codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

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CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
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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 Canada, European Community, Denmark, New Zealand, Norway, United States of America, IADSA, and IUFoST)

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 Session in 2004, Australia presented a discussion paper for the Committee's consideration based on the EWG's initial consideration of issues relating to the development of risk analysis principles.

The report of the 2004 CCNFSDU session[1] required that a discussion paper be prepared for the next session of the CCNFSDU that:

1. Describes the scope of nutritional risk analysis and interpretation of Codex risk analysis terminology in relation to nutrition;

2. Describes the role of the risk assessor and risk manager and place of risk communication as they apply to the Committee and FAO/WHO; and

3. Examines other risk analysis models that are developed or being developed by other Codex Committees or Ad Hoc Task Forces to assist consideration of the most appropriate format and level of detail for principles and guidelines that will best serve the Committee's purposes.

[1], ALINORM 05/28/26 paragraph 142 (Report of the 26th Session CCNFSDU, 2004)

This discussion paper considers these 3 elements with a view to laying the foundation for subsequent development of principles and guidelines for the application of risk analysis to the work of CCNFSDU. Several questions posed for consideration by the EWG are reproduced in this document to facilitate delegations' consideration of the matter. Forging agreement on a general direction for each of these elements will be an important basis for the Committee's advancement of this work.

RECOMMENDATION

The Committee is invited to consider the elements and questions raised in this paper with a view to forging agreement on the foundational elements of risk analysis applicable to the work of CCNFSDU, before work proceeds to the development of principles and guidelines.

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

To provide a context for this work, this Section:

a) Provides an overview of the *scope* of risk analysis issues that are 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) Provides an overview of 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[2]. 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*[3] (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 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, a current Joint FAO/WHO Nutrient Risk Assessment Project has as an objective the identification of internationally applicable principles and methods that may be used in the conduct of risk assessment for nutrients and related substances, with a focus on risk associated with excessive intakes[4]. It is also anticipated that the outcome of this project will inform the development or revision of Codex texts that address nutrient risk.

II. SCOPE OF RISK ANALYSIS AS APPLIED TO THE WORK OF THE CCNFSDU

A. Overview

5. As previously noted, the work of CCNFSDU is highly varied[5]. It includes Codex general standards that are applied horizontally (e.g. scientific basis of health claims, general principles for the addition of essential nutrients to foods), and Codex commodity standards for foods for special dietary uses that are applied vertically (e.g. infant formula standard and processed cereal-based foods for infants and young children). The Committee's work is also varied in that it drafts provisions for commodity standards that are intended to provide a *sole* source of nutrition (Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes) and for others that are intended to supplement other foods in the diet (e.g. Processed Cereal-Based Foods for Infants and Young Children). The Committee also provides technical advice to the Codex Committee on Food Labelling on matters related to nutritional labeling such as nutrient definitions and nutritional criteria in support of certain claims.

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[2] Procedural Manual, 14th edition, p. 45.
[3] Procedural Manual, 14th edition, pp. 101-107.
[4] Nutrient Risk Assessment Project. http://www.who.int/ipcs/highlights/nutrientraproject/en/print.html
[5] CX/NFSDU 04/10 (Discussion Paper on the Application of Risk Analysis to the Work of the CCNFSDU).

B. Role of the CCNFSDU versus Other Codex Committees in the Conduct of Risk Assessment and Risk Analysis

6. The CCNFSDU has primary responsibility for certain sections in standards for foods for special dietary uses that may involve risk analysis, namely essential composition and quality factors. A current example is the establishment of minimum and maximum levels of essential nutrients as well as maximum levels of optional constituents in the infant formula standard.

7. In the development of Codex standards and related texts for foods for special dietary uses, the terms of reference direct the Committee to cooperate with other committees where necessary. The CCNFSDU coordinates its work with other Codex committees in drafting provisions pertaining to food additives, contaminants, and hygiene, in which the other committee may have primary responsibility for risk analysis and/or primary responsibility for referring an issue to an expert body such as Joint Expert Committee on Food Additives (JECFA) for a risk assessment.

