codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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TO: Codex Contact Points
Interested International Organizations

FROM: Secretary, Joint FAO/WHO Food Standards Programme
FAO, 00100 Rome, Italy

SUBJECT: **PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS**

DEADLINE: **30 October 2001**

COMMENTS:

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BACKGROUND

The 16th Session of the Committee on General Principles considered the Proposed Draft Working Principles for Risk Analysis and agreed on several amendments to the text. However, it could not come to a consensus on the Scope and the use of precaution in risk analysis, especially in risk management. The Committee therefore agreed to request the Commission for clarification on the Scope of the Working Principles; i.e., whether they were intended exclusively for application in the framework of Codex, or by Member governments, or by both. The Committee also requested the advice of the Commission on how Codex should react when scientific data were insufficient or incomplete and evidence of a risk to human health existed, in particular whether it should proceed to elaborate a standard or related text.

The 24th Session of the Codex Alimentarius Commission confirmed the initial mandate of the Committee on General Principles to complete the principles for risk analysis within Codex as a high priority, with a view to their adoption in 2003. It also agreed that the Committee should develop guidance to governments subsequently or in parallel, as appropriate in view of its programme of work. The Commission also decided how it should proceed when scientific data were insufficient or incomplete (ALINORM 01/41, paras. 81-83).

Following the decision of the Commission, the Secretariat has redrafted the *Principles* for Risk Analysis for application within Codex, including the position of the Commission on precaution in risk management. The revised text also includes the amendments made by the last session of the Committee on General Principles and some editorial changes for clarification purposes, in conformity with the decision of the Committee (ALINORM 01/33A, para. 74). The changes made are further explained in the Introduction to the revised text.

Governments and international organizations wishing to submit comments should do so in writing, preferably by email, to the above addresses **before 30 October 2001**.

PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS

Introduction to the revised document

As the Working Principles are intended for application within Codex, the first paragraph of the Scope was amended to delete the reference to governments. No amendment was required in the sections on Risk Analysis and Risk Assessment as the recommendations currently included in the text were generally applicable to Codex.

In the section on Risk Management (para. 31), the components of risk management were retained as defined by the *Joint FAO/WHO Expert Consultation on Risk Management and Food Safety* with a note indicating that "implementation" was not relevant in Codex.

The section on precaution on risk management (previous paras. 34-35) was replaced by the position of the Commission as the text should refer only to risk management in Codex at this stage.

Risk Analysis – General Aspects

The proposals concerning precaution in risk analysis were included in this section as the Committee had agreed to consider these recommendations further at its next session, as a separate issue from "precaution in risk management". The text corresponds to Appendix V of ALINORM 01/33A (previous paragraphs 5 and 5bis proposed by Australia). The provisions concerning risk assessment policy were also included in this section as agreed by the Committee.

Risk Management

The *Criteria for the Consideration of the Other Factors referred to in the Second Statement of Principles* adopted by the 24th Session of the Commission clarify the integration of "other factors" in the decision process as related to risk analysis, including risk management. It is therefore proposed to include a reference to the *Criteria* in the section addressing other factors (para. 35) and to delete the paragraph indicating that "guidelines should be developed" in this area as it is now superfluous (para. 36). The Criteria are attached to the present document as Annex 2 for ease of reference and they will be included in the revised Procedural Manual.

As regards the action to be taken in Codex when scientific data are insufficient or incomplete and evidence of a risk to human health exists, the position adopted by the Commission was included as paragraph 40. This replaces the entire section on "precaution in risk management" which was addressed to governments.

Risk Communication

As this section was not discussed by the last session of the CCGP due to time constraints, no amendments were made. Some comments had been submitted to the Committee but at that time, the principles were applicable both to Codex and to governments. Governments and international organizations are therefore invited to provide comments on risk communication, with the understanding that the current Principles are intended for application only in the framework of Codex.

Definitions

As agreed by the Committee, a Glossary of Definitions of the terms used in the *Working Principles* was added as Annex 1. The list includes all the definitions related to risk analysis already adopted by the Commission and two additional definitions: *Risk Assessment Policy* (as agreed by the Committee), and *Risk Evaluation* as defined by the Joint FAO/WHO Expert Consultation on Risk Management and Food Safety. Comments are also invited on the need for additional definitions, if required.

PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS

(At Step 3 of the Procedure)

SCOPE

1) The principles for risk analysis are intended for application in the framework of the Codex Alimentarius.

2) The primary purpose of risk analysis in the Codex Alimentarius Commission is protecting the health of consumers while at the same time ensuring fair practices in the food trade.

3) The objective of the Working Principles is to ensure that food safety aspects of Codex standards and related texts are based on risk analysis [and to provide an objective basis for measures to protect the health of consumers].

