

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
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ORGANIZATION



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Agenda Item 7

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES Twenty-ninth Session

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ESTABLISHMENT AND APPLICATION OF RISK ANALYSIS PRINCIPLES BY THE COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES AT STEP 3

Governments and interested international organizations are invited to submit comments on the attached Proposed Draft Principles at Step 3 (see Appendix) and should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see *Procedural Manual of the Codex Alimentarius Commission, sixteenth Edition*) preferably by email to: to Dr Rolf Grossklauss, Chairman of the Committee, Bundesinstitut für Risikobewertung (BfR), P.O. Box 33 00 13, 14191 Berlin, Germany (Fax: +49 228 5294965; Email: ccnfsdu@bmelv.bund.de), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy (fax:+39 06 570 54593; email: codex@fao.org) **by 1 October 2007.**

Background

The matter of the application of risk analysis for the work of the Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) had been considered by the Committee during the last few sessions.

During the 28th Session of CCNFSDU (ALINORM 07/30/26, para. 143) it was agreed to start new work on the establishment and application of risk analysis principles by the Committee on Nutrition and Foods for Special Dietary Uses and that the Project Document, prepared by Australia, would be forwarded to the 30th Session of the Commission for consideration of new work proposals.

The 30th Session of the Codex Alimentarius Commission (2-7 July 2007) agreed to the Committee's proposal for new work to develop risk analysis principles and their application to the work of the CCNFSDU (ALINORM 07/30/REP, para 96 and Appendix VII).

Timeframe

The agreed Proposal presented the following timeframe:

- First draft to be considered by 29th session of CCNFSDU 2007 at Step 3;
- Proposed to advance to Step 5 by 30th session of CCNFSDU scheduled for 2008;
- Proceed to Step 8 by 31st session of CCNFSDU scheduled for 2009.

The 2008-2013 Strategic Plan adopted by the Commission at its 30th session requires CCGP to review the consistency of risk analysis principles elaborated by the relevant Codex committees by 2011 and the Commission to review risk analysis principles developed by relevant Codex committees by 2013.

In accordance with the Proposal for New Work, the Committee should decide whether to proceed to develop subsidiary guidelines for nutritional risk analysis by its 30th Session scheduled for 2008.

Recommendations

That the Committee:

- 1 Considers and provides comment on the appended draft Nutritional Risk Analysis Principles.
- 2 Determines whether to retain the text in square brackets in paragraphs 10 and 12 which refer to food potentially eligible to bear a health claim.
- 3 Provides guidance on the further development of the discussion presented in paragraph 33 currently shown in square brackets.
- 4 Decides an appropriate title for Nutritional Risk Analysis Principles destined for publication in the Codex Procedural Manual (and consequential amendment to paragraph 4 in square brackets).

Two options are proposed that differ in scope of application:

A Nutritional Risk Analysis Principles for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses (or sub-option **Application of Risk Analysis Principles by the Committee on Nutrition and Foods for Special Dietary Uses**). The first sub-option was the title of the Committee's Proposal for New Work and the second sub-option is the title of the current agenda paper. Both sub-options anticipate that the Nutritional Principles would be applied only by CCNFSDU; or

B Principles for Nutritional Risk Analysis for Application in the Framework of the Codex Alimentarius. This title uses the same language as the title of the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* published in the Procedural Manual. This option anticipates that the Nutritional Principles would be applied by CCNFSDU plus any other relevant Codex activity that would result in documentation being referred to the CCNFSDU for endorsement in accordance with its 4th term of reference. This is a more accurate reflection of paragraph 7 in the attached Appendix.

- 5 Agrees to advance the draft Principles for Nutritional Risk Analysis to Step 5.