8. With regard to Codex labeling provisions, some of this Committee's current work involves risk analysis through setting criteria related to labeling requirements (e.g. the Draft Revised Standard for Gluten-Free Foods), while other labeling provisions in commodity standards may address health and safety aspects (e.g. the safe preparation and use of these products), but not involve quantitative risk assessment. Given that the Codex Committee on Food Labelling is charged with endorsing or amending (rather than developing) draft specific provisions on labeling prepared by other Codex Committees, it is unclear where the primary responsibility lies for analysis of risks associated with foods for special dietary use that are generally managed by labeling to protect public health and safety.

9. With this in mind, and 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. Therefore it is proposed that CCNFSDU should confine the scope of its principles and guidelines for risk analysis to the work for which it has primary responsibility in accordance with its terms of reference. Similarly, CCNFSDU should be guided by available documentation prepared by other committees when developing provisions that are the domain of those committees such as food additives.

QUESTION 1: What is your view on confining the scope of the Committee's principles and guidelines on risk analysis to the work for which it has primary responsibility?

C. Role of the CCNFSDU in Providing Guidance Related to Risk Assessment and Risk Analysis

10. This discussion paper and the potential development of principles and guidelines for the application of risk analysis to the work of the CCNFSDU is one example of this Committee's work to provide guidance related to risk analysis for nutrients and related food components. The Codex *General Principles for the Addition of Essential Nutrients to Foods* is another example that addresses aspects of risk specific to nutrients including nutrient excesses, deficits and imbalances[6]. The current work identifying general principles for establishing maximum and minimum values for the essential composition of infant formula has also provided an opportunity to consider the principles related to risk analysis for nutrients.

11. 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 of CCNFSDU to ensure a consistent approach to the application of risk analysis to nutrition-based standards within the work of Codex. CCFNSDU should also ensure that where issues arise that are not primarily the Committee's responsibility, these should be referred

[6] Refer to CAC/GL 09-1987 (amended 1989, 1991)

to the appropriate committee to undertake the required risk analysis on behalf of CCNFSDU or to provide a scientific assessment of the issue.

12. The Codex *Statements of Principle Relating to the Role of Food Safety Risk Assessment* [7], also referenced in the Codex Working Principles, facilitate understanding of the role of risk assessment in the context of CCNFDSU work. Both the first and fourth statements introduce some flexibility in discussion of 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. Although these statements emphasize the importance of a quantitative approach to risk assessment where possible, they also countenance the possibility of a qualitative approach to risk assessment or no risk assessment appropriate to the context. The Codex Working Principles[8] also make reference to taking account of qualitative information in risk assessment.

QUESTION 2: Within the Committee's primary responsibility, what aspects of work could be subject to qualitative risk assessment or not require the application of risk analysis?

Comments provided by members of the EWG:
On the assumption that assessment of risks that are usually managed through labeling of foods for special dietary use is within the Committee's primary responsibility, development of labeling provisions for the purposes of consumer safety might result from a qualitative risk assessment.

III. NUTRITIONAL RISK ANALYSIS IN THE CCNFSDU AND CONSIDERATION OF TERMINOLOGY

A. Overview

13. The application of a risk assessment approach to nutrients and related food components requires recognition that nutrients and related substances are unlike non-nutrients in that they provide health benefits[9]. Consequently, the work of the CCNFSDU often involves the analysis of risks for nutrients and related food components from two perspectives:

    1) harm resulting from excessive intakes; and

    2) harm resulting from intakes that are too low.

    The establishment of minimum and maximum levels of nutrients and related food components in infant formula is an example of current work that involves both aspects.

14. 'Related food component' is a general term that refers to dietary constituents that impact on health. Consideration will need to be given to the scope of this term. For example it might include properties of food such as energy content, all substances with physiological effects, or with only specific effects. Allergens in food might also be regarded as a hazard that poses nutritional risks. An example of related food components relevant to current CCNFSDU work is the permission for optional ingredients in the infant formula draft standard.

15. The discussion below identifies Codex risk analysis terms related to food safety[10] and *proposes minimal modifications* to these terms or definitions, where necessary, to address risk associated with both excessive and inadequate intakes of nutrients and related food components in the work of the

[7] Procedural Manual, 14th edition, p. 190.
[8] Procedural Manual, 14th edition, p 103, paragraph 20
[9] Background Paper, FAO/WHO Nutrient Risk Assessment Project, October, 2004. p. 11
[10] Procedural Manual, 14th edition, pp. 45-47.

CCNFSDU. In addition, it is proposed to define a new term, "nutritional risk". In this discussion, the term "nutrient" is sometimes used to refer to both "nutrients and related food components".

