

PROPOSED DRAFT PRINCIPLES FOR RISK ANALYSIS²

(At Step 3 of the Procedure)

SCOPE

1. The purpose of these Principles is to provide a framework for the conduct of risk analysis applied to food safety issues, as guidance to governments for food safety, in order to facilitate the application of risk analysis to food safety issues.

RISK ANALYSIS - GENERAL ASPECTS

2. The overall objective of risk analysis applied to food safety is to ensure public health protection.
3. Health and food safety aspects of decisions and recommendations should be based on a risk assessment, as appropriate to the circumstances.
4. The risk analysis process ~~and all its components~~ should be
 - applied consistently,
 - open, transparent and documented
5. The risk analysis process should follow a structured approach incorporating the three distinct but closely linked components of risk analysis (risk assessment, risk management and risk communication), each being integral to the overall risk analysis process. The three components of risk analysis should be applied within an overarching framework of strategies and policies to manage food related risks to human health.
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 parties³.
7. Effective communication and consultation with all interested parties should be ~~ensured~~ established and maintained throughout the risk analysis process.
8. There should be a functional separation of risk assessment and risk management, to the extent practicable, 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.
9. 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 process. The risk management options selected should reflect the assumptions used for the risk assessment, the degree of uncertainty and the characteristics of the hazard.

Risk Assessment Policy

10. Determination of risk assessment policy should be included as a specific component of risk management.
11. Risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties, in order to ensure that the risk assessment process is systematic, complete, unbiased and transparent.
12. The mandate given by risk managers to risk assessors should be as clear as possible.
13. Where necessary, risk managers should ask risk assessors to evaluate the potential changes in risk

² These principles are intended for governments and will be incorporated into the Codex Alimentarius.

³ 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” (see definition of “Risk Communication”)

resulting from different risk management options.

RISK ASSESSMENT

~~Health and food safety aspects of decisions and recommendations should be based on a risk assessment, as appropriate to the circumstances. (transferred to RISK ANALYSIS – para. 3)~~

14. Food safety risk assessment should be soundly based on science, should incorporate the four steps of the risk assessment process, i.e. hazard identification, hazard characterization, exposure assessment and risk characterization, and should be documented in a transparent manner.

15. 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

16. Government officials involved in risk assessments should have no personal interests or biases with regard to the subjects of their risk assessments. Information on the identities of these government experts, their individual expertise and their professional experience should be publicly available. Experts from outside government 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. 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.

17. 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.

18. Risk assessment should take into account relevant ecological and environmental conditions, production, transport, 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.

19. (former para. 20) 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, as appropriate. Acute, chronic (including long-term), cumulative and/or combined adverse health effects should be taken into account in carrying out risk assessment, where relevant.

20. (former para. 19) Constraints, uncertainties and assumptions having an and their impact on the risk assessment should be explicitly considered at each step in the risk assessment process and documented in a transparent manner. Expression of uncertainty or of variability in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable.

21. The report of the risk assessment should include the scope and purpose of the risk assessment carried out, the background of the request, the information considered, the scientific reasoning and the conclusions of the risk assessors. The report should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment, and minority opinions. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors.

22. 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

23. Risk management should follow a structured approach including ~~risk evaluation~~ preliminary risk management activities⁴, ~~assessment~~ evaluation of risk management options, implementation of management decisions, monitoring and review of the decision taken.⁵

⁴ 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.

⁵ *FAO/WHO Expert Consultation on Risk Management and Food Safety and Joint FAO/WHO Consultation on Principles and Guidelines for Incorporating Microbiological Risk Assessment in the Development of Food Safety Standards*

24. Risk management decisions should be determined primarily by human health considerations, and unjustified differences in the level of consumer health protection should be avoided. Consideration of other legitimate factors relevant to the risk management options may be appropriate, particularly in the determination of the measures to be taken. These considerations should not be arbitrary and should be made explicit.

25. In achieving agreed outcomes, risk management should take into account relevant ecological and environmental conditions, production, transport, 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.

25 bis) The risk management process should be transparent, consistent and fully documented. Decisions and recommendations on risk management should be documented, and, where appropriate, clearly identified in national standards and regulations so as to facilitate a wider understanding of the risk management by all interested parties.

26. 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. The outcome of the ~~risk evaluation process~~ preliminary risk management activities should be combined with the ~~assessment~~ evaluation of all available risk management options in order to reach a decision on management of the risk.

27. Risk management should take into account the economic consequences and the feasibility of risk management options and recognize the need for alternative options. When different risk management options are equally effective in protecting the health of the consumer, the measure chosen should be the one that is the least restrictive to trade.

28. Where appropriate, implementation of the risk management decision should be followed by monitoring both the effectiveness of the control measures and their impact on risk to the exposed consumer population, to ensure that the purpose of the measure is met.

29. Post-market monitoring may be an appropriate risk management measure in specific circumstances. The objective, need and utility of post market monitoring should be considered, on a case-by-case basis, during risk assessment and its practicability should be considered during risk management.

30. Specific tools may be needed to facilitate the implementation and enforcement of risk management measures. These may include appropriate analytical methods; reference materials; and, the tracing of products for the purpose of facilitating withdrawal from the market when a risk to human health has been identified or to support post-market monitoring as required according to the circumstances.

31. Risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions. Decisions should be evaluated regularly and updated as necessary to reflect new scientific knowledge and other information relevant to risk analysis.

32. [When relevant scientific evidence is insufficient to objectively and fully assess risk from a hazard in food, and where there is reasonable evidence from a preliminary risk assessment to suggest that adverse effects on human health may occur, but it is difficult to evaluate their nature and their extent, it may be appropriate for risk managers to apply precaution through interim measures, in order to protect the health of consumers without awaiting additional scientific data and full risk assessment. However, additional information should be sought, a more complete risk assessment should be performed, and the measures taken reviewed, all in a reasonable time frame.]

33. ~~[In such situation]~~ *The following considerations should be taken into account when deciding on the measures to be applied, especially as regards interim measures:*

- (a) Examination of the full range of management options should be undertaken with all the stakeholders. This should include an assessment of the potential advantages and disadvantages of the alternative measures, including, where appropriate, flexibility and cost, effectiveness considerations.*
- (b) There should be a transparent explanation of the need for the measures and the procedures followed to establish them.*
- (c) The decisions/measures taken are proportional to the potential extent of the health risk and based on the available scientific data.*

- (d) *The decisions/asures taken are consistent with those taken in similar circumstances, based on all the available pertinent information, including available scientific information.*
- (e) *The measures taken are the least trade restrictive to achieve protection of the health of consumers.*
- (f) *The decisions/asures are subject to an on-going, transparent review process involving interested stakeholders.*
- (g) *Information should continue to be gathered to strengthen the scientific evidence. The original decisions should be reviewed and decisions taken to retain, modify, strengthen or rescind any measures as appropriate in the light of such information]*

RISK COMMUNICATION

34. Risk communication should:

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

35. Risk analysis should include clear, interactive and documented communication, amongst risk assessors and risk managers, and reciprocal communication with all interested parties in all aspects of the process.

36. Risk communication should be more than the dissemination of information. Its major function should be to ensure that all information and opinion essential for effective risk assessment and risk management is exchanged among interested parties and incorporated into the decision making process. ~~Ongoing reciprocal communication amongst all interested parties should be an integral part of the risk analysis process.~~

37. Risk communication involving interested parties 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 process, and minority opinions.