APPENDIX

**PROPOSED DRAFT ESTABLISHMENT AND APPLICATION OF RISK ANALYSIS
PRINCIPLES BY THE COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL
DIETARY USES AT STEP 3**

SECTION 1 – BACKGROUND

1. The *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* (hereafter cited as “Working Principles”) has established general guidance on risk analysis to Codex Alimentarius. These Working Principles were adopted in 2003 and published in this Procedural Manual.
2. The objective of the 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”. By its reference to health aspects in addition to food safety, the objective provides clearer direction for risk analysis to apply to nutritional matters that are within the mandate of the Codex Alimentarius Commission and its subsidiary bodies.

SECTION 2 – INTRODUCTION

3. Codex nutritional risk analysis addresses nutrients¹ and related substances² and the attendant risk to health from their inadequate and/or excessive intake. Nutritional risk analysis applies the same general approach as traditional food safety risk analysis to consideration of excessive intakes of nutrients and related substances. However, unlike many constituents of food that are the subject of traditional food safety risk analysis such as food additives, chemical (pesticide and veterinary drug) residues, microbiological pathogens, contaminants and inherent constituents such as allergens, nutrients and related substances are inherent constituents that are biologically essential (in the case of essential nutrients) or in other ways potentially favourable to health. Nutritional risk analysis therefore adds a new dimension to traditional risk analysis by also considering risks directly posed by inadequate intakes.
4. The [*Nutritional Risk Analysis Principles for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses // Application of Risk Analysis Principles by the Committee on Nutrition and Foods for Special Dietary Uses OR Principles for Nutritional Risk Analysis for Application in the Framework of the Codex Alimentarius*] presented in this document (hereafter cited as “Nutritional Principles”) are subsidiary to and should be read in conjunction with the Working Principles.
5. These Nutritional Principles are framed within the three-component structure of the Working Principles, but with an added initial step to formally recognize Problem Formulation as an important preliminary risk management activity.
6. Consistent with their important role in providing scientific advice to the Codex Alimentarius Commission and its subsidiary bodies, FAO and WHO and their joint expert consultations and expert bodies including, but not limited to, the Joint FAO/WHO Expert Committee on Food Additives

¹ Nutrient is defined by Codex *General Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 09-1987) to mean:

Any substance normally consumed as a constituent of food:

- (a) which provides energy; or
- (b) which is needed for growth and development and maintenance of healthy life; or
- (c) a deficit of which will cause characteristic biochemical or physiological changes to occur.

Essential nutrient means any substance normally consumed as a constituent of food which is needed for growth and development and the maintenance of healthy life and which cannot be synthesized in adequate amounts by the body.

² A related substance is an inherent constituent of food (other than a nutrient) that has a potentially favourable impact on health.

(JECFA) are acknowledged as the primary source of nutritional risk assessment advice to Codex Alimentarius. This role however, does not preclude the choice of alternative sources of scientific advice such as appropriate international expert groups or organizations if and when justified.

SECTION 3 – SCOPE AND APPLICATION

7. The Nutritional Principles are established to guide the Codex Alimentarius Commission and its subsidiary bodies—primarily but not exclusively the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)—in applying nutritional risk analysis to their work. This guidance potentially extends beyond CCNFSDU since the Committee is also mandated, in accordance with its 4th term of reference, “to consider, amend if necessary, and endorse provisions on nutritional aspects” of foods including those resulting from application of nutritional risk analysis that are developed by other Codex subsidiary bodies.
8. Nutritional risk analysis considers the risk of adverse health effects from inadequate and/or excessive intakes of nutrients and related substances, and the predicted reduction in risk from proposed management strategies. In situations that address inadequate intakes, such a reduction in risk might be referred to as a nutritional benefit.
9. The food constituents of primary interest in nutritional risk analysis are inherent components of food and/or intentionally added to food and are identified as:
 - nutrients that may reduce the risk of inadequacy (e.g. vitamin) and those that may increase the risk of adverse health effects (e.g. trans fatty acids and some vitamins at excessive intake); or
 - related substances² (e.g. some non-vitamin A carotenoids) that may increase the risk of adverse health effects at excessive intake and may also reduce the risk of other adverse health effects at low intake.
10. Other food constituents of interest in nutritional risk analysis include:
 - nutrients that increase the risk of adverse health effects (e.g. saturated fatty acids) and that coexist in a food matrix with a nutrient(s) or related substance(s) of primary interest associated with reduction of the risk of inadequacy or adverse health effects at low intake;
 - [nutrients that increase the risk of adverse health effects in a food potentially eligible to carry a health claim].
11. Where appropriate, the application of quantitative nutritional risk analysis may guide decision making on quantitative content provisions for nutrients and related substances in certain Codex texts (e.g. minimum and/or maximum levels of nutrients and optional ingredients in infant formula).
12. Nutritional risk analysis should be as quantitative as possible, although a qualitative risk-based approach drawing on the principles of nutritional risk analysis could assist the development of Codex texts in such situations as:
 - formulating general principles related to nutritional composition (e.g. principles for the addition of nutrients to foods);
 - [formulating general principles for assessing or managing risks related to foods potentially eligible to bear a health claim];
 - managing risks by labelling advice in relation to consumption of foods of certain nutrient-related³ composition, including foods for special dietary use; and

