codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 9 **CX/NFSDU 06/28/9**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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

Sheraton Chiangmai Hotel, Chiang Mai, Thailand,

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

(Prepared by Australia with the assistance of members of the Electronic Working Group: Canada, China, Denmark, European Commission, France, Germany, Ghana, Japan, Republic of Korea, Mexico, New Zealand, Norway, Portugal, Thailand, United States of America, AIDGUM, CRN, EHPM, IADSA, ICBA, IDACE, IDF, IFT, JIHFS, NHF, and WHO)

BACKGROUND

The 25th Session of the CCNFSDU, November 2003, established an Electronic Working Group on Risk Analysis (EWG), led by Australia, to prepare a discussion paper on the application of risk analysis to the work of CCNFSDU. At the 26th and 27th Sessions in 2004 and 2005 respectively, Australia presented discussion papers for the Committee's consideration based on the EWG's initial and subsequent consideration of issues relating to the development of risk analysis principles and possibly guidelines.

The 2005 CCNFSDU session[1] established the terms of reference for the 2006 Electronic Working Group to:

1. Further consider issues raised in agenda paper CX/NFSDU 05/27/10 October 2005 (Revised) and to present recommendations; and

2. Submit a proposal for new work to develop risk analysis principles and possibly guidelines for application to the work of the CCNFSDU.

[1], ALINORM 06/29/26, paragraph 151 (Report of the 27th Session CCNFSDU, 2005)

DISCUSSION PAPER

This revised Discussion Paper further considers the issues raised in the 2005 Discussion Paper[2]: scope and terminology of risk analysis; roles of risk assessor and risk manager and use of risk communication; and models for development of principles and guidelines. Following responses from some Members[3] of EWG to the questions raised in the 2005 Discussion Paper, a revised version of the Discussion Paper containing draft recommendations was circulated to the EWG for comment[4] in 2006.

This final version of the Discussion Paper presented to the 28th session of CCNFSDU incorporates revisions based on EWG comments received in 2006 and proposes recommendations on all key considerations in order to establish the framework for subsequent development of principles and possibly guidelines for the application of nutritional risk analysis to the work of CCNFSDU. Forging agreement on these key considerations will be important to advance the Committee's work on risk analysis.

Draft Proposal for New Work

A draft proposal for new work to develop risk analysis principles and possibly guidelines for submission to the next session of the Commission was also circulated to the EWG for their comment. A revised draft proposal is given at Attachment 2.

RECOMMENDATIONS

1 Discussion Paper

The Committee is invited to consider the discussion and recommendations given in the Discussion Paper with a view to reaching agreement on the foundational elements of risk analysis applicable to the work of CCNFSDU, before work proceeds to the development of principles and possibly guidelines, commencing in 2007.

These recommendations relate to definition, scope, terminology and relevant factors for nutritional risk analysis; consecutive development of nutritional risk analysis principles then possibly guidelines; and relevant approaches to risk assessment of nutritional issues.

2 Draft proposal for new work

The Committee is also invited to approve the draft proposal for new work at Attachment 2 for submission to the Commission for their approval in 2007.

3 Forward work plan

The Committee is invited to endorse the proposed schedule of work for development of principles and possible guidelines within the Commission's timeframe as given in the draft Strategic Plan.

Subject to the Commission's approval in 2007:

develop first draft of nutritional risk analysis principles for 29th Session CCNFSDU 2007;

advance draft to Step 5 by 30th Session CCNFSDU 2008;

decide on development and first draft of possible guidelines by 30th Session CCNFSDU 2008;

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[2] CX/NFSDU 05/27/10 October 2005 (Revised) Discussion paper on the application of risk analysis to the work of CCNFSDU.
[3] Canada, CRN, European Community, IADSA, New Zealand, United States
[4] Canada, CRN, European Community, IADSA, New Zealand, NHF, United States

advance draft principles to Step 8 (possible draft guidelines to Step 5) by 31st Session CCNFSDU 2009;

(advance possible draft guidelines to Step 8 by 32nd Session CCNFSDU 2010);

submit principles and possible guidelines to CCCP for consideration by 2011;

submit principles and possible guidelines to Commission for adoption by 2013.

SECTION 1 OVERVIEW OF SCOPE AND TERMINOLOGY OF RISK ANALYSIS FOR CCNFSDU

To provide a context for this work, this Section provides an overview of:

a) The *scope* of risk analysis issues addressed in Codex texts that are the responsibility of the CCNFSDU, with an emphasis on the scope of risk analysis issues pertaining to nutrients and related food components; and

b) Codex risk analysis *terminology* in relation to risk analysis issues addressed in CCNFSDU texts, with an emphasis on the interpretation of Codex and other terminology that is applicable to risk analysis issues pertaining to nutrients and related food components.

I. INTRODUCTION

1. Risk analysis is a process consisting of three components: risk assessment, risk management, and risk communication[5]. It is used to enhance the scientific basis of regulatory decisions.

2. Codex has identified *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*[6] (Codex Working Principles). The objective of these principles is to provide guidance to the Codex Alimentarius Commission and the joint FAO/WHO expert bodies and consultations, so that food safety[7] and health aspects of Codex standards and related texts are based on risk analysis.

3. While these Codex Working Principles recognize that the dual purposes of the Codex Alimentarius are to protect the health of consumers and ensure fair practices in food trade, they note that Codex decisions and recommendations on risk management should have as their primary objective the protection of the health of consumers. Toward this objective, the Codex Alimentarius Commission has adopted Codex standards, codes of practice, guidelines and other recommendations in an effort to manage risk from a variety of substances that have the potential to cause an adverse health effect (e.g. contaminants, microbiological agents, food additives, and nutrients and related food components).

4. In addition, the Joint FAO/WHO Technical Workshop on Nutrient Risk Assessment held in May 2005 had as its general aim: to specify the nature of an international model for the establishment of upper levels of intake for nutrient substances and to provide clarification of the specific nutrient risk assessment process. The FAO/WHO Workshop Report[8] presents a model for establishing upper levels of intake for nutrients and discusses in detail: appropriate terminology; differentiating features from classic risk assessment; and considerations, process including an initial step of

[5] Codex Procedural Manual, 15th edition, p.44
[6] Codex Procedural Manual, 15th edition, pp.101-107
[7] The Codex Recommended International Code of Practice General Principles of Food Hygiene (CAC/RCP1-1969, rev. 4 (2003)) defines Food Safety for its purposes as 'assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use'.
[8] FAO/WHO *A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances*, accessed 20 April at http://www.who.int/ipcs/highlights/full_report.pdf

problem formulation, applicability and limitations of the steps involved in the conduct of nutrient risk assessment. Its international approach and detailed discussion of nutrient risk assessment methodology provided useful guidance in progressing this discussion paper and should provide future guidance for CCNFSDU in risk assessments of excess of nutrients and related components.

II. SCOPE OF APPLICATION OF RISK ANALYSIS TO THE WORK OF THE CCNFSDU

A. Overview

5. CCNFSDU's terms of reference (TOR)[9] describe four activities that together constitute the Committee's responsibility. These terms of reference are:

   (a) to study specific nutritional problems assigned to it by the Commission and advise the Commission on general nutrition issues;

   (b) to draft general provisions, as appropriate, concerning the nutritional aspects of all foods;

   (c) to develop standards, guidelines, or related texts for foods for special dietary uses, in cooperation with other committees where necessary;

   (d) to consider, amend if necessary, and endorse provisions on nutritional aspects proposed for inclusion in Codex standards, guidelines and related texts.

6. CCNFSDU's activities mainly involve development, review and revision of: Codex standards and guidelines for foods for special dietary uses (TOR (c)); and general texts including principles and guidelines that address nutritional matters (TOR (b)).

7. Examples of TOR (b) include the development of Codex general texts that are applied horizontally e.g. the scientific basis of health claims[10], *General Principles for the Addition of Essential Nutrients to Foods*[11]. The Committee also provides technical advice to the Codex Committee on Food Labelling (CCFL) on matters related to nutritional labeling such as nutrient definitions and nutritional criteria in support of certain claims.

8. In accordance with TOR (c), CCNFSDU has or is currently developing commodity standards for foods for special dietary uses that are applied vertically e.g. Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants[12]; Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children[13]. The commodity standards range from foods that provide the sole source of nutrition to those that partially contribute to the diet.

9. CCNFSDU shares responsibility for development of provisions in standards for foods for special dietary uses that are the domain of other committees (e.g. food additives), and for provisions related to nutrition in Codex texts developed by other committees (e.g. Biotechnology Taskforce). These activities are covered by TOR (c) and (d) respectively. It is uncertain whether the Commission has ever sought advice on nutritional matters in accordance with TOR (a).

