

# 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, Codex Alimentarius Commission  
FAO, Viale delle Terme di Caracalla, 00100 Italy

SUBJECT: **REQUEST FOR COMMENTS ON WORKING PRINCIPLES FOR RISK ANALYSIS**

DEADLINE: **15 November 1999**

COMMENTS: **To:** Secretary  
Codex Alimentarius Commission  
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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 and 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.

Proposed Draft Working Principles were considered by the 13<sup>th</sup> Session of the CCGP and redrafted in the light of the discussion held at the meeting for consideration by the 14<sup>th</sup> Session of the CCGP. The Committee agreed on a number of amendments to the sections concerning Risk Analysis, Risk Assessment and Risk Assessment Policy, but decided that they could not be finalized at this stage as the Working Principles should be considered as a whole and further discussion was required especially on Risk Assessment Policy (ALINORM 99/33A, paras. 17-26).

The Committee discussed certain aspects of Risk Management, especially the opportunity to include a reference to the precautionary principle, and could not come to a conclusion on this issue. It was therefore agreed that the section on Risk Management, as presented in the working document, would be circulated for further comments (paras. 27-34). The Committee also agreed that comments would be sought on a definition of the precautionary principle or a statement of a precautionary approach and the conditions under which it would be applied, and that the Secretariat would prepare an analysis of all relevant aspects and proposals for further consideration. In order to prepare this document and to facilitate the discussion on the Working Principles as a whole, governments and international organizations are therefore invited to present specific comments on the precautionary principle or approach, which should be distinct from the comments concerning the other sections of the Working Principles.

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 15 November 1999**.

## PROPOSED DRAFT CODEX WORKING PRINCIPLES FOR RISK ANALYSIS

(At Step 3 of the Procedure)

### RISK ANALYSIS

The primary purpose of risk analysis in Codex is the protection of public health.

1. The three components of risk analysis (risk assessment, risk management and risk communication) should be documented separately and systematically, with the documentation accessible to interested parties. To use the risk analysis process in an effective way, there is a need for communication and interaction where appropriate between the parties involved in these three components.
2. The risk analysis procedures used by Codex and those used by other relevant international intergovernmental [and non-governmental] bodies should be harmonized where appropriate.
3. The needs of developing countries should be specifically identified and addressed in the different stages of the Codex risk analysis process.
4. The risk analysis process used in Codex should be as consistent, open and transparent.

### RISK ASSESSMENT

5. Health and safety aspects of Codex decisions and recommendations should be based on a risk assessment, as appropriate to the circumstances.
6. 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.
7. Risk assessment should be based soundly on science, should incorporate the four steps of the risk assessment process and should be documented in a transparent manner, indicating any constraints, uncertainties and assumptions and their impact on the risk assessment.
8. 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.
9. Risk assessments should be based on realistic exposure scenarios, with consideration of different situations being defined by risk assessment policy. They should be applicable to susceptible and high risk population groups. Both acute and chronic (including long-term) adverse health effects should be recognized in carrying out risk assessment
10. 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.
11. Risk estimates should wherever possible include a numerical expression of uncertainty, and this should be conveyed to risk managers in a readily understandable form<sup>1</sup>. 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.
12. Risk assessment may include non-measurable, qualitative data.
13. There should be increased recognition of differences between acute and chronic (*including long-term*) adverse health effects in carrying out risk assessments
14. There should be a functional separation of risk assessment and risk management, while recognising that some interactions are essential for a pragmatic approach.

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<sup>1</sup> Within the framework of Codex, the responsibility for providing advice to governments 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 Committee and Consultations.

**RISK ASSESSMENT POLICY**

15. Determination of risk assessment policy should be included as a specific component of risk management.
16. The mandate given by risk managers to risk assessors must be clearly specified and delineated.
17. [Risk managers should try to ensure that the mandates given to risk assessors are achievable and correspond to the capacity and expertise of the risk assessors].
18. Risk managers should invite all interested parties to submit proposals and comments to ensure that the risk assessment process is systematic and complete.

**RISK MANAGEMENT**

19. Risk management should follow a structured approach.
20. Protection of human health should be the primary consideration in risk management decisions.
21. Risk management should be focused on agreed outcomes rather than on processes.
22. 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.
23. 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”.
24. 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.
25. 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.
26. Issues of a general nature in the elaboration of food standards and related should be clearly identified and consistently addressed texts according to risk analysis principles.
27. Risk management decisions should take into account conditions prevailing in all countries, where possible, without affecting the agreed outcome.
28. [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. ]

**RISK COMMUNICATION<sup>2</sup>**

29. 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.
30. A risk communication strategy should be proactive and include a plan specifying how information is to be communicated.
31. Risk managers should include an assessment of uncertainty in risk estimates in their communication with the public.

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<sup>2</sup> 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.

**DOCUMENTATION**

32. 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.

33. 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