16. The following discussion of terminology and definitions therefore is for the purpose of CCNFSDU decision making, rather than for direct adoption by other parts of Codex Alimentarius. Even so, there are two alternate and subtle approaches that could be adopted to assist the Committee with its primary responsibility for risk analysis associated with excessive and inadequate intakes of nutrients and related food components:

    1) Strictly maintain the *Definitions of Risk Analysis Terms Related to Food Safety*, but adapt their interpretation to the above nutritional context where applicable, and not propose any new terms to define; or

    2) Modify the existing terms and definitions and create new term(s) with definitions only as necessary to address both aspects of risk relevant to a nutritional context.

17. While the first approach proposes the least modification of existing Codex risk analysis terminology and definitions and is generally applicable to risk associated with excessive nutrient intakes, its focus on food safety may not be applicable to risk from inadequate nutrient intakes.

18. Consequently, the second approach is proposed below, to better encompass both aspects of risk and facilitate understanding of risk analysis in a nutritional context. By adapting rather than replacing existing Codex terminology and proposing new terminology only when necessary, account is taken of the 2004 FAO/WHO *Review on the Provision of Scientific Advice to Codex and Member Countries* that specifically identified the need to harmonize terminology, methodology and outputs for chemical and microbiological hazards and biotechnological and nutritional issues[11]. It is proposed to adopt only those terms relevant to nutritional risk analysis.

QUESTION 3: Do you support the second approach to modify definitions only where necessary as shown in Section 1: Parts IIIB, IIIC and IIID below?

Comments provided by members of the EWG:
1) It will be important for consistency, across the full spectrum of disciplines using risk assessment approaches, to maintain definitions as similar as possible. However, we agree that there are unique aspects of the nutritional context (including but not limited to risks of inadequate as well as excessive intakes) which may not be fully appreciated by those accustomed to a "traditional" toxicological risk assessment approach.

2) We support the second approach to modify definitions where appropriate. We agree that the CCNFSDU has primary responsibility for risk analysis as it relates to both excessive and inadequate intakes of nutrients and related food components. We also agree that the Codex Definitions of Risk Analysis Terms Related to Food Safety is an appropriate starting point to consider risk analysis terms and definitions for nutrients and related food components. We believe that only minimal modification of Codex risk analysis terms and definitions may be needed to encompass both aspects of nutrient risk, and propose to introduce new terminology only when necessary. We further note that it may be important to identify work in the CCNFSDU that pertains to food safety given that this type of work may be considered in setting priorities for future Codex work.

[11] ALINORM 04/27/10G (Agenda Item 16, 27th Session CAC, 2004)

B. "Hazard", "Risk", and "Nutritional Risk"

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

20. The Codex definition of "hazard" is appropriate for CCNFSDU use. The key concepts are 'agent' and 'condition of food' which, when applied to a nutrient or related food component, represents respectively excessive or inadequate amounts in food that may cause an adverse health effect.

    No change to the Codex definition proposed.

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

22. While the Codex definition of "risk" refers only to a hazard *in* food; and a hazard (as defined above) *in* food could conceptually link to an inadequate presence or amount of a nutrient, the repetition of the phrase, "or as a condition of" elaborates the meaning of risk and related terms to apply to both excessive and inadequate nutrient amounts. This modification creates the model from which to derive a possible new definition of "nutritional risk" and is also consistent with the Codex definition of "hazard" which includes this phrase.

23. ***Nutritional Risk*** *(proposed new term):* A function of the probability of an adverse health effect from excessive or inadequate intake of nutrients and related food components and the severity of that effect, consequential to a hazard(s) in or as a condition of food.

24. It may be helpful for the CCNFSDU to develop an operational definition of "nutritional risk" that specifically refers to both aspects of risk that are specific to nutrients and related food components that could be applied in the work in this Committee (i.e. risk associated with excessive or inadequate intakes of nutrients and related food components). The proposed operational definition considers the nature of the work of this Committee as defined by its terms of reference. On the other hand, 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 and other medical risk criteria, and food insecurity and other dietary risk criteria[12].

C. Terms Relating to Risk Analysis and its Components

25. ***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 proposed.

26. ***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.

27. The term (intake) has been added to the third step in this definition as an alternative to "exposure" to apply as appropriate to assessments of both excessive and inadequate nutrient intakes. For risk assessment associated with excessive nutrient intake, it is generally agreed that these four steps apply[13]

[12] 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.