³ For the purpose of these Nutritional Principles, the descriptive term ‘nutrient-related’ refers to one or more nutrients and/or related substances, as the case may be.

- advising on risk-risk analysis (e.g. risk associated with a significantly reduced or entirely avoided consumption of a nutritious, staple food in response to a dietary hazard such as a contaminant present in that food.
13. Nutritional risk analysis does not apply to consideration of traditional food safety risks in the context of assessing food additives, chemical residues, microbiological pathogens, contaminants or allergens, including when the food constituent could be also regarded as a nutrient or related substance. It also does not apply to the general aspects of food labelling that manage risks related to a food's storage, preparation and use.

SECTION 4 – DEFINITIONS

14. The *Definitions of Risk Analysis Terms Related to Food Safety* in this Procedural Manual provide suitable generic definitions of risk analysis, risk assessment, risk management, risk communication and risk assessment policy. When applied in a nutritional risk analysis context, these high-level risk analysis terms should be prefaced by 'nutritional' and their existing definitions appropriately adapted by replacement of relevant existing terms and definitions with those listed below.
15. However, other *Definitions of Risk Analysis Terms Related to Food Safety* have been modified to reference inadequate intake as a nutritional risk factor. Some new terms also have been defined to provide further clarity. The modified or newly developed subsidiary definitions are as follows:

Nutritional risk – A function of the probability of an adverse health effect associated with inadequate or excessive intake of a nutrient or related substance and the severity of that effect, consequential to a nutrient-related hazard(s) in food.

Adverse health effect⁴ – A change in the morphology, physiology, growth, development, reproduction or life span of an organism, system, or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences.

Nutrient-related³ **hazard** – A nutrient or related substance in food that has the potential to cause an adverse health effect depending on inadequate or excessive level of intake.

Nutrient-related hazard identification – The identification of a nutrient-related hazard in a particular food or group of foods.

Nutrient-related hazard characterization – The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with a nutrient-related hazard.

Dose response assessment – The determination of the relationship between the magnitude of intake of (or exposure to) (i.e. dose) a nutrient or related substance and the severity and/or frequency of associated adverse health effects (i.e. response).

Upper level of intake⁴ – the maximum level of habitual intake from all sources of a nutrient or related substance judged to be unlikely to lead to adverse health effects in humans.

Highest observed intake⁴ – the highest level of intake observed or administered as reported within a stud(ies) of acceptable quality. It is derived only when no adverse health effects have been identified.

Intake (Exposure) assessment – The qualitative and/or quantitative evaluation of the likely intake of a nutrient or related substance from food as well as intake from other relevant sources such as food supplements.

⁴A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances. Report of a joint FAO/WHO technical workshop 2005, WHO, 2006.

Nutrient-related 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 nutrient-related hazard identification, nutrient-related hazard characterization and intake assessment.