4) 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, while the responsibility for risk assessment normally lies with the Joint FAO/WHO Expert Committees and Consultations.

RISK ANALYSIS - GENERAL ASPECTS

5) The risk analysis process used in Codex should be:

- consistent
- open and transparent
- consistent with the *Statements of Principle Concerning the Role of Science and the Extent to which Other Factors are Taken into Account*

6) The risk analysis process should follow a structured approach comprising the three components of risk analysis (risk assessment, risk management and risk communication), each component being integral to the overall risk analysis process.

7) 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 open to scrutiny by consumers and their representative organizations, and other interested parties.

8) Effective communication and consultation with all interested parties should be ensured throughout the risk analysis process.

9) The three components of risk analysis should be applied within an overarching framework of strategies and policies to manage risk. 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 and to reduce any conflict of interest over the functions to be performed by risk assessors and risk managers. However it is recognized that risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential for practical application.

10) [Precaution is an essential element of risk analysis. This is particularly important where scientific evidence is insufficient and negative effects on health are difficult to evaluate. Precaution should be exercised through the use of appropriate assumptions in the risk assessment and the choice of risk management options that reflect the confidence in the available scientific information.]

11) [Many sources of uncertainty exist in the process of risk assessment of food borne hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis process. As the degree of scientific uncertainty increases, the assumptions used for the risk assessment and the risk management options selected should become more cautious and conservative.]

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 process.

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

14) Risk assessment policy consists of documented guidelines for scientific judgement and policy choices to be applied at appropriate decision points during risk assessment.[1]

15) To ensure that the risk assessment process is systematic, complete and transparent, risk assessment policy should be established by risk managers preferably in advance of risk assessment, in consultation with risk assessors and all other interested parties.

16) The mandate given by risk managers to risk assessors should be as clear as possible, taking into account available scientific evidence and any constraints affecting the risk assessment process.

17) Where necessary, risk managers may ask risk assessors to evaluate the potential risk reduction resulting from different risk management options.

RISK ASSESSMENT*

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

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

20) Experts responsible for risk assessment should be selected in a transparent manner on the basis of their expertise and their independence with regard to the interests involved and 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 and experience.

21) Risk assessment should be consistent with the *Statements of Principle Concerning the Role of Science and the Extent to which Other Factors are Taken into Account* and should incorporate the four steps of the risk assessment process, i.e. hazard identification, hazard characterization, exposure assessment and risk characterization.

22) Risk assessment should use available quantitative information to the greatest extent possible and risk characterisations should be presented in a readily understandable and useful form. Risk assessment may also take into account qualitative information.

23) Risk assessment should take into account all available scientific data and 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.

24) Recognizing that primary production in developing countries is largely through small and medium enterprises, risk assessment should be based on data from different parts of the world, including that from developing countries. This data should particularly include epidemiological surveillance data and exposure studies.

25) Explicit consideration should be given to variability and other sources of uncertainty at each step in the risk assessment process.

26) Any constraints, uncertainties and assumptions and their impact on the risk assessment should be documented in a transparent manner, including constraints that are likely to influence the quality of the risk estimate. Expression of uncertainty or variability in risk estimates may be qualitative or quantitative.

27) 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

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[1] This paragraph is also included in the Definitions (Annex 1) and might be deleted later if the Definitions are retained in the final text.

* Reference is made to the *Statements of Principle Concerning the Role of Science and the Extent to which Other Factors are Taken into Account.*

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.

28) The conclusions of the risk assessment should be conveyed to risk managers in a readily understandable form. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessor.

29) To ensure a transparent risk assessment, a formal record, including a summary, should be prepared and made available to other risk assessors and interested parties so that they can review the assessment. It should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment, and minority opinions.

RISK MANAGEMENT

30) Risk management decisions should have as their primary objective the protecting the health of consumers. Decisions on acceptable levels of risk should be determined primarily by human health considerations, and unjustified differences in the level of acceptable risk should be avoided.[2]

31) Risk management should follow a structured approach, be grounded on science-based risk assessment and take into account other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade, as appropriate. The risk management framework includes risk evaluation[3], assessment of risk management options, implementation of management decisions, and monitoring and review[4].

32) 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 and the prevalence of specific adverse health effects.

33) The risk management process should be transparent, consistent and fully documented. Risk management decisions 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.

34) Risk management options should be evaluated/assessed in terms of the scope and purpose of risk analysis and the ability to achieve the required level of consumer protection. The option of not taking any action should also be considered, as required.

35) The outcome of the risk evaluation process should be combined with the assessment of available risk management options in order to reach a decision on management of the risk. In arriving at a decision on risk management, protection of consumers' health should be the primary consideration, with other legitimate factors being considered as appropriate[5], in accordance with the *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles*

36) ~~Guidelines should be defined for the integration in the risk management process of legitimate factors other than science relevant for the health protection of consumers and for the promotion of fair practices in food trade~~.