[13] 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.

[14] [15], although certain terms and definitions have sometimes been adapted for nutrients such as the addition of intake above. The following is an example of their application to nutrient risk assessment as discussed in the background paper of the Joint FAO/WHO Nutrient Risk Assessment Project[16]

"*Hazard identification is followed by hazard characterization and produces an Upper Level of Intake (UL) (i.e., a quantitative level of total intake at which, or below, no harm is expected to occur assuming nutrient adequacy is met). An exposure (or intake) assessment is carried out to compile and analyze information about the exposure within the population of interest. The information obtained from exposure assessment is combined with the UL and other hazard characterization information to produce a risk characterization that identifies the proportion of the population likely to exceed the UL. Risk characterization also highlights important considerations including the severity and nature of the adverse effect and identification of any special groups at risk.*"

28. 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.

29. ***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 proposed.

30. ***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 proposed.

D. Terms Relating to Risk Assessment and Its Four Components

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

32. 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, we propose that the phrase, "in, or condition of, food" be added. This is also consistent with the Codex definition of "hazard" which includes this phrase.

33. ***Hazard Characterization:*** The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents or components, which may be present in food<u>, or as 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.

[14] 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.
[15] Background Paper, FAO/WHO Nutrient Risk Assessment Project, October, 2004. p. 11-16.
[16] Background Paper, FAO/WHO Nutrient Risk Assessment Project, October, 2004. p. 9-10.

34. 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, we propose that the phrase, "as a condition of food" be added. This is also consistent with the Codex definition of "hazard" which includes this phrase. Hazard characterization could include assessment of bioavailability (see paragraph 54).

35. ***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).

36. The term "intake" (see paragraph 27) would be added. It is noted that 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[17]. It is assumed that a "dose-response assessment" could be applied to risk assessment regarding inadequate nutrient intakes.

QUESTION 4: What is your view on whether a dose-response assessment could apply to risk assessments of inadequate nutrient intakes?

37. ***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 (such as sunlight exposure affecting vitamin D status). 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. Paragraphs 57-58 provide further discussion on this subject.

38. 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[18] [19], and with approaches that have been used to estimate inadequate nutrient intakes, although often with much uncertainty.

39. As further discussed in Division IV, complex qualitative and quantitative evaluations, including mathematical modeling, may be necessary in order to consider usual total daily 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. Influences on dietary choice may be more amenable to qualitative evaluation.

40. ***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.

41. This is the fourth step in risk assessment. It is proposed to add the term "intake", as discussed in paragraph 27.

E. Other Codex Risk Analysis Terms

[17] 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.
[18] Ibid.
[19] 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.

42. ***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.

43. This definition applies to both excessive and inadequate nutrient intakes.

No changes to the Codex definition.

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

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

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

47. This definition applies to both excessive and inadequate nutrient intakes.

No changes to the Codex definition.

48. ***Food Safety Objective (FSO):*** The maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP).

49. ***Performance Criterion (PC)***: The effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a PO or an FSO.

50. ***Performance Objective (PO)***: The maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to an FSO or ALOP, as applicable.

51. The three terms above are most applicable in the context of microbiological hazard analysis as they are defined in CX/FH 04/6, section 6.2. Although these terms may not be immediately relevant to nutritional risk assessment, consideration may need to be given to the need for equivalent terms as experience with the application to risk analysis develops.

F. Other Terms

52. Other terms such as "nutritional quality" and "nutritional safety" have been suggested to differentiate between respective concepts associated with dietary inadequacy and excess. These terms are currently used, but not defined, in paragraph 3.1.1 of Section A *Draft Revised Standard for Infant Formula*[20]. On the other hand, "nutritional safety" [21] was used, in addition to and distinct from "food safety", in a previous draft of the *Scientific Basis of Health Claims* to encapsulate such concepts discussed below as dietary balance, excessive intake, relevance to population groups of interest. The term has been deleted from the current draft to be considered at the Committee's 2005 session[22]. 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 being 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[23].