10. CCNFSDU's terms of reference describe the total extent of the Committee's work, but as noted above, the responsibility for some activities are shared with other Codex committees. The particular role of CCNFSDU relative to other Codex committees is elaborated in the next sections B, C and D.

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[9] Codex Procedural Manual, 15th edition, p.134
[10] CX/NFSDU 06/28/7 Proposed draft recommendations on the scientific basis of health claims, at Step 3.
[11] CAC/GL 09-1987 (amended 1989, 1991)
[12] ALINORM 06/29/26, Appendix IVA (Report of the 27th Session, CCNFSDU, 2005)
[13] ALINORM 06/29/26, Appendix II (Report of the 27th Session, CCNFSDU, 2005)

B. Role of the CCNFSDU in the Conduct of Risk Analysis for Nutrients and Related Food Components

11. Horizontal texts previously developed by CCNFSDU have addressed aspects of nutritional risk[14], for example the aforementioned *General Principles for Addition of Essential Nutrients to Foods*[11] include reference to nutrient hazards such as nutrient excess, deficit and imbalance. Similarly, other horizontal texts might address elements relevant to nutritional risk analysis, such as identification of potential hazards for assessment or possible risk management mechanisms.

12. Certain sections in standards for foods for special dietary uses that address nutritional aspects involve risk analysis, namely essential composition and quality factors. A current example is the establishment of minimum and where appropriate, maximum (or guideline) levels of essential nutrients as well as maximum levels of optional constituents (related food components) in the draft revised infant formula standard[12].

13. CCNFSDU's work on standards for foods for special dietary uses may involve risk analysis through setting compositional criteria that support labeling requirements e.g. the Draft Revised Standard for Gluten-Free Foods[15]. The 2005 CCNFSDU Discussion Paper[2] sought clarification on whether CCNFSDU should be responsible for analysis of risks usually managed by labeling to protect public health and safety. These labeling provisions range from general instructions for appropriate storage, preparation and use; implementation of WHO policy such as age of introduction of solids; to qualitative or quantitative nutrient-specific requirements e.g. identification of protein source of infant formulas; compositional criteria for 'gluten free' claims; or requirements such as that proposed in the draft revised infant formula standard[12]: "products containing less than 0.5 mg Iron (Fe)/ 100 kcal shall be labeled with a statement to the effect that when the product is given to infants over the age of four months, their total iron requirements must be met from other additional sources". CCFL is charged with endorsing or amending (rather than developing) all such provisions.

14. Although these types of labeling requirements might ultimately serve to mitigate nutritional risks including those from particular allergenic substances, nutritional risks can be divided into those where the hazard is directly nutrient related; and those that are consequential to another type of hazard such as a microbial hazard resulting from inappropriate storage or preparation.

15. For the purposes of Codex Alimentarius, nutritional risk analysis underpinned by either a quantitative or qualitative risk assessment should be confined to risks arising from nutrient-related hazards and not consequential to other hazard types. This approach builds on the idea of the Committee's 'primary responsibility' that was put forward in the 2005 Discussion Paper[2] and which was generally supported by responses from the EWG.

16. Further consideration is needed in relation to nutritional risks potentially associated with decisions about the permission or prohibition of nutrition and health claims in labeling of foods for special dietary use. In this case, the potential hazard may relate to both the composition of a food potentially carrying a claim as well as the intake of that food relative to other foods in the diet. If considered within nutritional risk analysis, it would extend the Codex definition of 'hazard' to include the relative intakes of foods in a dietary context. (see Section IV, A, "Total dietary intake context").

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[14] Proposed in this paper to be defined as "A function of the probability of an adverse health effect associated with excessive or inadequate intake of nutrients and related food components and the severity of that effect, consequential to a nutrient-related hazard(s) in food."

[15] CL 2006/5 - NFSDU

C. Role of the CCNFSDU in the Conduct of Other Risk Analysis

17. In the development of Codex standards and related texts for foods for special dietary uses, CCNFSDU cooperates with other committees in developing provisions pertaining to food additives, contaminants, and hygiene. This may involve risk analysis that is subject to endorsement by another committee and/or referral of a matter to an expert body e.g. the Joint FAO/WHO Expert Committee on Food Additives (JECFA) for a risk assessment. Although CCNFSDU is responsible for development of these provisions, the content does not relate to a nutritional matter and may be guided by documentation prepared by other committees.

D. Role of the CCNFSDU in Providing Guidance Related to Risk Analysis

18. Where other Codex committees and task forces are developing risk analysis guidelines that incorporate nutritional elements e.g. Biotechnology Taskforce, it would be expected that these guidelines would be developed with the collaboration and guidance of CCNFSDU to ensure a consistent approach to the application of risk analysis to nutrition-based standards within the work of Codex. This is one example where the Committee would be expected to consider, amend if necessary, and endorse the provisions in accordance with its 4th terms of reference.

E. Conclusions

19. Given the integrated nature of the work of Codex committees in the development and maintenance of Codex texts, it is important that each committee's principles and guidelines are discrete and germane to the work of that committee while avoiding unnecessary overlap and duplication. Risk analysis that is discrete and germane to the work of CCNFSDU (including its endorsement role) has a nutritional focus i.e. relates directly to hazards from nutrients and related food components; it is hereafter described as **nutritional risk analysis**.

20. The application of nutritional risk analysis is appropriate to certain provisions in standards for foods for special dietary uses, specifically those related to the section entitled 'ESSENTIAL COMPOSITION AND QUALITY FACTORS'. However, it is also relevant to development of horizontal texts such as general principles as well as certain labeling intended to protect public health and safety that mitigates nutritional risks arising from nutrient-related hazards.

21. Although CCNFSDU might also apply risk analysis to other components of its work in developing provisions related to food additives and contaminants, hygiene and some labeling requirements, this form of risk analysis is differentiated from nutritional risk analysis and as such, the Committee would necessarily rely on approaches, principles and guidelines developed by other committees for this purpose.

F. Recommendations

22. It is recommended that CCNFSDU confine the scope of its principles and possibly guidelines for risk analysis to the development, review and revision work within its Terms of Reference that collectively:

    (a) considers all three components of risk analysis (i.e. risk assessment, risk management, and risk communication);

    (b) has a specific focus on nutritional risk, including risk associated with excessive or inadequate intake of nutrients and related food components;

    (c) applies to provisions in standards for foods for special dietary uses relating to the section entitled 'ESSENTIAL COMPOSITION AND QUALITY FACTORS', and also to labeling

intended to protect public health and safety that serves to mitigate potential risks arising from nutrient-related hazards; and

(d) is relevant to horizontal texts with a nutritional focus.

23. Such risk analysis as described in the preceding paragraph is to be known as **nutritional risk analysis**.

24. Recognizing CCNFSDU's 4th TOR and the horizontal nature of some of the Committee's texts, nutritional risk analysis principles and guidelines should apply to relevant work undertaken by CCNFSDU *and* other committees within the Codex Alimentarius.

III. NUTRITIONAL RISK ANALYSIS AND CONSIDERATION OF TERMINOLOGY

A. Overview

25. The application of risk analysis to nutrients and related food components is unique in that it requires recognition that nutrients and related substances are unlike non-nutrients in that they are biologically essential or have a demonstrated favorable impact on health[16]. Consequently, the work of the CCNFSDU often involves the analysis of risks of nutrients and related food components from two perspectives:

(a) harm resulting from excessive intakes (conceptually the same as for food safety); and

(b) harm resulting from intakes that are too low.

The establishment of minimum and where appropriate, maximum (or guideline) levels of nutrients and related food components in infant formula[12] is an example of current work that addresses both aspects of risk.

26. In this discussion paper, 'nutrients and related food components' refer to dietary constituents that may have a favorable and possibly unfavorable impact on health, depending on levels of intake. The group of optional ingredients in the draft revised infant formula standard[12] is an example of related food components under current consideration by CCNFSDU. The term 'nutrient-related' is intended to encompass nutrients and related food components.

27. The purpose of the discussion of terminology and definitions is to establish the terminology for development of nutritional risk analysis principles and possibly guidelines. The discussion identifies relevant Codex *Definitions of Risk Analysis Terms Related to Food Safety* [17]. In the interests of harmonization, the discussion recommends only minimal modification to existing terms and definitions where necessary to address risk associated with both excessive and inadequate intakes of nutrients and related food components and certain risks managed by nutrient-related labeling to protect public health and safety.

28. In the 2005 Discussion Paper[2], two possible approaches to terminology relevant to nutritional risk analysis had been proposed: no change to definitions created within a food safety context; or modification to expand the scope to better encompass nutrient inadequacy within nutritional risk.

