



**NATIONAL
HEALTH
FEDERATION**

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NHF COMMENTS ON:

**PRINCIPLES FOR NUTRITIONAL RISK ANALYSIS
FOR APPLICATION IN THE FRAMEWORK OF THE
CODEX ALIMENTARIUS**

Please find below the proposed NHF revisions to the existing draft document given in 'track changes' mode.

These comments have been made by NHF's scientific advisory team and take into account issues raised at the Workshop on the Application of Risk Analysis to the work of CCNFSDU (29 October 2006, Chiang Mai) as well as discussions held between scientists at the European Food Safety Authority (EFSA) Colloquium 6: Risk-benefit analysis of foods: methods and approaches, 13-14 July 2006, Tabiano, Italy, which have now been published (EFSA Colloquium 6 Summary Report: *Risk-benefit analysis of foods: methods and approaches*, 13-14 July 2006, Parma, Italy. 156 pp.).

We look forward to the next EWG meeting on 11 September at 29CCNFSDU and await details of venue and time.

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DRAFT INCLUDING NHF PROPOSED REVISIONS

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

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 scope 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 or high intakes of nutrients and related substances. However, unlike the many subjects of food safety risk analysis such as food additives, chemical (pesticide and veterinary drug) residues, microbiological pathogens, contaminants and some inherent constituents such as allergens; nutrients and related substances are also inherent constituents of food 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 risk analysis that also considers the risk directly posed by inadequate intakes.
4. The *Principles for Nutritional Risk Analysis for Application in the Framework of the Codex Alimentarius* presented in this document (hereafter cited as “Nutritional

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.

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 Codex Alimentarius and its subsidiary bodies, FAO and WHO 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 by exceptional circumstances.

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 risks resulting from management efforts to mitigate those risks. In a nutritional context, such a reduction in risk might be referred to as a nutritional benefit.
9. Nutritional risk analysis, using methods as quantitative as possible (see also #10 and 11), pertains to:
 - nutrients of primary interest that reduce risk (e.g. vitamins, minerals) in individuals with inadequate diet or may increase risk (e.g. trans fatty acids); or
 - related substances² (e.g. fibre) that potentially benefit health; and
 - the nutrient composition of the food matrix in which risk-increasing nutrients (e.g. saturated fatty acids) coexist with the nutrient or related substance of primary interest; or
 - [these risk-increasing nutrients are present in a food eligible to carry a health claim].
10. The application of nutritional risk analysis is intended to guide decision making on quantitative content provisions for nutrients and related substances in Codex texts (e.g. minimum and/or maximum levels of nutrients and optional ingredients in infant formula).
11. Although nutritional risk analysis should be as quantitative as possible, 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);
 - [managing risks to health associated with a potential increase in consumption of foods eligible to bear a health claim that also contain amounts of risk-increasing nutrients];
 - managing risks related to inappropriate consumption of foods of certain nutrient-related³ composition, including foods for special dietary use; and
 - advising on risk/nutritional benefit situations that contemplate 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.
12. Nutritional risk analysis does not apply to consideration of food safety risks from food additives, chemical residues, microbiological pathogens, contaminants or allergens, or to the general aspects of labelling foods that manage risks related to appropriate storage, preparation and use.

SECTION 4 – DEFINITIONS

13. The *Definitions of Risk Analysis Terms Related to Food Safety* in this Procedural Manual provide a suitable basis for development of subsidiary definitions of risk analysis terms applied to a nutritional context.
14. In particular, the generic definitions of risk analysis, risk assessment, risk management, risk communication and risk assessment policy are generally applicable to nutritional risk analysis.
15. However, for the purposes of Nutritional Risk Analysis, several subordinate definitions to the existing generic *Definitions of Risk Analysis Terms Related to Food Safety* have been developed to incorporate *inter alia* reference to inadequate intake as a nutritional risk factor. Some new terms also have been defined to provide further clarity. The modified, subordinate definitions or those newly developed 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.