Bioavailability⁵ – The proportion of the ingested nutrient or related substance that is absorbed and utilised through normal metabolic pathways. Bioavailability is influenced by dietary factors such as chemical form, interactions with other nutrients and food components, and food processing/preparation; and host-related intestinal and systemic factors.

Homeostatic mechanism⁴ – A mechanism effected through a system of controls activated by negative feedback that allow the maintenance of normal body functions in the presence of a variable nutrition environment.

SECTION 5 – PRINCIPLES FOR NUTRITIONAL RISK ANALYSIS

16. These Nutritional Principles build on and respect the Codex Working Principles.
17. Nutritional risk analysis comprises three components: risk assessment, risk management and risk communication. Particular emphasis is given to an initial step of Problem Formulation as a key preliminary risk management activity.

PRELIMINARY NUTRITIONAL RISK MANAGEMENT ACTIVITIES

18. Preliminary nutritional risk management activities should have regard to the particular sections in the Working Principles titled General Aspects of Risk Analysis, and Risk Assessment Policy.

Nutritional Problem Formulation⁴

19. Nutritional Problem Formulation is necessary to identify the purpose of a nutritional risk assessment and is a key component of preliminary nutritional risk management activity because it fosters interactions between risk managers and risk assessors to help ensure common understanding of the problem and the purpose of the risk assessment.
20. Such considerations should include whether a nutritional risk assessment is needed and if so:
 - the priority it should be accorded;
 - who should conduct and be involved in the nutritional risk assessment, nutritional risk management and nutritional risk communication processes;
 - the need for development of nutritional risk assessment policy;
 - how the nutritional risk assessment will provide the information necessary to support the nutritional risk management decision;
 - whether data are available to embark on an evaluation of nutritional risks;
 - what level of resources are available; and
 - the timeline for completing the assessment.
21. Specific information to be gathered for nutritional problem formulation may include:
 - a detailed inventory of prior knowledge;
 - identification of the (sub)populations to be the focus for the risk assessment, geographical areas or consumer settings to be covered;

⁵ Gibson R.S. The role of diet- and host-related factors in nutrient bioavailability and thus in nutrient-based dietary requirement estimates. Food and Nutrition Bulletin 2007;28(suppl):S77-100.

- relevant route(s) of exposure; and
- the health endpoints to be considered.

NUTRITIONAL RISK ASSESSMENT

22. The Codex *Working Principles for Risk Assessment* are generally applicable to nutritional risk assessment. Additional nutritional risk assessment principles to consider within the Codex framework are identified below.

Nutrient-Related Hazard Identification and Hazard Characterization

23. These two steps are often globally relevant because they are based on available scientific and medical literature that contribute data from diverse population groups. This global relevance for characterization of hazard does not, however, preclude the possibility of a (sub)population-specific hazard.
24. Nutritional risk assessment should take into consideration the nutrient-related hazard(s) posed by both inadequate and excessive intakes. This may include consideration of hazard(s) posed by excessive intakes of accompanying risk-increasing nutrients in the food vehicle(s) under consideration.
25. Nutrient-related hazard identification and characterization should recognize current methodological differences in assessment of nutritional risk of inadequate and excessive intakes, and scientific advances in these methodologies.
26. Nutrient-related hazard characterization should take into account homeostatic mechanisms for essential nutrients, and limitations in the capacity for homeostatic adaptations. It may also take into account bioavailability including factors affecting the bioavailability of nutrients and related substances such as different chemical forms.
27. Nutrient reference standards that may be used to characterize nutrient-related hazard(s) related to adequacy include measures of average requirement. Some globally applicable nutrient reference standards for average requirement have been published by FAO/WHO. Official regional and national nutrient reference standards are also available and have been periodically updated to reflect scientific advances. These are more likely to relate to nutrients than to related substances.
28. Nutrient reference standards that may be used to characterize nutrient-related hazard(s) related to excessive intakes include upper levels of intake. Some globally applicable reference standards of upper level of intake have been published by FAO/WHO. In addition, the establishment of international upper levels of intake and highest observed intake that build on recommendations⁴ may be considered in the future. Some periodically-updated nutrient reference standards are available from regional and national authorities. For some related substances, such standards developed from a systematic review of the evidence are available only in the peer-reviewed scientific literature.
29. The assessment of inadequate and excessive levels of intake of particular nutrients and related substances should take into account the availability of all such scientifically determined reference sources, as appropriate. When using such reference standards for nutrient and related substances in nutritional risk assessment, the bases for their derivation should be considered.