29. The EWG members universally agreed with a degree of modification, although differing views were expressed on the extent to which modification of the existing terms and definitions and creation of new term(s) with definitions were necessary. One suggestion suggested prefacing each term by the descriptor 'nutrient' or 'nutritional' as appropriate. The majority however, favored

[16] FAO/WHO *A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances*, accessed 20 April at http://www.who.int/ipcs/highlights/full_report.pdf, p.1

[17] Codex Procedural Manual, 15th edition, pp.44-46

minimal modification of Codex terminology to describe risks associated with inadequate and excess intake.

30. Although the ensuing discussion prefers 'nutritional risk' to 'risk', the use of the descriptor 'nutritional' has not been routinely applied to the relevant risk analysis terminology in this discussion paper. However, it is recognized that such routine use of 'nutrient/nutritional' as a descriptor might become necessary depending on how the nutritional risk analysis documentation is framed.

31. The definitions of food safety risk terms relevant to nutritional risk analysis are therefore mostly unchanged, but their interpretation may be adapted to operate within a context of nutritional risk analysis. By adapting rather than replacing existing Codex terminology and proposing new terminology only where necessary, account is taken of the 2004 FAO/WHO *Review on the Provision of Scientific Advice to Codex and Member Countries*[18] that specifically identified the need to harmonize terminology, methodology and outputs for chemical and microbiological hazards and biotechnological and nutritional issues.

B. 'Hazard', 'Risk', and 'Nutritional Risk'

The following three sections discuss the relevance of Codex *Definitions of Risk Analysis Terms Related to Food Safety* [17] for the development of documentation for nutritional risk analysis.

32. ***Hazard:*** A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

The key concepts in the definition are *agent* and *condition of food* which, when applied to a nutrient or related food component respectively, represent excessive or inadequate amounts in food that may cause an adverse health effect. The hazard may relate to distinct chemical forms or all forms of the nutrient or related food component. Interpreting *condition of food* in the context of nutritional risk analysis to mean inadequate amounts of a nutrient or related food component suitably separates the two concepts of excess and inadequacy yet appropriately links both concepts to adverse health effects.

A member of the EWG did not support this approach. In their view, the term *condition of food* was not sufficiently clear; also 'hazard' should be replaced by 'nutrient compound' (as the subject of the risk assessment) or 'nutrient' (as in nutrient identification/characterization) because *hazard* conveys a meaning of only danger or risk compared with *nutrient* which conveys potential benefit as well as potential risk. The majority however, favored minimal modification of Codex terminology to describe hazards associated with inadequate and excess intake.

The Codex approach differs from that recently put forward in the FAO/WHO Workshop Report[19]. After a review of definitions from ICPS, Codex Alimentarius and IUPAC, the Workshop Report defined 'hazard' for the purposes of risk assessment of nutrient excess (subsequently described therein as nutrient hazard), and 'adverse health effect' as follows:

Hazard is the inherent property of a nutrient or related substance to cause adverse health effects depending upon the level of intake.

and

[18] ALINORM 04/27/10G (Agenda Item 16, 27th Session CAC, 2004)
[19] FAO/WHO *A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances*, accessed 20 April at http://www.who.int/ipcs/highlights/full_report.pdf, pp. 2-23

Adverse health effect is 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.

The FAO/WHO Workshop Report[20] considered that 'inherent property' of a nutrient in the above definition of 'hazard' was responsible for the **risk** associated with high levels of intake and also for the **effects** associated with biological essentiality or favorable health impact, however it was **not** responsible for the **risk** associated with deficiency states; rather, that type of risk was caused by the absence or insufficient amounts of a nutrient.

Given the term 'adverse health effect' is also incorporated into the Codex definition of 'hazard' and 'risk', the WHO definition of *adverse health effect* has utility for the purposes of CCNFSDU in that its meaning could apply equally to consequences of excess and inadequate intakes of nutrients.

It is recommended that the Codex definition of 'hazard' be adopted since it can be interpreted to encompass concepts of excess and inadequacy. It is acknowledged that 'condition of food' is a general term that relies on knowledge of the specific definition for its intended meaning in the context of nutritional risk, however as text is further developed, it might be useful to develop subsidiary terms that separately and more precisely define hazards related to nutrient excess and to nutrient inadequacy.

33. ***Risk:*** A function of the probability of an adverse health effect and the severity of that effect consequential to a hazard(s) in food.

The Codex definition of 'risk' refers to a hazard only *in* food, although it is acknowledged that 'hazard' (as defined above) conceptually links to an inadequate presence or amount of a nutrient. Rather than modify this definition of 'risk' or overlay a nutritional interpretation, it is considered more appropriate to develop a separate but related definition of 'nutritional risk' as the foundation of nutritional risk analysis.

It is recommended that the Codex term 'risk' be retained including to serve as a model for development of a definition for 'nutritional risk'.

34. ***Nutritional Risk (recommended new term):*** A function of the probability of an adverse health effect associated with excessive or inadequate intake of nutrients and related food components and the severity of that effect, consequential to a nutrient-related hazard(s) in food.

The fundamental difference between 'risk' and 'nutritional risk' relates to the additional concept of adverse health effects resulting from nutrient inadequacy. It is therefore important for the definition of 'nutritional risk' to refer to both types of nutrient-related risk i.e. those associated with excessive or inadequate intake of nutrients and related food components in foods. The previous inclusion of the term 'or condition of' in this definition of nutritional risk was deleted because the definition of 'hazard':

(a) is qualified as 'nutrient-related'; and

(b) already incorporates the concept of inadequacy through use of 'or condition of'.

It is recognized that 'nutritional risk' or 'nutrition risk' may be defined in various ways for various purposes at the national, regional, and global level. For some purposes, these terms may be defined very broadly, and encompass a wide range of anthropometric risk criteria, biochemical

[20] Ibid p.23.

and other medical risk criteria, and food insecurity and other dietary risk criteria[21]. However for the purposes of Codex nutritional risk analysis, consideration of risk is restricted to the consequences of nutrient-related hazards in food.

C. Terms Relating to Nutritional Risk Analysis and its Components

35. ***Problem Formulation:*** This term is not found within the suite of Codex risk analysis definitions. However, the FAO/WHO Workshop Report[22] considered that a preliminary problem formulation step was necessary to ensure common understanding of the problem between risk assessors and risk managers and to refine the problem formulation as needed.

Problem formulation is a preliminary activity that considers among other things:

(a) whether a risk assessment is needed;

(b) who should be involved in the risk assessment and risk management processes;

(c) how the assessment will provide the information necessary to support the risk management decision;

(d) whether data are available to embark on an evaluation of risks; and

(e) what level of resources is available; and the timeline for completing the risk assessment.

Because this preparatory activity involves both risk assessors and risk managers prior to the conduct of the risk assessment, it should be considered as a preliminary activity to risk analysis.

36. ***Risk Analysis:*** A process consisting of three components: risk assessment, risk management and risk communication.

This definition applies to both excessive and inadequate nutrient intakes.

No change to the Codex definition required.

37. ***Risk Assessment:*** A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure (intake) assessment, and (iv) risk characterization.

The Codex *Statements of Principle Relating to the Role of Food Safety Risk Assessment* [23], referenced in the Codex Working Principles, introduce some flexibility in the use of risk assessments. The first statement sets out that health and safety aspects of Codex decisions and recommendations should be based on a risk assessment, as appropriate to the circumstances whereas the fourth statement requires that risk assessment should use available quantitative information to the greatest extent possible.

The FAO/WHO Workshop Report[24] compared the steps involved in classic non-nutrient risk assessment with the requirements of nutrient risk assessment and given the nature of data evaluation, concluded that hazard identification and hazard characterization were better reflected

[21] Food and Nutrition Board, Institute of Medicine, National Academy of Sciences. WIC Nutrition Risk Assessment: A Scientific Assessment. Washington, D.C. National Academy Press, 1996

[22] FAO/WHO *A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances*, accessed 20 April at http://www.who.int/ipcs/highlights/full_report.pdf, pp.18-19

[23] Codex Procedural Manual, 15th edition, p.161

[24] FAO/WHO *A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances*, accessed 20 April at http://www.who.int/ipcs/highlights/full_report.pdf, pp.18, 35, 103

as closely linked, integrated activities performed for the most part as a single step—one characterized by iterations and refinements in data gathering and evaluation. Although this approach has merit and could be borne in mind when developing principles for nutritional risk assessment, no additional terms or modifications to definitions are contemplated at this stage.