37) In order to avoid unjustified trade barriers, risk management should ensure transparency and consistency in the decision-making process in all cases.

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2 Joint FAO/WHO Expert Consultation on Risk Management and Food Safety

3 See *Definitions* in Annex 1

4 Joint FAO/WHO Expert Consultation on Risk Management and Food Safety. In the framework of Codex, the Implementation "component" is not relevant.

5 Joint FAO/WHO Expert Consultation on Risk Management and Food Safety. *Criteria for the Consideration of the Other Factors referred to in the Second Statement of Principles* have been adopted by the 24th Session of the Commission (see Annex 2). The *Criteria* address the question of the integration of other factors in relation to risk analysis, including risk management.

38) Risk management should take into account the economic consequences and the feasibility of risk management options in developing countries. Risk management should also recognize the need for flexibility in the establishment of standards, guidelines and other recommendations, consistent with the protection of consumers' health.

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 updated as necessary to reflect new scientific knowledge and other information relevant to risk analysis.

40) 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.[6]

RISK COMMUNICATION

41) Risk analysis should include clear, interactive and documented communication, between risk assessors and risk managers, and communication with consumers and other interested parties in all aspects of the process.

42) A major function of risk communication is establishing a process whereby information and opinion essential to effective risk assessment and risk management is exchanged between all interested parties.

43) In their communication with the public, risk managers should include a transparent explanation of the risk assessment policy and risk assessors should identify the uncertainty in risk estimates. The need for specific measures and the procedures followed to determine them should also be clearly explained.

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

45) An assessment of uncertainty in risk estimates should be included in the communication process with the public and other interested parties.

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

ANNEX 1

DEFINITIONS

Definitions included in the Procedural Manual

Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Risk: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.

Risk Analysis: A process consisting of three components : risk assessment, risk management and risk communication.

Risk Assessment: A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.

Hazard Identification: The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.

Hazard Characterization: The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents which may be present in food. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable.

Dose-Response Assessment: The determination of the relationship between the magnitude of exposure (dose) to a chemical, biological or physical agent and the severity and/or frequency of associated adverse health effects (response).

Exposure Assessment: The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant.

Risk Characterization: The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.

Risk Management: The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.

Risk Communication: The interactive exchange of information and opinions throughout the risk analysis process concerning hazards and risks, 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

Other Definitions

Risk Assessment policy consists of documented guidelines for scientific judgement and policy choices to be applied at appropriate decision points during risk assessment.

Risk Evaluation[7]

- 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 conduct of risk assessment
- commissioning of risk assessment
- consideration of risk assessment result

[7] Joint FAO/WHO Expert Consultation on Risk Management and Food Safety (section 6. Risk Management Framework)

ANNEX 2

STATEMENTS OF PRINCIPLE ON THE ROLE OF SCIENCE IN THE CODEX DECISION-MAKING PROCESS AND THE EXTENT TO WHICH OTHER FACTORS ARE TAKEN INTO ACCOUNT

CRITERIA FOR THE CONSIDERATION OF OTHER FACTORS REFERRED TO IN THE SECOND STATEMENT OF PRINCIPLE

- when health and safety matters are concerned, the *Statements of Principle Concerning the Role of Science* and the *Statements of Principle Relating to the Role of Food Safety Risk Assessment* should be followed;
- other legitimate factors relevant for health protection and fair trade practices may be identified in the risk management process, and risk managers should indicate how these factors affect the selection of risk management options and the development of standards, guidelines and related texts;
- consideration of other factors should not affect the scientific basis of risk analysis; in this process, the separation between risk assessment and risk management should be respected, in order to ensure the scientific integrity of the risk assessment;
- it should be recognized that some legitimate concerns of governments when establishing their national legislation are not generally applicable or relevant world-wide;[8]
- only those other factors which can be accepted on a world-wide basis, or on a regional basis in the case of regional standards and related texts, should be taken into account in the framework of Codex;
- the consideration of specific other factors in the development of risk management recommendations of the Codex Alimentarius Commission and its subsidiary bodies should be clearly documented, including the rationale for their integration, on a case-by-case basis;
- the feasibility of risk management options due to the nature and particular constraints of the production or processing methods, transport and storage, especially in developing countries, may be considered; concerns related to economic interests and trade issues in general should be substantiated by quantifiable data;
- the integration of other legitimate factors in risk management should not create unjustified barriers to trade[9]; particular attention should be given to the impact on developing countries of the inclusion of such other factors.

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[8] Confusion should be avoided between justification of national measures under the SPS and TBT Agreements and their validity at the international level

[9] According to the WTO principles, and taking into account the particular provisions of the SPS and TBT Agreements