QUESTION 5: Should "nutritional quality" and "nutritional safety" be terms used in risk

[20] ALINORM 05/28/26, Appendix IV(A). (Report of the 26th Session of CCNFSDU, 2004)
[21] CX/NFSDU 04/9, Appendix 1, section 2.2 (Agenda Item 8, 26th Session CCNFSDU, 2004)
[22] CX/NFSDU 05/27/9 (Agenda Item 8, 27th Session CCNFSDU, 2005)
[23] Based on PASSCLAIM. Eur JNutr 2003; 42 [Suppl 1]: 96-111

analysis or defined for use in the work of CCNFSDU? If so, suggest definitions and explain the place of these terms relative to other proposed terms and definitions in this paper. Also explain why these additional terms may be needed and how defining them could help the work of CCNFSDU (perhaps by providing examples).

There are divergent views on this from members of the EWG. One view is that there is no need to define these terms unless the need for them can be established. The opposing view is that definitions are required. Possible definitions are:

Nutritional Safety: A concept encompassing excessive intakes of nutrients and nutrient imbalances which can lead to direct adverse health effects or secondary nutrient deficiencies.
Nutritional Quality: Consideration of the adequacy of nutrient content in a food, in the context of the Total Diet, bioavailability of the nutrient including the presence of enhancers and inhibitors, and influences on dietary choice, where emphasis on one food or nutrient may alter the pattern of food intakes with consequent changes in nutritional status of individuals or population groups.

IV. ISSUES RELATED TO NUTRITIONAL RISK ASSESSMENT IN THE WORK OF THE CCNFSDU

Below is discussion of certain issues that relate to risk assessment of nutrients and related food components that are applicable to the work of this Committee.

A. Factors to Consider in Nutritional Risk Assessment

53. Nutritional risk analysis can borrow certain concepts from food safety risk analysis. In addition, nutritional risk analysis of the allergenicity of foods and consequent health effects might also be applicable. However, additional concepts are needed in risk assessment for nutrients and related food components. One concept already identified related to the two aspects of risk from nutrients and related food components, i.e., the potential for harm from intakes that are too low in addition to those that are too high. Other concepts and considerations specific to nutritional risk assessment are identified below.

Bioavailability and Nutrient Interactions

54. The bioavailability of a nutrient relates to its absorption and can be defined as its accessibility to normal metabolic and physiological processes[24] [25]. Bioavailability influences a nutrient's beneficial effects at physiological levels of intake and also may affect the nature and severity of adverse 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[26].

55. 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.

[24] 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.
[25] 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.
[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. p.13.

56. 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 or intake assessment.

Total Diet (or Intake) Context/Dietary Balance

57. Nutritional risk assessment also considers the "total diet" 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 (including fortified foods, dietary (food) supplements, and in the case of minerals—water) over longer periods of time. The term 'total intake' is therefore preferred to 'total diet'.

58. As noted in the background paper for the FAO/WHO Nutrient Risk Assessment Project, typically the analysis includes the application of statistical adjustment factors and other intake assessment tools that allow conclusions about the amount of a substance being consumed on a "usual" basis and prevent the tails of the intake distributions from inflating the estimates[27]. It further notes 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, and to take into account nutrient bioavailability[28]. Modeling may also be used to evaluate "what-if" scenarios in the development of fortification programs and for other purposes.

59. A related concept to total intake is "dietary balance". The design and promotion of foods permitted modified composition through Codex texts such as dietary (food) supplements and fortified foods can result in alterations in overall dietary profiles for consumers of such products. Most foods contain several nutrients and thus the displacement of one or more foods by other foods needs to be evaluated in terms of overall balance and adequacy. In this context, principles for compositional modification of the food supply need to be considered to avoid creating other nutritional risks resulting from dietary distortion in response to such modifications.

B. Additional Factors to Consider in International Nutritional Risk Assessment

60. As previously noted, the work of the CCNFSDU involves two aspects related to nutritional risk assessment: 1) the *conduct* of risk assessment, and 2) the development of *principles and guidance* related to risk assessment. In identifying when each type of work is appropriate, it may be helpful to consider the type of data that is needed for each of the four risk assessment steps and its relevance. This is addressed in the excerpt below from the background paper for the Nutrient Risk Assessment Project[29] in which comments were invited on the distinction between global and population relevance for the four steps:

Hazard Identification and Hazard Characterization. "*First, there are those steps that are based on the available scientific/medical literature and intended to identify and interpret the biological physiological and chemical evidence for the relationship between intake and the potential for harm to humans. These data by their nature are relevant across wide and diverse populations, i.e. they tend to reflect the science pertaining to all humans. They have global relevance*."