The term 'intake' has been added to the third step in this definition as an alternative to 'exposure' to apply to assessments of both excessive and inadequate nutrient intakes as appropriate. This is consistent with the approach taken by the FAO/WHO Workshop Report[25] which preferred 'intake' to 'exposure' because 'intake' was a more familiar term relating to nutrients than 'exposure'. Nevertheless, it was acknowledged that 'exposure' was applicable when referring to total body burden from the cumulative, systemic amount of the substance from all sources, both food and non-food, such as in the case of vitamin D.

For risk associated with inadequate nutrient intake, the four steps in risk assessment could apply with minimal modification of Codex risk analysis terms and definitions as discussed in the next Section D on risk assessment terms.

38. ***Risk Management:*** The process, distinct from risk assessment of weighting 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.

This definition applies to both excessive and inadequate nutrient intakes.

No changes to the Codex definition required.

39. ***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.

This definition applies to both excessive and inadequate nutrient intakes.

No changes to the Codex definition required.

D. Terms Relating to Risk Assessment and Its Four Components

40. ***Hazard Identification:*** The identification of biological, chemical, and physical agents <u>in, or a condition of, food</u> capable of causing adverse health effects which may be present in<u>, or associated with,</u> a particular food or group of foods.

This is the first step in risk assessment. In order for the Codex definition of 'hazard identification' to be applicable to hazards associated with inadequate intake, the phrase, 'in food, or a condition of food' is added. This is also consistent with the Codex definition of 'hazard' which includes this phrase.

41. ***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<u>, or with a condition of food</u>. 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.

[25] Ibid. p.26

This is the second step in risk assessment. In order for the Codex definition of 'hazard identification' to be applicable to hazards associated with inadequate intake, the phrase, 'or with a condition of food' is added. This is also consistent with the Codex definition of 'hazard' which includes this phrase. Hazard characterization could include assessment of bioavailability. Whether a statement similar to the others on the requirement for a dose response assessment, in this case for hazards associated with a condition of food, will depend on future considerations of the methodology to be applied.

42. ***Dose-Response Assessment:*** The determination of the relationship between the magnitude of exposure to, or intake of (dose) a chemical, biological or physical agent and the severity and/or frequency of associated adverse health effects (response).

For consistency, the term 'intake' is added as an alternative to 'exposure'.

Certain definitions of dose-response assessment that have been applied to excessive nutrient intakes have used the term 'intake' rather than 'exposure' to refer to dose[26]. The FAO/WHO Workshop Report [27] preferred the term 'intake' to 'dose' because *intake* suggested a continuous distribution on average whereas *dose* implied a finite number of discrete and well-defined quantities. Although 'dose' perhaps implies a greater degree of precision of nutrient intake than could be achieved from food, it nevertheless adequately encapsulates the concept of incremental intake relevant to dose response.

The question of whether a 'dose response assessment' could be applied to hazard characterization regarding inadequate nutrient intakes will depend on future considerations of appropriate methodologies.

43. ***Exposure (Intake) Assessment:*** The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposure from other sources if relevant. For nutrients and related food components, exposure (intake) assessment typically involves the evaluation of the distribution of usual total daily intakes for the general population and/or other population(s) of interest.

This is the third step in risk assessment. 'Intake' has been added to the Codex term and definition to apply to assessment of both excessive and inadequate nutrient intake. The second sentence added is consistent with definitions that have been used in establishing upper levels of intake for nutrients[27,28], and with approaches that have been used to estimate inadequate nutrient intakes, although often with much uncertainty.

As further discussed in Division IV, complex qualitative and quantitative evaluations, including mathematical modeling, may be necessary in order to consider usual total dietary intakes i.e. all significant sources of intake of the nutrient, factors which can influence nutrient bioavailability e.g. other nutrients, enhancers, inhibitors and other factors that may influence dietary choice.

44. ***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 or intake assessment.

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[26] Food and Nutrition Board, Institute of Medicine, National Academy of Sciences. Dietary Reference Intakes: A Risk Assessment Model for Establishing Upper Intake Levels for Nutrients. Washington, D.C. National Academy Press, 1996. pp.8-9

[27] FAO/WHO *A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances*, accessed 20 April at http://www.who.int/ipcs/highlights/full_report.pdf, p.26

[28] European Commission, Scientific Committee on Food. Guidelines of the Scientific Committee on Food for the Development of Tolerable Upper Intake Levels for Vitamins and Minerals SCF/CS/NUT/UPPLEV/ll Final. 28 November 2000. p.4

This is the fourth step in risk assessment. It is proposed to add the term 'intake', as discussed in relation to Exposure Assessment.

E. Other Codex Risk Analysis Terms

45. ***Risk Assessment Policy:*** Documented guidelines on the choice of options and associated judgments for their application at appropriate decision points in the risk assessment such that the scientific integrity of the process in maintained.

This definition applies to both excessive and inadequate nutrient intakes.

No changes to the Codex definition required.

46. ***Risk Profile:*** The description of the food safety or nutritional risk problem and its context.

It is proposed to add the phrase 'or nutritional risk' to encompass risk from inadequate as well as excessive nutrient intakes.

47. ***Risk Estimate:*** The quantitative estimation of risk resulting from risk characterization.

This definition applies to both excessive and inadequate nutrient intakes.

No changes to the Codex definition required.

F. Other Terms

48. Other terms such as 'nutritional quality' and 'nutritional safety' had previously been suggested to differentiate between respective concepts associated with dietary inadequacy and excess. 'Nutritional safety and adequacy' is currently shown, but not defined, in paragraph 3.1.1 of Section A Draft Revised Standard for Infant Formula[12], and 'nutritional quality' (of protein) is given in the draft revision of the Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Use by Infants and Young Children[29].

49. Within the European setting, the consideration of the substantiation of health claims has included reflection on the concept of 'nutritional safety'. In this context the following aspects were considered as encompassed within 'nutritional safety': dietary significance; interactions with other constituents of the diet; impact on metabolic pathways and physiological function; the intended consumer and vulnerable groups; and overall assessment of potential adverse effects; and quality assurance[30].

50. The concept of 'nutritional benefit' has also newly arisen within Codex. For example, the 2006 meeting of the Codex Committee on Food Additives and Contaminants (CCFAC) has considered a discussion paper[31] that proposes terms of reference for an Expert Consultation to conduct a comparative risk benefit assessment of fish consumption, including if possible, quantitative comparisons of human health risks and benefits of fish consumption. Other risk analysis terms include 'safety analysis', or 'safety assessment', 'risk-risk analysis' and 'risk ranking'.

51. All these terms can describe nutritional outcomes. The EWG did not regard the elaboration of definitions for these terms as being necessary at this time, although some Members could foresee the possible need to do so after the Committee has more experience with nutritional risk analysis.

[29] CX/NFSDU 06/28/6
[30] Based on PASSCLAIM. Eur J Nutr 2003; 42 [Suppl 1]: 96-111
[31] CX/FAC 06/38/37 (Discussion paper on the guideline levels for methylmercury in fish).

G. Conclusions

52. After a review of Codex *Definitions of Risk Analysis Terms Related to Food Safety*[17], and relevant terminology contained in the FAO/WHO Workshop Report[8], it is concluded that the Codex terms provide a suitable basis for the development of terminology for nutritional risk analysis to address risk associated with both excessive and inadequate intakes of nutrients and related food components. However, minimal modifications have been made to some terms to include where necessary conceptual reference to nutrient inadequacy, use of the term 'intake' as an alternative to 'exposure', and to introduce 'nutritional risk' as the foundational term. It is further concluded that a preliminary step of problem formulation as described in the FAO/WHO Workshop Report[22] should be introduced.

53. Terms referring to nutritional outcomes such as 'nutritional safety' or to risk assessment techniques are not defined at this stage however, with more experience in nutritional risk analysis, it may become necessary to do so given that such terms appear in Codex drafts and texts.

H. Recommendations

For the purposes of nutritional risk analysis, it is recommended that:

54. A problem formulation step be introduced to precede the conduct of a nutritional risk analysis.

55. The following defined Codex terms be used without amendment:

- hazard; risk analysis, risk management; risk communication; risk assessment policy; risk estimate.

56. The following Codex terms and/or their definitions be modified by inclusion of additional text relevant to nutrient inadequacy or intake:

- Risk, risk assessment; hazard identification; hazard characterization; dose-response assessment; exposure assessment; risk characterization; risk profile.

57. The new term 'nutritional risk' be defined as:

- A function of the probability of an adverse health effect <u>associated with excessive or inadequate intake of nutrients and related food components</u> and the severity of that effect, consequential to a <u>nutrient-related</u> hazard(s) in food.