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.

⁴ Report of a joint FAO/WHO technical workshop 2005. A model for establishing upper levels of intake for nutrients and related substances, WHO, 2006.

Nutrient-related hazard³

A nutrient or related substance in food that has the potential to cause an adverse health effect depending on inadequate or excessive levels 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).

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.

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.

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.

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 regarding the general aspects of risk analysis, and risk assessment policy.

Nutritional Problem Formulation⁴

19. Nutritional Problem Formulation is a key component of preliminary nutritional risk management activity because it fosters interactions between risk managers and risk assessors to ensure common understanding of the problem and the purpose of the risk assessment.

20. Such considerations may 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 and nutritional risk management processes;
- a 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 sufficient data are available to embark on an evaluation of nutritional risks to given populations or subpopulations;
- what level of resources are available; and
- the timeline for completing the assessment.

NUTRITIONAL RISK ASSESSMENT

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

Nutrient-Related Hazard Identification/Hazard Characterization

22. 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 subpopulation-specific hazard. The implications of any subpopulation-specific hazard should not necessarily be factored into population-wide risk management decisions as label warnings may be sufficient. Accordingly, risks associated with inadequate intake may be incurred if risk management decisions are based on the assumption that the whole population is as sensitive as the most sensitive group.

23. 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 as well as assessment of both risks and benefits in different subpopulations.

24. 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.
25. 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 the bioavailability of different chemical forms of nutrients and factors affecting bioavailability of nutrients and related substances.
26. Nutrient reference standards that characterize nutrient-related hazard(s) include measures of average requirement and upper levels of intake. Globally applicable nutrient reference standards are published by FAO/WHO. Official regional and national nutrient reference standards are also available. Information on upper levels of intake of related substances is growing and becoming more widely disseminated however very few reference standards developed from a systematic review of the evidence that exists for inadequate or suboptimal levels of intake of related substances.

Nutrient-Related Intake Assessment/Risk Characterization

27. These two steps are generally specific to the population(s) or subpopulation(s) under consideration for risk assessment. The populations relevant to Codex consideration are populations at large in Codex member countries or these countries' particular subpopulation groups defined according to physiological parameters such as age or state of health.
28. Nutrient-related intake assessment should consider the composition and types of foods and relevant food supplements⁶ consumed by the target population(s).
29. 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 usual 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 minerals, water.
30. The *CCFAC Policy 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

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.

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.

31. Nutrient-related hazard identification and characterization should take into account the totality of available evidence, including evidence from peer reviewed studies, relevant reports and medical records. Hazard identification should be specific to given chemical forms or species of nutrient and relevant to stated target populations.⁷
32. In order to make direct comparisons between the risk and benefits associated with nutrient intakes as well as making meaningful and scientifically valid communications of nutrient risks and benefits, it may be necessary to develop a common scale of measurement for both risks and benefit (e.g. using Disability Adjusted Life Years [DALYs] or Quality Adjusted Life Years (QUALYs))⁷

NUTRITIONAL RISK MANAGEMENT

33. The Codex *Working Principles for Risk Management* are generally applicable to nutritional risk management. Additional principles to consider in nutritional risk management within the Codex framework are identified below.
34. 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, labelling advice intended to mitigate nutritional risks to public health, and formulation of relevant general principles.
35. 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

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

SECTION 6 – SELECTION OF RISK ASSESSOR

37. 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

⁷ European Food Safety Authority (EFSA) Colloquium 6 Summary Report: *Risk-benefit analysis of foods: methods and approaches*, 13-14 July 2006, Parma, Italy. 156 pp.

such as appropriate international expert groups or organizations if and when justified by exceptional circumstances.

38. All requests for risk assessment advice should be accompanied by terms of reference and where appropriate risk analysis policy to provide guidance to the risk assessor. These parameters should be established by the relevant Codex subsidiary body.

SECTION 7 – REVIEW PROCESS

39. 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.