codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 10 **CX/NFSDU 03/10**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
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APPLICATION OF RISK ANALYSIS TO THE WORK OF THE CCNFSDU

(Prepared by Australia)

BACKGROUND

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

1. At the 24th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) in 2002, it was agreed that Australia would prepare a paper discussing the application of risk analysis to the future work of CCNFSDU (ALINORM 03/26A, paragraph 126).

2. The subject of risk-based decision making has been considered by CCNFSDU for several years. The matter was initially raised to draw attention to developments in risk analysis occurring in Codex committees and expert bodies that are responsible for the traditional aspects of food safety and to consider the relevance of these developments for CCNFSDU.

3. CCNFSDU first considered the matter of dietary modelling to inform a risk-based approach for its decision making at its 20th session in 1996. After discussion of the potential to incorporate nutrient intake (dietary exposure) assessments within a risk-based approach at its 22nd Session in 2000, it was agreed that CCNFSDU would proceed with the development of a methodology for the application of risk assessment to relevant Codex standards and related texts (ALINORM 01/26, paragraphs 128-131).

4. At its 23rd Session in 2001, CCNFSDU concluded that a necessary first step to the implementation of a risk-based approach was to request FAO/WHO to extend their current work on reference recommended nutrient intakes to establish, where possible, upper limits for vitamins and minerals (ULs). FAO/WHO agreed to the Committee's request (ALINORM 03/26, paragraphs 138-143).

5. The 24th Session of CCNFSDU in 2002 discussed FAO's report on progress towards the establishment of ULs (CX/NFSDU 02/9). As a first step, FAO proposed the development of a generic technical report outlining the general principles to be adopted in approaching ULs. This work would precede the safety assessment of individual vitamins and minerals over the next several years and adhere to the [then draft] Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius. CCNFSDU's attention was also drawn to the joint FAO/WHO Project to Update Principles and Methods for the Risk Assessment of Chemicals in

Foods which offered a possible vehicle for the development of such a report (ALINORM 03/26A, paragraph 120).

CODEX ALIMENTARIUS COMMISSION

6. The Report of the Evaluation of the Codex Alimentarius and Other FAO and WHO Food Standards Work was considered by the Codex Alimentarius Commission in February 2003 (ALINORM 03/25/3). In its statement on the outcome of the Evaluation, the Commission agreed that the scientific base for risk analysis including food safety risk assessment should be strengthened to improve the efficiency and effectiveness in providing expert scientific advice to the Commission and Member Nations and to improve risk communication (ALINORM 03/25/5 Appendix II).

7. In July 2003, the Commission adopted the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius (Working Principles for Risk Analysis) (ALINORM 03/41, Appendix IV; and paragraphs 142-148). This key document is reproduced in the Addendum/Attachment to this agenda paper.

FAO AND WHO

8. In response to the Evaluation, FAO and WHO have initiated a consultative process on the means to improve the provision of scientific advice, including risk assessment, to the Codex system. The process is expected to conclude in 2005 and result in the establishment of sustainable working arrangements.

KEY DEVELOPMENTS IN RISK ANALYSIS

9. Several key developments within Codex and the supporting FAO/WHO system have recently concluded or are in train that will influence CCNFSDU's direction and progress towards the possible inclusion of risk analysis in its decision making.

10. The Working Principles for Risk Analysis provide the joint FAO/WHO expert bodies and consultations and relevant Codex committees with a structured approach to the implementation of all three components of risk analysis—risk assessment, risk management and risk communication—so that the food safety and health aspects of Codex standards and related texts are based on risk analysis.

11. These Working Principles emphasise the functional separation of risk assessment and risk management processes but stress the iterative and interactive nature of decision making between these processes for practical application. The Working Principles also establish that, within the Codex framework and its procedures, the responsibility for risk assessment lies primarily with the expert bodies, whereas responsibility for risk management decisions (and input into determination of risk assessment policy (paragraph 13)) lies with the Codex Alimentarius Commission and its subsidiary bodies such as committees.

12. In adopting the Working Principles for Risk Analysis, the Commission requested that relevant Codex committees develop or complete specific guidelines on risk analysis in their respective areas, consistent with the overarching Working Principles for inclusion in the Procedural Manual, as recommended in the Action Plan (ALINORM 03/41, paragraph 147).

RISK ASSESSMENT

13. FAO/WHO report at Agenda Item 2 of this meeting (CX/NFSDU 03/2) that, given the current review of the provision of scientific advice from FAO/WHO, commitments made at the Committee's last meeting in relation to the establishment of ULs (see point 5 above) have been deferred and some aspects of the activity have been scheduled to commence in the biennium 2004-2005.