Nutrient-Related Intake Assessment and Risk Characterization

30. These two steps are generally specific to the (sub)population(s) under consideration for risk assessment. The populations relevant to Codex consideration are populations at large in Codex member countries or particular subpopulation groups in these countries defined according to physiological parameters such as age or state of health.

31. Nutrient-related intake assessment should consider the composition and types of foods and relevant food supplements⁶ consumed by the target population(s). It may also take into account, the bioavailability of nutrients and related substances in the foods consumed.
32. Nutrient-related intake assessment and risk characterization should be applied within a total diet context. Where feasible, it would typically involve the evaluation of the distribution of habitual total daily intakes for the target population(s). This approach recognizes that nutrient-related risks are often associated with total intakes from multiple dietary sources, including fortified foods, food supplements, and in the case of certain minerals, water.
33. [The *Policy of the Codex Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups* (CCFA Policy) in this Procedural Manual outlines an approach that could serve as a model for FAO/WHO in their risk assessment role to provide international estimates of total intake of nutrients or related substances as appropriate and as required. Based on this example, information for nutritional risk assessment could be collected through centralized data calls by FAO/WHO to Codex member countries for relevant dietary intake assessments such as baseline and previously devised scenario intakes. These data could then be evaluated noting the variability in approaches and assumptions that might have been used by contributors throughout the world.]

NUTRITIONAL RISK MANAGEMENT

34. The *Codex Working Principles for Risk Management* are generally applicable to nutritional risk management. Additional nutritional risk management principles to consider within the Codex framework are identified below.
35. Nutritional risk management can be effected through quantitative measures or qualitative guidance elaborated in Codex texts. Such risk management could involve decisions about nutrient composition, consideration of the suitability of foods containing risk-increasing nutrients for certain purposes or (sub)populations, labelling advice intended to mitigate nutritional risks to public health, and formulation of relevant general principles.
36. Nutritional risk assessment policy should be articulated as appropriate for the selected risk assessor prior to the conduct of the nutritional risk assessment.

NUTRITIONAL RISK COMMUNICATION

37. The *Codex Working Principles for Risk Communication* are generally applicable to nutritional risk communication.

SECTION 6 – SELECTION OF RISK ASSESSOR

38. Consistent with their important role in providing scientific advice to Codex Alimentarius and its subsidiary bodies, FAO and WHO are acknowledged as the primary source of nutritional risk assessment advice to Codex Alimentarius. However, this role does not preclude the choice of alternative sources of advice such as appropriate international expert groups or organizations if and when justified.
39. All requests for risk assessment advice should be accompanied by terms of reference and where appropriate risk assessment policy to provide guidance to the risk assessor. These parameters should be established by the relevant Codex subsidiary body.

⁶ *Codex Guidelines for Vitamin and Mineral Food Supplements* (CAC/GL 55 – 2005) define food supplements as sources in concentrated forms of those nutrients or related substances alone or in combinations, marketed in forms such as capsules, tablets, powders solutions, etc., that are designed to be taken in measured small unit quantities but are not in a conventional food form and whose purpose is to supplement the intake of nutrients or related substances from the diet.

SECTION 7 – REVIEW PROCESS

40. These Nutritional Principles should be reviewed by CCNFSDU at appropriate intervals after implementation to ensure currency and consistency with good regulatory practice and subsequent to any future amendments to the Codex Working Principles.