58. The following defined Codex terms are not relevant to nutritional risk analysis:

- food safety objective; performance criterion; performance objective.

59. No additional terms should be identified and defined until a need for such terms becomes apparent after more experience with nutritional risk analysis.

IV. ISSUES RELATED TO NUTRITIONAL RISK ASSESSMENT

The following provides a discussion of certain issues that relate to risk assessment of nutrients and related food components.

A. Factors to Consider in Nutritional Risk Assessment

Differences in methodological approach to assessment of adequacy and excess

60. It is relevant to consider that the present methodological 'gold standard' for establishment of the threshold of adequacy of a nutrient is (or is similar to) the estimated average requirement (EAR) approach i.e. determination of the midpoint of the population distribution of individual nutrient requirements. Upper limits as references for safety on the other hand, are typically determined by a no or low observable adverse effect level (NOAEL/LOAEL) and uncertainty factor approach which is based on sensitive (rather than average) members of the population distribution. This is a fundamental distinction in the characterization of adequacy and excess reflecting historical conceptual differences between nutrition and toxicology.

    Given these distinctions, should risk assessment methodology replace the current approach to nutrient intake recommendations? Although the concept seems valid, development and application of such a risk assessment methodology would take much time and effort. Therefore, CCNFSDU should not take actions to apply specific methodologies to assessment of risk of inadequacy until such methodologies are developed and well established in the scientific community.

Scientific evidence for risk assessment

61. The Codex Working Principles state that risk assessment should be based on all available scientific data and use quantitative information to the greatest extent possible[32]. A systematic approach and agreed criteria for inclusion /exclusion of data for quantitative risk assessment is important to ensure that a risk assessment is based on relevant and quality evidence. Such an approach should utilize all available, relevant and meaningful data including from unpublished sources as appropriate.

Homeostatic Mechanisms

62. As described in the FAO/WHO Workshop Report[33], the human body has evolved specific homeostatic mechanisms for essential nutrients, but not necessarily for related compounds, that regulate acquisition, retention, storage and excretion. For example blood concentrations of some essential nutrients do not change significantly with changes in intake. Upon an increase or decrease in intake, homeostatic responses of some type occur and such responses may vary by age/sex/lifestage. However, homeostatic adaptations have a limited capacity and can be overwhelmed by excessive intakes. At extremes, as the capacity of the homeostatic mechanism is exceeded, the incidence and/or impact of specific adverse health effects increases. In contrast, the risk from substances that are the subject of classic risk assessment correlates only with increase in intake. Consideration of such mechanisms is relevant to hazard characterization.

    It is noted that the limitations of homeostatic adaptations equally apply to nutrient inadequacy and deficiency.

Adverse Effects and Biomarkers of Effects

63. Adverse health effects can be characterized according to the previously given definition of this term and can range from being mild and reversible to life threatening. The FAO/WHO Workshop Report[34] presents a sequence of generic effects in order of increasing severity that is further divided into groups of lower order biochemical changes and higher order clinical signs and

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[32] Codex Procedural Manual, 15th edition, p.103

[33] FAO/WHO *A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances*, accessed 20 April at http://www.who.int/ipcs/highlights/full_report.pdf, pp.26-28

[34] Ibid. pp.28-34

symptoms of varying degrees of significance and reversibility. Under certain circumstances, some of the biochemical or other subclinical changes could constitute appropriate biomarkers or surrogates for adverse health effects. Appropriate biomarkers are regarded as those that generally reflect a measurable biochemical, physiological, behavioral or other alteration within an organism that, depending upon the magnitude, can be recognized by way of a validated relationship as causally associated with an established or possible health impairment or disease. Such biomarkers should be relevant, feasible, valid, reproducible, sensitive and specific. Consideration of adverse health effects is relevant to hazard characterization.

Bioavailability and Nutrient Interactions

64. The bioavailability of a nutrient relates to its absorption and can be defined as its accessibility to normal metabolic and physiological processes[35]. Bioavailability influences a nutrient's beneficial effects at physiological levels of intake and also may affect the nature and severity of adverse health effects due to excessive intakes. Factors that affect bioavailability, either adversely or beneficially, include the concentration and chemical form of the nutrient, other factors in foods, the nutrition and health status of the individual and excretory losses[36].

65. Nutrients may interact with other nutrients, non-nutrients, and the food matrix. For example, within the gastrointestinal tract, some nutrients compete for the same carrier for absorption. Non-nutrients that are added to food can interact with nutrients in a way that lowers nutrient absorption and/or utilization. Additionally certain contaminants in foods may partially mediate their toxic effects by interfering with the utilization of a nutrient.

66. Factors that affect nutrient absorption and utilization either favorably or unfavorably would need to be taken into consideration in the risk assessment process and could be included in the hazard characterization and/or exposure (intake) assessment.

Total Dietary Intake Context/Dietary Balance

67. Nutritional risk assessment also considers the 'total dietary intake' in various ways. For example, as indicated earlier, the third step of the risk assessment process i.e. exposure or intake assessment, typically includes the evaluation of the distribution of usual total daily intakes for the population(s) of interest. This approach recognizes that risks associated with nutrients and related food components often are related to total intakes from multiple sources (comprising food including fortified and specially formulated foods, dietary (food) supplements, and in the case of minerals—water).

68. This is similar to the definition of 'dietary intake' given in the FAO/WHO Workshop Report[37] as "the quantitative amount of the nutrient substance ingested from sources that generally include foods (and beverages) fortified foods, specially formulated foods (sometimes called functional foods), dietary/food supplements, water and other non-drug products such as botanical and plant extracts." Furthermore, the FAO/WHO Workshop Report differentiates between 'dietary intake' that refers to ingested nutrients and 'dietary consumption' that refers to the food etc. sources of nutrients.

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[35] European Commission, Scientific Committee on Food. Guidelines of the Scientific Committee on Food for the Development of Tolerable Upper Intake Levels for Vitamins and Minerals. SCF/CS/NUT/UPPLEV/ll Final. 28 November 2000. p.5

[36] Food and Nutrition Board, Institute of Medicine, National Academy of Sciences. Dietary Reference Intakes: A Risk Assessment Model for Establishing Upper Intake Levels for Nutrients. Washington, D.C. National Academy Press, 1996. p.13

[37] FAO/WHO *A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances*, accessed 20 April at http://www.who.int/ipcs/highlights/nutreintproject_may18/en/index.html, p.65

69. Intake assessment involves the combination of data on the composition and consumption of dietary items to estimate the total nutrient intake for the population of interest. As noted in Chapter 5 of the FAO/WHO Workshop Report[38], the intake assessment typically aims to assess nutrient intake from all relevant sources over a long period of time. The application of statistical adjustment factors and other intake assessment tools that allow conclusions about the amount of a nutrient or related component being consumed on a 'usual' or 'habitual' basis and prevent the tails of the intake distributions from inflating the estimates[39]. The FAO/WHO Workshop Report discusses the many difficulties and uncertainties associated with estimating usual total daily nutrient intakes from available databases on intake and composition of food and dietary (food) supplements. Complex analytical approaches and modeling are sometimes used to estimate usual total daily nutrient intakes. Modeling may also be used to evaluate 'what-if' scenarios in the development of fortification programs and for other purposes.

70. A related concept to total intake is 'dietary balance'. The promotion of foods permitted compositional modification and labeling claims by Codex texts such as fortified foods may encourage consumers to inappropriately increase consumption of promoted foods, potentially leading to dietary imbalance. The evaluation of the potential for such dietary imbalance or distortion would be highly problematic. The evidence required would be difficult to obtain and globally apply since the factors that influence dietary choice are multifactorial and culturally specific. It is therefore not possible to take account of potential impacts on 'dietary balance' in quantitative nutritional risk assessments when assessing compositional modifications in Codex texts.

    However, consideration of 'dietary balance' may be relevant to development of principles addressing, or decisions about, permitting or prohibiting certain nutrition and health claims on foods for special dietary use. In this case, the potential for subsequent nutritional risks resulting from possible dietary distortion could be assessed as part of the supporting qualitative nutritional risk assessment. Such assessments might already exist in underpinning international policy recommendations to which the CCNFSDU has regard.

Risk Benefit Assessment

71. There has been recent interest in pursuing development of principles and methodologies for risk benefit assessments. These assessments would be applied when there was a need to define an intake range within which the balance of risk and benefit was acceptable for risk management purposes. Such a need might arise when a food or food substance is associated with both potential health risks and benefits and particularly when the level of intake associated with risk and benefit are close. However, there is currently no agreement on the general principles or approaches for conducting a quantitative risk benefit analysis for food and food ingredients. One of the main challenges for such an exercise is to define a common scale of measurement for comparing the risk and the benefits[40]. When further developed, such assessments may be a key methodology for nutritional risk analysis in the future.

