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

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*²⁰; 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 Commission²¹, each component being integral to the overall risk analysis.

²⁰ See Appendix: *General Decisions of the Commission*, page 185

²¹ See *Definitions of Risk Analysis Terms Related to Food Safety*, page 45.

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 parties²².
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.
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.
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.

²² 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”)

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 ASSESSMENT*²³

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 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, 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

²³ Reference is made to the Statements of Principle Relating to the Role of Food Safety Risk Assessment: See Appendix: General Decisions of the Commission, page 1905.

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 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

27. 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 as 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.

28. Risk management should follow a structured approach including preliminary risk management activities²⁴, evaluation of risk management options,

²⁴ 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;

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 Principles²⁵.

29. 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 the guidance given in paragraph 10.

30. 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.

31. 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.

32. 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.

33. 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.

34. 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

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.

²⁵ See Appendix: *General Decisions of the Commission*, page 195.

the potential impact of such measures on trade among its Member countries and select measures that are no more trade-restrictive than necessary.

35. 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.

36. 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

37. 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 parties; and
- viii) exchange information in relation to the concerns of interested parties about the risks associated with food.

38. 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 parties in all aspects of the process.

39. 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.

40. 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, and minority opinions that had been expressed in the course of the risk assessment (see para. 25).

41. 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 parties while respecting legitimate concerns to preserve confidentiality (See para. 6).

コーデックス委員会の枠組みの中で適用される
リスク分析の作業原則
(仮訳)

範囲

- 1) このリスク分析の原則は、コーデックス委員会の枠組みの中で適用するためのものである。
- 2) この作業原則の目的は、コーデックス規格と関連文書における食品の安全性と健康に関する事項がリスク分析に基づくものとなるよう、コーデックス委員会及びFAO/WHO合同専門家委員会・会議に対して指針を提供することにある。
- 3) コーデックス委員会の枠組み及びその手続きにおいて、リスク管理に関する助言を与える責任はコーデックス委員会とその下部組織（リスク管理者）にある一方、リスク評価の責任は主にFAO/WHO合同専門家委員会・会議（リスク評価者）にある。

リスク分析 — 一般事項

- 4) コーデックスにおいては、リスク分析を、
 - 一貫して適用し、
 - 公開し、透明性を確保するとともに、文書化し、
 - 「コーデックス委員会の意思決定過程における科学の役割と、どの程度科学以外の要素を考慮するかに関する原則声明」及び「食品の安全性に関するリスク評価の役割に関する原則声明」に即して行い、
 - 新たな科学的データに照らして適切に評価し、検討するべきである。
- 5) リスク分析は、別個であっても密接に関連するリスク分析の3要素（リスク評価、リスク管理、リスクコミュニケーション）からなる構造化された手法に従うべきである。これらのリスク分析の要素はコーデックス委員会で定義されており、それぞれの要素はリスク分析全体において不可分なものである。
- 6) リスク分析の3要素を、透明性が確保された方法で、完全かつ系統的に文書化するべきである。機密性を保つための正当な懸念を尊重すると同時に、すべての関係者が文書を手入手できるようにするべきである。
- 7) あらゆる関係者との効果的なコミュニケーションと協議を、リスク分析過

程全体を通して確保すべきである。

8) リスク分析の3要素は、食品に関連する人の健康へのリスクの管理のすべてを包括するような枠組みの中で適用されねばならない。

9) リスク評価の科学的な完全性を保証し、リスク評価者及びリスク管理者の機能の混同を避け、利害の衝突を減らすために、リスク評価とリスク管理は機能的に分離すべきである。しかしながら、リスク分析は反復的過程と認識されており、リスク管理者とリスク評価者との間の相互作用は、リスク分析を実際的に適用するために不可欠である。

10) 人の健康へのリスクが存在するという証拠はあるが、科学的データが不足していたり不十分であったりする場合には、コーデックス委員会は規格を作成すべきではないが、利用可能な科学的証拠の裏付けがあれば実施規範のような関連文書の作成を検討すべきである。

11) 予防的措置はリスク分析の固有の要素である。食品に関連する人の健康に対する危害要因のリスク評価やリスク管理の過程に多くの不確実性をもたらす要因が存在する。利用可能な科学的情報における不確実性及び変動性の程度をリスク分析の中できちんと検討すべきである。コーデックス委員会が規格や関連文書を作成できるほど十分な科学的な証拠がある場合は、リスク評価の際の仮定やリスク管理の選択は、不確実性の程度や危害要因の特性を反映すべきである。