[27] Background Paper, FAO/WHO Nutrient Risk Assessment Project, October, 2004 pp.13-14.
[28] Lewis CJ et al. Estimated folate intakes: data updated to reflect fortification, increased bioavailability, and dietary supplement use. Am J Clin Nutr 1999;70:198-207.
[29] Background Paper, FAO/WHO Nutrient Risk Assessment Project, October, 2004 pp.15-19.

Exposure Assessment and Risk Characterization. "*Second, there are those steps based on information about the population[30] targeted for risk assessment. This information would include data about dietary consumption patterns and food composition, which in turn underpin the exposure assessment step. The exposure assessment is population relevant, i.e. is dependent on the types of foods consumed and dietary patterns within a region or nation-state. Risk characterization includes considerations of the globally relevant hazard characterization within the context of the exposure assessment. This would cause risk characterization to be population relevant.*"

61. As further noted in this background paper, these considerations do not preclude addressing principles for all four steps in risk assessment. However, while the application of principles for hazard identification and characterization results in outcomes, notably the UL, that could be globally relevant, the application of principles for exposure assessment and risk characterization produces outcomes that are population relevant[31].

62. The context of the decision making is therefore important in determining the extent to which risk assessments can be quantified. CCNFSDU has previously established minimum and/or maximum levels of various nutrients in standards for foods for special dietary use and presumably this option should continue to be available as appropriate.

QUESTION 6: Under what circumstances, if any, would intake modeling be useful to inform CCNFSDU decisions when global intake assessments based on actual data are not possible?

Comments provided by Members of the EWG:
1) In general we perceive that there are likely to be difficulties in modeling intakes of individual foods on a global level because of a high degree of variability among and within populations.
2) If circumstances are such that a particular decision affects primarily one region or population, it may still be advisable, where possible, for some intake modeling to be done to establish the risk curve for the nutrient or related food component under consideration. The authorities for the affected region(s) or population(s) can then undertake whatever additional modeling is required to establish where they fall upon the risk curve.

SECTION 2 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 risk analysis by CCNFSDU in conjunction with other bodies including FAO/WHO. It also discusses the place of risk communication in such work.

I. INTRODUCTION

63. 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[32].

64. 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

[30] The term "population" in discussions pertaining to nutrient risk assessment in the international context refers to nations/regions with a common food supply and dietary patterns and which would be expected to differ from other nations/regions in this respect.
[31] Background Paper, FAO/WHO Nutrient Risk Assessment Project, October, 2004 p.16.
[32] Procedural Manual, 14th edition, p. 101, paragraph 3

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[33]. 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 an a transparent manner[34].

65. FAO/WHO are currently reviewing the process for provision of scientific advice to Codex Alimentarius. The Commission recently recommended that FAO/WHO adopt the following criteria when prioritizing Codex requests for scientific advice[35]: 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.

66. 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* 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 this Committee and the Codex Committee on Food Labelling[36].

II. ROLES IN RISK ANALYSIS

67. Below are identified three approaches to risk assessment of issues for which CCNFSDU has primary responsibility. All of these assume that CCNFSDU 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 in paragraph 64.

APPROACH 1: USE OF INTERNATIONAL EXPERTS CONVENED BY FAO/WHO

68. 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[37]. FAO/WHO will also address the establishment of Nutrient Reference Values for carbohydrates and fats by expert consultation in the future[38].

69. 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.

70. FAO/WHO has recently experienced a vast increase in requests for a wide variety of scientific advice[39]. 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 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.

[33] Procedural Manual, 14th edition, p. 102, paragraph 9
[34] Procedural Manual, 14th edition, p. 103, paragraph 18
[35] ALINORM 05/28/3, paragraph 75 (Report of the 55th Session of Executive Committee)
[36] ALINORM 05/28/41 paragraph 234 (Report of the 28th Session of Codex Commission)
[37] ALINORM 05/28/41 paragraph 219 (Report of the 28th Session of CAC)
[38] ALINORM 05/28/26 paragraph 40 (Report of the 26th Session CCNFSDU)
[39] CX/EXEC 05/55/6 Part II (Agenda Item 6b, 55th Session Executive Committee, February 2005)

APPROACH 2: USE OF INTERNATIONAL EXPERTS CONVENED BY CCNFSDU OR BY CCNFSDU MEMBERS OR OBSERVER ORGANIZATIONS, WITH TERMS OF REFERENCE FROM THE CCNFSDU