B. Additional Factors to Consider in International Nutritional Risk Assessment

72. As previously noted, nutritional risk assessment can be either quantitative or qualitative. In identifying when each type of approach is appropriate, it may be helpful to consider the type of data needed for each of the four risk assessment steps and its relevance. The excerpt below from

[38] Ibid. pp.65-96

[39] Background Paper, FAO/WHO Nutrient Risk Assessment Project, October 2004, accessed 20 April at http://www.who.int/ipcs/highlights/en/nrbackground.pdf, pp.13-14

[40] The description of risk benefit analysis is based on material associated with the announcement of EFSA colloquium 6: Risk-benefit analysis of foods: methods and approaches, held July 2006.

the FAO/WHO Workshop Report[41] elaborates the distinction between global and population relevance for the four steps:

"Globally-relevant steps: Some steps in the assessment process are based on the available scientific/medical literature. These steps identify and interpret the biological physiological and chemical evidence for relationships between intake and the potential for harm to humans. By their nature, these data are relevant across wide and diverse (sub) populations. That is, they reflect science pertaining to humans regardless of their region of origin; they have global relevance and application. This global relevance for characterization of hazard does not, of course, preclude the possibility of a subpopulation-specific hazard.

Population-specific steps: Other steps use information about the (sub) population being targeted for risk assessment. This information includes data about the consumption of foods and supplements and about the composition of the food and supplements consumed—data used in the exposure/intake assessment step. The exposure/intake assessment is population relevant. That is, it is dependent on the types of foods and supplements consumed and on dietary patterns within a region or nation-state. Since risk characterization includes considerations of the globally relevant hazard characterization within the context of the exposure/intake assessment, risk characterization also is population relevant."

73. Consequently, it is important for the CCNFSDU to consider the implications of the above population specific steps in the conduct of quantitative global nutrient risk assessments. The EWG recognized the difficulties in conducting a quantified global dietary intake assessment but on this point, it is useful to recall that the Codex Working Principles state that risk assessment should be based on all available scientific data and use quantitative information to the greatest extent possible[32], and that risk assessment may also take qualitative information into account. Alternatively, it may be determined that a quantitative or qualitative risk assessment is not possible on a global basis, but that the identification of general principles are appropriate for certain Codex provisions.

74. The *Risk Analysis Principles Applied by the CCFAC*[42] state that JECFA is responsible for evaluating exposure to additives, contaminants, and naturally occurring toxicants and that in so doing, it should take account of regional differences in food consumption patterns. The *CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Foods of* (sic) *Food Groups*[43] guides JECFA to use available data from member countries and from GEMS/Food Operating Program to estimate total dietary exposure to a contaminant or toxin. These data sources may be supplemented by national consumption data to estimate total dietary exposure particularly for vulnerable groups such as children. It is understood that JECFA routinely issues data calls for dietary intake assessments from around the world and deals as best it can with the complexity of results based on different dietary intake methodology and data sources and the associated range of underlying assumptions.

It should be noted, however, that the applicability of a national or regional total usual intake estimate of nutrients and related components to international Codex nutrient-related texts has additional challenges, considering among other things, the varying nutrient composition of foods among countries, including fortified foods and dietary supplements, as well as differences in food consumption patterns. A related consideration is that most Codex food standards are for foods that constitute only part of consumers' total diet, again underscoring the need to consider flexibility with nutrient provisions for their appropriate application at the national /regional level.

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[41] FAO/WHO *A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances*, accessed 20 April at http://www.who.int/ipcs/highlights/nutreintproject_may18/en/index.html, pp.20-21
[42] Ibid. pp.108-113
[43] Ibid. pp.114-115

75. The context of decision making is therefore important in determining the extent to which risk assessments could be quantified. Since exposure assessments aim to be routinely conducted as part of a risk assessment of additives and contaminants, the CCNFSDU might further explore their applicability to nutritional risk assessments. CCNFSDU has previously established minimum and/or maximum levels of various nutrients in standards for foods for special dietary uses and the Committee should strive to base its future decisions about compositional provisions on nutritional risk assessments that are as quantitative as possible, where appropriate. Some decisions about nutrient-related labeling requirements could be amenable to guidance from qualitative nutritional risk assessments e.g. label identification of protein sources of infant formula.

76. Owing to the scale of nutrient risk assessment work, a prioritization model should be considered to ensure that the development of a Codex text focuses on those subjects for risk analysis with the greatest potential to cause harm.

C. Conclusions

77. Several concepts and factors essential to nutritional risk assessment provide a clear differentiation from classic risk assessment of non-nutrients. These include the need to mitigate risk of nutritional inadequacy or deficiency in addition to risk of excess, recognizing also the current methodological differences used to assess nutrient inadequacy and excess. Also, the relevance of physiological homeostatic mechanisms; the selection of most appropriate adverse effects as critical endpoints; factors affecting bioavailability of nutrients; and the range of ingested sources of nutrients and related components.

    The FAO/WHO Workshop Report[8] presents a model for establishing upper levels of intake for nutrients and discusses in great detail: appropriate terminology; the differentiating features from classic risk assessment; and considerations, process, applicability and limitations of the steps involved in the conduct of nutrient risk assessment.

78. The concept of ‘dietary balance’ introduces the possibility of risks of dietary distortion resulting from regulatory decisions about compositional modification or the promotion of foods. Because of the difficulty in determining a globally relevant approach to address possible risks associated with dietary distortion, ‘dietary balance’ should not be a consideration in nutritional risk assessments related to compositional modifications in Codex texts. However, such consideration could be relevant to development of principles addressing, or decisions about, the appropriate appearance of nutrition and health claims on foods for special dietary use.

79. Although the FAO/WHO Workshop Report[41] described the latter two steps of risk assessment as population relevant, the Codex system is moving to increase its use of appropriate risk assessments in the standards setting process. For a considerable period, JECFA and CCFAC have acted as risk assessor and risk manager respectively in the establishment of international regulatory controls on additives, contaminants and toxins in food. As noted previously however, the application of national or regional total usual intake estimates of nutrients and related components to international Codex nutrition-related texts may pose additional challenges. The Committee should therefore discuss further whether a similar process for intake assessments to that established by JECFA could be used in nutritional risk assessments. (This remark does not anticipate the establishment of a similar nutrition joint expert committee to JECFA).

80. The context of decision making is important in determining the extent to which risk assessments should be quantified and the priority given to them. Given the practices adopted in the conduct of intake assessment by other parts of the Joint FAO/WHO Food Standards Programme, their applicability for nutritional risk assessment should be considered.

81. There has been recent interest in pursuing development of principles and methodologies for risk benefit assessments of food. Such assessments may be a key methodology for nutritional risk analysis in the future.

D. Recommendations

82. The following concepts in the conduct of, and principles for, nutritional risk assessment are recommended to be taken into consideration: the need to mitigate risk of nutritional inadequacy or deficiency in addition to risk from nutrient excess; the relevance of physiological homeostatic mechanisms; the selection of most appropriate adverse effects as critical endpoints; factors affecting bioavailability of nutrients; and the range of ingested sources of nutrients and related components.

83. The concept of 'dietary balance' should not be considered in nutritional risk assessment in support of compositional modifications in Codex texts. However, such consideration of 'dietary balance' could be relevant to development of principles addressing, or decisions about, the appropriate appearance of nutrition and health claims on foods for special dietary use.

84. In nutritional risk assessment, consideration should be given to the applicability of a process similar to that used by JECFA for the intake assessment step.

85. Where appropriate, CCFNSDU should strive to base its future decisions about compositional provisions on nutritional risk assessments that are prioritized, based on all appropriate available evidence, and as quantitative as possible. Decisions about nutrient related labeling requirements could be amenable to guidance from qualitative nutritional risk assessments.

SECTION 2 RISK ANALYSIS MODELS FOR APPLICATION TO WORK OF CCNFSDU – FORMAT, LEVEL OF DETAIL OF PRINCIPLES AND GUIDELINES

86. This Section discusses the various models of risk analysis documentation that have been developed within the Codex system by subsidiary bodies and raises issues associated with the development of risk analysis documentation for CCNFSDU.

I. INTRODUCTION

87. A number of subsidiary bodies of Codex Alimentarius have commenced or completed documentation of principles and guidelines on risk analysis. Attachment 1 provides an overview of available risk analysis documentation as at 2005.