12) リスク分析の各段階で責任をもつ組織は開発途上国のニーズや現状を個々に認識し、斟酌すべきである。

リスク評価方針

13) リスク評価方針の決定を、リスク管理の特定の要素として含むべきである。

14) リスク評価に先立って、リスク評価者やその他のすべての利害関係者と協議した上で、リスク管理者がリスク評価方針を制定すべきである。この手続きの目的は、リスク評価が系統的で、欠けたところがなく、公正であって透明性の保たれたものとなるよう保証することである。

15) リスク管理者からリスク評価者への指示（または諮問）は、できる限り

明確であるべきである。

16) リスク管理者は、複数あるリスク管理の選択肢の各々を採用した場合に起こりえるリスクの変化を評価するよう、必要に応じてリスク評価者に求めるべきである。

リスク評価

17) 実施される個々のリスク評価の範囲や目的を、明確に示すべきであり、その範囲や目的はリスク評価方針と一致しているべきである。リスク評価の成果とその代替となりうる成果を明確にするべきである。

18) その人の専門知識や専門技術、経験、さらには利害関係がないことを考慮し、透明性の保たれた方法に従って、リスク評価に対して責任を有する専門家を選出するべきである。発生する可能性のあるすべての利害関係を公表することを含め、これらの専門家の選出に使用される手続きを文書化するべきである。この公表においては、専門家各々の専門知識や専門技術、経歴、独立性について明確に詳述するべきである。専門家委員会・会議は開発途上国からの専門家も含めて、世界の各地域から専門家を効果的に参加させることを保証するべきである。

19) リスク評価を、「食品の安全性に関するリスク評価の役割に関する原則声明」に従って行うべきであり、リスク評価は、4つの段階、すなわち、危害要因特定、危害要因判定、暴露評価、リスク判定を含むべきである。

20) リスク評価は、すべての入手可能な科学的なデータに基づくべきである。また、利用可能な定量的な情報を最大限使用するべきである。また、リスク評価においては定性的な情報についても考慮してよい。

21) リスク評価では、フードチェーン全体において用いられる伝統的な方法を含めた生産・貯蔵・取り扱いの方法及び分析・サンプリング・検査法、健康への特定の悪影響（病気や中毒など）の流行の程度を考慮に入れるべきである。

22) リスク評価では、開発途上国も含め世界の各地域からデータを求め、使用するべきである。これらのデータには、特に疫学サーベイランスデータや、分析・暴露データを含むべきである。開発途上国から当該データが入手できない場合には、委員会は FAO/WHO にこの目的のために期限付きの研究に着手するよう要請するべきである。しかし、これらのデータが得られるまでリスク評

価の実施を不当に遅延するということがあってはならず、そのようなデータが入手できた段階でリスク評価を再検討するべきである。

23) リスク評価に影響を及ぼす制約や不確実性、仮定については、リスク評価の各段階で明確に検討し、透明性のある方法で文書化するべきである。リスク推定値の不確実性あるいは変動性は、定性的・定量的どちらで示すことも可能だが、科学的に成し遂げられる限り定量的に示すべきである。

24) リスク評価は、リスク評価方針によって明確にされたさまざまな状況を考慮に入れた上、現実的な暴露シナリオに基づくべきである。このシナリオには、影響を受けやすい集団やリスクの高い集団に対する考慮を含むべきである。もしその必要があれば、リスク評価の実施に際して、急性的、慢性的（長期間も含む）、累積的及び/又は複合的に生じる健康への悪影響を考慮するべきである。

25) リスク評価の報告においては、あらゆる制約、不確実性、仮定、及びこれらがリスク評価に及ぼす影響について示すべきである。少数派の意見についても記録するべきである。リスク管理決定に与える不確実性の影響を解消する責任は、リスク管理者にあるのであって、リスク評価者にあるのではない。

26) リスク評価結果（もしあればリスク推定値も含む）は、容易に理解ができるとともに実用的な形式でリスク管理者に提供されるべきであり、その他のリスク評価者や利害関係者がリスク評価結果を検討できるように、彼らにも提供するべきである。

リスク管理

27) コーデックスには、消費者の健康の保護と食品貿易の公正な取引の保証という2つの目的があることが認められているとはいえ、リスク管理に関するコーデックス委員会の決定と勧告は、消費者の健康の保護を第一の目的とするべきである。異なる状況の下での類似したリスクへの対応において、消費者の健康保護の水準に不当な格差が生じることは避けるべきである。

28) リスク管理は、リスク管理の初期作業、リスク管理の選択肢の評価、リスク管理において決定された政策や措置のモニタリングと見直し、を含む構造的な手法に即して行うべきである。リスク管理の選択肢の決定はリスク評価に基づき、もしその必要があれば「原則の第2の声明において言及された他要因を考慮するための基準」に従って、消費者の健康保護と公正な食品貿易・取引の促進に関連する他の正当な要因を考慮するべきである。