14. The Joint FAO/WHO Committee on Food Additives (JECFA) has carried out safety assessments for 19 nutrient supplements (including dietary supplements, nutrients, nutrient adjuncts, and nutrient agents). The principles and procedures used by JECFA are applicable for the safety assessments that support the determination of ULs. The current Joint FAO/WHO Project to Update Principles and Methods for the Risk Assessment of Chemicals in Foods proposes to include nutrients including vitamins and minerals. The final report is expected in 2005. The Principles and Methods for Assessment of Risk from Essential Trace Elements[1], published in 2002 by the International Programme on Chemical Safety, provides an example of a contemporary approach to risk assessment of certain essential nutrients.

RAMIFICATIONS OF THESE DEVELOPMENTS FOR CCNFSDU

15. The formal adoption of the Working Principles for Risk Analysis provides for the first time, a structured framework for consideration of risk analysis and establishment of the roles of the different players within the entire Codex and supporting FAO/WHO system.

16. The objective of the Working Principles is to provide guidance so that the food safety and health aspects of Codex standards and related texts are based on risk analysis. The inclusion of 'health' in that objective extends the application of the Working Principles beyond the traditional context of food safety to other relevant Codex texts that deal with health matters such as nutrition. The Working Principles can therefore be interpreted to provide an unequivocal direction from the Commission that, since nutrition matters directly impact upon health, relevant aspects of CCNFSDU's work should be based on risk analysis.

17. Although CCNFSDU previously agreed to proceed to develop a methodology for the application of risk assessment to relevant Codex texts (see point 3), the Committee's consideration of the broader risk-based approach revealed a wide diversity of views. So far, discussion has focused only on some components of risk assessment, notably the establishment of ULs and estimation of nutrient intake (dietary exposure).

18. The adoption by the Commission of the Working Principles for Risk Analysis provides CCNFSDU with an opportunity to reaffirm its commitment to the implementation of a risk-based approach in decision making, and to clarify its role in relation to risk management and to signal its desire to firmly establish sustainable working arrangements with FAO and WHO as the risk assessors.

19. The Commission's request to relevant committees (asserted in this paper to include CCNFSDU) to develop specific guidelines on risk analysis in their respective domains for eventual inclusion in the Procedural Manual (see point 12) commands a response. CCNFSDU should therefore commence as soon as practicable, the elaboration of such guidelines in cooperation with FAO and WHO in order to guide its own decision making and to be ready to take full advantage of the future establishment of an integrated system of provision of scientific advice. This work would most expeditiously proceed by the establishment of an electronic group working out of session.

20. Although the development of such guidelines and the future establishment and operation of renewed workable arrangements between CCNSDU and FAO and WHO will take time in accordance with agreed priorities, this system has the potential to facilitate the resolution of several difficult risk management issues on which the Committee has not achieved consensus to date.

21. Documents under development within the Codex system that serve as examples of specific guidelines on risk analysis for use by individual committees or other bodies include: 'Proposed draft principles and guidelines for the conduct of microbiological risk management' (CX/FH 03/7; Codex Committee on Food Hygiene; 35th Session, 2003), and 'Proposed draft principles for the risk analysis of foods derived from modern biotechnology' (ALINORM 01/34A, Appendix II; Intergovernmental Task Force on Foods Derived from Biotechnology, 2nd Session, 2001).

[1] International Programme on Chemical Safety 2002. Principles and Methods for the Assessment of Risk from Essential Trace Elements, Environmental and Health Criteria 228, WHO, Geneva.

RECOMMENDATIONS

22. It is recommended that CCNFSDU formally acknowledge that the Working Principles for Risk Analysis are highly relevant to its work.

23. It is further recommended that CCNFSDU agree to elaborate specific guidelines on risk analysis within its area of responsibility, consistent with its terms of reference and according to the Codex Working Principles for Risk Analysis. To expedite this work, the Committee is urged to establish an electronic working group operating out of session and to commence work as soon as practicable with a view to developing a draft text to be considered at a future meeting of CCNFSDU.

Appendix

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*; 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 Commission[2], 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 parties[3].

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

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2 See *Definitions of Risk Analysis Terms Related to Food Safety,* page 43-44 12th Edition Codex Alimentarius Commission Procedural Manual.

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")

consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence.[4]

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 ASSESSMENT[5]

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 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.

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

5 Reference is made to the Statements *of Principle Relating to the Role of Food Safety Risk Assessment*

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 activities[6], evaluation 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 Principles* [7].

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.

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6 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.

7 These criteria have been adopted by the 24th Session of the Commission (see Procedural Manual 12th Edition - Appendix, page 165)

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 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).

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 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.

Other Definitions

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.