88. The available documents provide two basic approaches to presentation:

    (a) Horizontal approach e.g. biotechnology: initial development of principles of risk assessment and management subsequently complemented by two sets of specific guidelines related to different types of food safety assessments – for plants and for microorganisms. As the documents state, risk assessment includes food safety assessment.

    (b) Vertical approach e.g. microbiology: initial development of combined principles and guidelines for risk assessment, subsequently complemented by combined principles and guidelines for risk management.

II. ISSUES

89. The nutrition community is generally not as familiar with the structure, concepts and terminology of risk analysis as the disciplines dealing with food safety that originally devised the risk analysis process, even though elements of risk analysis have been previously applied to nutritional

contexts. It is therefore important that the content of the nutritional risk analysis documents are as clearly articulated and unambiguous as possible.

90. A horizontal approach enables a full set of principles to be developed that apply to the 3 components of risk analysis. It also provides flexibility to tailor different sets of subsidiary guidelines to disparate types of work. However, the horizontal approach requires both risk assessors and managers to contribute to the process, which first requires the risk assessors to be engaged in the process, although articulation of risk assessment policy is the responsibility of the risk manager. A vertical approach accords well with the functional separation of risk assessment and risk management in that development of risk assessment or risk management principles and guidelines could occur independently of each other, although such an approach does not preclude development of several sets of guidelines.

91. A number of relevant concepts and analytical tools already exist within other areas of Codex activity e.g. exposure assessment for food additives, contaminants and toxins in foods that may have relevance to the assessment of excess consumption of certain nutrients in the diet. Where there is such commonality, the potential exists for other documentation to be adapted rather than creating completely new text. This has the advantage of ensuring that there is appropriate consistency in the application of risk analysis to similar activities.

92. The EWG held differing views on the particular way forward. The Codex Alimentarius terminology in relation to risk analysis documentation regards principles as high order precepts supported as appropriate by (one or more) guidelines that are more practically and operationally oriented.

A. Conclusions

93. The development of a complete set of nutritional risk analysis principles (horizontal approach) should be the next step given that:

    (a) the Codex Working Principles are already established;

    (b) the imperative and timetable for the development of risk analysis principles encompassing risk assessment, management and communication, by all relevant Codex committees is set out in the Codex Draft Strategic Plan 2008-2013; and

    (c) only few Member countries have in-depth experience with national implementation of nutritional risk analysis.

94. This work would establish the framework for the commencement of the application of nutritional risk analysis throughout Codex Alimentarius, principally by CCNFSDU. In time, with further experience gained, CCNFSDU could subsequently decide to develop more operational guidelines for risk assessment, risk management or both.

B. Recommendations

95. It is recommended that nutritional risk analysis principles (horizontal approach) be developed as the next step in order to meet the requirements of the Commission as set out in the Draft Strategic Plan 2008-2013.

SECTION 3 ROLES OF RISK ASSESSOR AND RISK MANAGER, AND USE OF RISK COMMUNICATION

This Section discusses the potential roles of the risk assessor and risk manager in the conduct of nutritional risk analysis by CCNFSDU and throughout the Codex Alimentarius in conjunction with other bodies including FAO/WHO. It also discusses the place of risk communication in such work.

I. INTRODUCTION

96. The Codex Working Principles refer to the division of responsibility for risk assessment and risk management within the international food standards setting system such that the Codex Alimentarius Commission and its committees are responsible for risk management, and joint FAO/WHO expert bodies and consultations are primarily responsible for risk assessment[44].

97. The Codex Working Principles stress the importance of a functional separation of these two roles 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 they also recognize the iterative nature of risk analysis and the necessity for risk assessors and managers to interact[45] and understand their respective processes. The selection of risk assessment experts should be based on their expertise, experience and independence; and such selection should ensure effective participation from different parts of the world, and be done in a transparent manner[46].

98. The Commission recently recommended that FAO/WHO adopt the following criteria when prioritizing Codex requests for scientific advice[47]: relevance to strategic objectives and priorities defined in the Strategic Plan; clear definition of the scope and objective and end use of such advice; public health and/or food trade significance and urgency, and needs of developing countries; availability of scientific knowledge and data; and high priority assigned by the Commission. FAO/WHO have elaborated a draft guideline for provision of scientific advice to Codex Alimentarius, including adoption of the aforementioned criteria for priority setting[48].

99. It is noted that FAO/WHO are currently engaged in discussions with the Commission on the WHO *Global Strategy on Diet, Physical Activity and Health*[49] and that the parent bodies have been invited to submit to the next Commission meeting, proposals for potential areas of action, including specific proposals for new work, for consideration by CCNFSDU and the CCFL. Consideration could be given to applying a risk analysis approach to implementation of agreed action proposals, where appropriate.

II. ROLES IN RISK ANALYSIS

100. Below are identified three approaches to risk assessment of nutritional issues. All of these assume that CCNFSDU nutritional risk analysis may make use of, but should not be based solely on, a single national or regional risk assessment, given the Codex risk assessment principles cited above in the Introduction to this Section. All three approaches are possible; it is expected that the particular circumstances would determine the most appropriate approach.

101. The potential for experts to be drawn from a broad range of sectors including academia, government, industry and consumer organizations would appear to vary according to the

[44] Procedural Manual, 15th edition, p.101, paragraph 3
[45] Procedural Manual, 15th edition, p.102, paragraph 9
[46] Procedural Manual, 15th edition, p.103, paragraph 18
[47] ALINORM 05/28/3, paragraph 75 (Report of the 55th Session of Executive Committee)
[48] ALINORM 05/28/41, paragraph 224 (Report of the 28th Session of Codex Commission)
[49] WHO *Global Strategy on Diet and Health* accessed 20 April at http://www.who.int/dietphysicalactivity/strategy/eb11344/strategy_english_web.pdf

approach. CCNFSDU should include this consideration in its determination of the most suitable approach to employ according to the particular circumstance.

A. Three Approaches to Risk Assessment of Nutritional Issues

Approach 1: Use of International Experts Convened by FAO/WHO

102. Although not identified as such, CCNFSDU acting as the risk manager has previously sought scientific advice from FAO/WHO on several matters; action has commenced in response to the Committee's present request for establishment of FAO/WHO reference upper limits for vitamins and minerals[50]. FAO/WHO will also address the establishment of nutrient reference values for carbohydrates and fats by expert consultation in the future[51].

103. In addition to the use of expert consultations convened by FAO/WHO, another potential means to obtain scientific advice from FAO/WHO is through a standing joint WHO/FAO expert committee similar to JECFA.

104. FAO/WHO has recently experienced a vast increase in requests for a wide variety of scientific advice[52]. Given this increase, combined with FAO/WHO's approach to priority setting and current budgetary constraints, and the dependence of the Codex standards setting process on timely provision of scientific advice, it is probably unreasonable to expect FAO/WHO to be the sole source of nutritional risk assessment advice to CCNFSDU under current circumstances. The Codex Working Principles also imply some flexibility by referring to FAO/WHO as primarily having responsibility for risk assessment advice.

Approach 2: Use of International Experts Convened by CCNFSDU or by CCNFSDU Members or Observer Organizations, with Terms of Reference from the CCNFSDU

105. In the event that FAO/WHO are unable to respond to the Committee's requests for advice in a timely manner, or if considered appropriate, other channels of advice could be considered such as international expert groups that are convened by the CCNFSDU or by a CCNFSDU member or international non-governmental organization with terms of reference from the CCNFSDU. However, for such assessments to be useful to CCNFSDU, they need to fulfill the parameters for risk assessment established by the Codex Alimentarius Commission and by the Committee acting as risk manager. The recent process with the international group convened by ESPGHAN[53] on infant formula composition with terms of reference from the CCNFSDU serves as an early prototype of this approach.

Approach 3: Use of the CCNFSDU and Expertise in CCNFSDU Member Countries or Observer Organizations

106. Given that the Codex Working Principles refer to the functional separation of risk assessment and management activities but not necessarily a structural separation, the CCNFSDU should give further consideration to the possibility of drawing on expertise resident in Member countries or international non-governmental organizations of the Committee to perform nutritional risk assessments as raised in the CCNFSDU 2004 agenda paper on risk analysis[54]. It is not known whether such a model has been attempted in other Codex committees or whether it could be practically implemented. The reference in the Codex Working Principles[45] to a functional separation of risk assessment and risk management activities would appear to indicate that a

[50] ALINORM 05/28/41, paragraph 219 (Report of the 28th Session of Codex Commission)
[51] ALINORM 05/28/26, paragraph 40 (Report of the 26th Session CCNFSDU)
[52] CX/EXEC 05/55/6 Part II (Agenda Item 6b, 55th Session Executive Committee, February 2005)
[53] European Society of Paediatric Gastroenterology, Hepatology and Nutrition
[54] CX/NFSDU 04/10 Annex (Discussion Paper on the Application of Risk Analysis to the Work of CCNFSDU).

process ought to be in place to facilitate risk assessment activities before decisions are made on risk management.