71. In the event that FAO/WHO are unable to respond to the Committee's requests for advice, 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[40] 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

72. Given that the Codex Working Principles refer to the functional separation of risk assessment and management activities but not necessarily a structural separation, the possibility of drawing on expertise resident in Member countries of the Committee to perform risk assessments was raised in last year's agenda paper on risk analysis[41]. "In some cases, [CCNFSDU] may also need to act as risk assessor and a functional separation between risk assessment and risk management should be implemented, where practicable". It is not known whether such a model has been attempted in other Codex committees or whether it is feasible or appropriate.

QUESTION 7: What are your views on the three approaches to risk assessment, taking into consideration the risk assessment principles in the Codex Procedural Manual? Under what circumstances might each approach be appropriate or feasible? Are there other options?

Comments provided by Members of the EWG:
The question is "who conducts the risk assessment": FAO/WHO, regional or national authorities, or CCNFSDU? There may be circumstances where any of these three may represent the best available option. The objective should be to arrive at an outcome that best meets the needs of the situation, based on sound, scientifically-based risk assessment and a transparent process. These options should be ranked as presented, with FAO/WHO being the preferred risk assessors, followed by regional or national authorities. Conduct of risk assessments by CCNFSDU itself may be the least practical alternative.

III. RISK COMMUNICATION

73. The Codex Working Principles describe 8 objectives of risk communication[42]. 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.

74. 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.

[40] European Society of Paediatric Gastroenterology, Hepatology and Nutrition
[41] CX/NFSDU 04/10 Annex (Discussion Paper on the Application of Risk Analysis to the Work of CCNFSDU).
[42] Procedural Manual, 14th edition, p. 106, paragraph 37

SECTION 3 RISK ANALYSIS MODELSFOR APPLICATION TO WORK OF CCNFSDU – FORMAT, LEVEL OF DETAIL OF PRINCIPLES AND GUIDELINES

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

75. 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.

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

    1) 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.

    2) 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.

77. The Codex Committee on Food Additives and Contaminants and its formally constituted counterpart JECFA have developed risk analysis principles; however the content specifically refers to the roles and responsibilities of each counterpart and references earlier work contained in relevant Codex general standards. As such, the document reads like a performance agreement between the two bodies rather than adapted principles.

78. A report of the Joint FAO/WHO Nutrient Risk Assessment Workshop: A model for establishing upper levels of intake for nutrients and related substances, held in May 2005, is expected in the near future. It is anticipated that the report would make an important contribution to the approach relating to nutrient risk assessment.

II. ISSUES

79. 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 risk analysis documents are as clearly articulated and unambiguous as possible.

80. A horizontal approach (refer Paragraph 76) enables a full set of principles to be developed that relate to the scope of risk analysis within CCNFSDU. It also provides flexibility to tailor different sets of guidelines to disparate types of work. However, it requires both risk assessors and managers to contribute to the process, which first requires the risk assessors to be brought into the process. A vertical approach accords well with the functional separation of risk assessment and management in that development of principles and guidelines could occur independently, although it also does not preclude development of several sets of guidelines.

81. Because of the varied nature and complexity of work undertaken by the CCNFSDU, and the selected level of detail of the documentation, it remains to be determined whether one set of principles and guidelines would serve the Committee’s purposes well; or whether a more divergent approach, in whatever format, would be more appropriate.

QUESTION 8: Do you have a preference for a particular model at this stage? Explain your reasoning.

82. 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 ensuring that there is appropriate consistency in the application of risk analysis to similar activities.

83. It is expected that developed principles and guidelines would be subject to review and revision after a period of implementation. This provides an opportunity to institute a phased approach commencing with high level documentation that could be elaborated and increased in complexity after further experience.

QUESTION 9: This discussion paper has referred to the development of both “principles and guidelines” to assist CCNFSDU in its risk analysis work. What are your views on the differences between these terms and on whether both are needed?

QUESTION 10: Are there other comments around these issues you wish to make?

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
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

Document	Developed by	Status	Purpose/Scope	Structure/Approach	For use by
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
5. Draft Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)	CCFH	ALINORM 05/28/13, Appendix III Step 5 of the Procedure	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 ALINORM 05/28/41 Appendix IV 2005	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