal communication with member countries and all interested parties² in all aspects of the process.

42) Risk communication should be more than the dissemination of information. Its major function should be to ensure that all information and opinion required for effective risk management is incorporated into the decision making process.

43) Risk communication involving interested parties⁴ should include a transparent explanation of the risk assessment policy and of the assessment of risk, including the uncertainty. The need for specific standards or related texts and the procedures followed to determine them, including how the uncertainty was dealt with, should also be clearly explained. It should indicate any constraints, uncertainties, assumptions and their impact on the risk analysis, and minority opinions that had been expressed in the course of the risk assessment (see para.25).

44) The guidance on risk communication in this document is addressed to all those involved in carrying out risk analysis within the framework of Codex Alimentarius. However, it is also of importance for this work to be made as transparent and accessible as possible to those not directly engaged in the process and other interested parties⁴ while respecting legitimate concerns to preserve confidentiality (See para. 6).

APPENDIX II

DEFINITIONS

DRAFT DEFINITIONS PROPOSED FOR INCLUSION IN THE PROCEDURAL MANUAL

Risk Assessment Policy: Documented guidelines on the choice of options and associated judgements for their application at appropriate decision points in the risk assessment such that the scientific integrity of the process is maintained.

Risk profile: The description of the food safety problem and its context.

Risk estimate: The quantitative estimation of risk resulting from risk characterization.

DEFINITION ADOPTED BY THE 24TH SESSION OF THE COMMISSION

Risk Communication: The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.