B. Conclusions

107. Responses from the EWG generally concurred with the suggested approaches and in the stated priority order, however some flexibility was considered necessary depending on the priority allocated by FAO/WHO to a response compared with the time available to the Committee, and the particular complexity and needs of the situation.

108. Transparency of decision making and adherence to the Committee's risk assessment principles were considered to be important for all approaches. It was also noted that all three approaches could take into consideration applicable national and/or regional risk assessments, noting the reservations about single source assessments above.

C. Recommendations

109. All 3 approaches i.e. use of international experts convened by FAO/WHO; use of international experts convened by CCNFSDU or by its members or observer organizations; use of the CCNFSDU and expertise in CCNFSDU member countries and observer organizations, are recommended to be considered appropriate for undertaking nutritional risk assessments.

110. Consideration should be given to the complexity and objective of the nutritional risk assessments as well as the likely priority that would be accorded by FAO/WHO in determining the appropriate approach to the conduct of a nutritional risk assessment.

111. Consistent with a functional separation of risk assessor and risk manager, member countries or observer organizations involved in the performance of individual risk assessments (Approach 3) should maintain the functional separation of risk assessment and risk management activities.

III. RISK COMMUNICATION

112. The Codex Working Principles describe 8 objectives of risk communication[55]. These objectives all promote adequate communication and sharing of information, not only between risk assessors and risk managers, but also with other 'interested parties' including consumers, industry and the academic community for the dual purpose of informing risk analysis decision making as well as those who would be affected by the decision.

113. Because of the inter-related and iterative nature of risk assessment and management processes, and the formality of the Codex structure, careful attention must be paid during the risk analysis process and beyond to the clarity, transparency and completeness of documentation and risk communication with all interested parties.

[55] Procedural Manual, 15th edition, p.106, paragraph 37

ATTACHMENT 1

CODEX RISK ANALYSIS DOCUMENTATION 2005

Document	Developed by	Status	Purpose/Scope	Structure/Approach	For use by
1. Working Principles for Risk Analysis for application in the framework of Codex Alimentarius	CCGP	Adopted, Procedural Manual, 14th edition	High level guidance for all Codex subsidiary bodies as appropriate	Scope General Aspects Risk Assessment Policy Risk Assessment Risk Management Risk Communication	Codex Alimentarius, FAO/WHO and other bodies as appropriate
2. Principles for the Risk Analysis of Foods Derived from Modern Biotechnology	*ad hoc* Codex Intergovernmental Task Force on Foods derived from Biotechnology	Adopted, CAC/GL 44-(2003)	Provides a framework for undertaking risk analysis on the safety and nutritional aspects of foods derived from biotechnology	Introduction Scope and Definitions Principles for: - Risk Assessment - Risk Management - Risk Communication Consistency Capacity Building and Information Exchange Review Process	Not specified

Document	Developed by	Status	Purpose/Scope	Structure/Approach	For use by
3. Guideline for the Conduct of Food Safety Assessment of Foods Derived From Recombinant-DNA Plants	*ad hoc* Codex Intergovernmental Task Force on Foods derived from Biotechnology	Adopted, CAC/GL 45-(2003)	Provides guidance on safety and nutritional aspects of biotech plant foods	Scope Definitions Introduction Unintended Effects Framework for Food Safety Assessment General Considerations Description (several) Characterization of Genetic Modification(s) Safety Assessment Other Considerations Potential Accumulation Use of Antibiotic Resistance Marker Genes Review of Safety Assessments	Not Specified
4. Principles and Guidelines for the Conduct of Microbiological Risk Assessment	CCFH	Adopted, CAC/GL -30 (1999)	Risk assessment of microbiological hazards in food	Introduction Scope Definitions General Principles Guidelines for Application General considerations Statement of Purpose Hazard Identification Hazard Characterization Risk Characterization Documentation Reassessment	Not Specified

Document	Developed by	Status	Purpose/Scope	Structure/Approach	For use by
5. Draft Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)	CCFH	ALINORM 05/28/13, Appendix III Adopted at Step 5 of the Procedure by 28th Session of CAC	Principles and guidelines provide a framework for the conduct of MRM	Introduction Scope Definitions General Principles for MRM General Considerations Preliminary MRM Activities Identification and selection of MRM options Implementation of MRM options Monitoring and Review	Codex and countries as appropriate (Specified in text)
6. Risk Analysis Principles applied by CCFAC	CCFAC	Adopted, Procedural Manual, 15th edition	Similar to a performance agreement between CCFAC and JECFA	Scope CCFAC and JECFA CCFAC JECFA CCFAC Policy for exposure assessment of contaminants and toxins in foods or food groups	CCFAC and JECFA

ATTACHMENT 2

PROPOSAL TO DEVELOP NUTRITIONAL RISK ANALYSIS PRINCIPLES FOR APPLICATION TO THE WORK OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES (CCNFSDU).

Draft prepared by Australia with assistance from Members of the Electronic Working Group on Risk Analysis

1 PURPOSE AND SCOPE OF THE PROPOSED WORK

The purpose of the work is to elaborate nutritional risk analysis principles in the first instance, potentially followed by more detailed and operationally focused guidelines, to guide the work of the CCNFSDU in the development and review of Codex texts on nutritional matters[56] within this Committee's Terms of Reference. The principles would be consistent with the Codex *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.*

2 RELEVANCE AND TIMELINESS

The proposed work responds to the Commission's request for relevant committees to develop risk analysis principles for application to their work. These principles are to be endorsed by CCGP by 2011 and adopted by the Commission by 2013 after which, they will be published in the Codex Procedural Manual as set out in the Codex Draft Strategic Plan (2008-2013).

3 MAIN ASPECTS TO BE COVERED

The principles and possible guidelines will relate to the conduct of, and procedures for, nutritional risk assessment, risk management and risk communication. They will establish the scope of nutritional risk analysis to be applied by CCNFSDU within its terms of reference, consider appropriate risk analysis terminology and applicability of qualitative and quantitative approaches to assessment of risk of nutrient inadequacy and excess of nutrient and related components, as well as elaborate other relevant factors.

The principles and possible guidelines will also identify:

appropriate sources of expert scientific risk assessment advice, and applicable selection criteria; and

the role of CCNFSDU in providing terms of reference for such advice.

4 ASSESSMENT AGAINST CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES

Application of a consistent approach to nutritional risk analysis within Codex Alimentarius will contribute to the development of appropriately based standards and related texts that serve to protect the health of consumers and ensure fair practices in the food trade.

5 RELEVANCE TO CODEX STRATEGIC OBJECTIVES

The work contributes to achievement of Objective 2 – Promoting widest and consistent application of scientific principles of risk analysis of the Codex Strategic Framework (2003-2007).

[56] For example, consideration of the nutritional adequacy of the composition of foods for infants and young children

6 INFORMATION ON THE RELATION BETWEEN THE PROPOSAL AND OTHER EXISTING CODEX DOCUMENTS

The principles and guidelines will be consistent with the Codex *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.* Nutritional assessment is discussed in Guideline documents developed by the *ad hoc* Codex Intergovernmental Task Force on Foods derived from Biotechnology.

7 IDENTIFICATION OF ANY REQUIREMENT FOR AND AVAILABILITY OF EXPERT SCIENTIFIC ADVICE

Noting the role of FAO/WHO expert and technical consultations as a primary source of risk assessment advice for Codex Alimentarius, including CCNFSDU, it will be important for the FAO and WHO to contribute their input to the nutritional risk assessment and communication sections. The recent publication of the Report of a Joint FAO/WHO Technical Workshop on Nutrient Risk Assessment is expected to considerably facilitate this process.

8 IDENTIFICATION OF ANY NEED FOR TECHNICAL INPUT TO THE DEVELOPMENT WORK FROM EXTERNAL BODIES

None foreseen.

9 TIMELINE FOR COMPLETION

Subject to the Commission's approval in 2007, a first draft of nutritional risk analysis principles would be developed for consideration by the 29th Session of the CCNFSDU 2007, and be proposed to advance to Step 5 by the 30th Session in 2008, then proceed to Step 8 by the 31st Session in 2009. These milestones are within the timeframe established by the Commission for consideration by CCGP and adoption by the Commission.

A decision on the need to develop subsidiary guidelines would be taken at a future time, but not later than the 30th session of CCNFSDU scheduled for 2008.