

**COUNCIL FOR RESPONSIBLE NUTRITION (CRN)  
WASHINGTON, DC, USA**

**CRN comments on**

**DRAFT DISCUSSION PAPER ON  
PRINCIPLES FOR RISK ANALYSIS FOR APPLICATION TO CCNFSU  
(Draft prepared by Australia for the EWG and distributed as filename: Discussion  
paper EWG 2 July 2004)**

1. INTRODUCTION

1. Acceptable as drafted.
2. Replace “introducing” with “establishing” in order to recognize that the intent propose and have accepted new principles.
3. Acceptable as drafted.
4. Acceptable as drafted.

2. SCOPE

5. Acceptable as drafted because it exactly repeats the Terms of Reference established in the Procedural Manual, 13<sup>th</sup> Edition.
6. Acceptable as drafted.

3. CODEX APPROACH TO FOOD, FOOD SAFETY AND RISK ANALYSIS

7. The citation is correct, but the definition is not very useful. Other authorities also have found “food” difficult to define, but a vague definition is not better than no definition and may be less useful. For use in the Principles of Risk Analysis, and in wider applications by the CCNFSU, CX/GP 04/20/5-Add.2 should be revised to include a more detailed and useful definition of “food.” The following expanded and more detailed definition was developed after consulting several medical and non-medical dictionaries. The suggested definition is presented with the words of the draft by Australia is in *italics*, with the suggested additional words in the non-italic font.

*“Food” means any substance, whether processed, semi-processed or raw which is intended for human consumption and is intended to provide essential and non-essential nutrients, energy and nourishment, and so support or sustain growth, vital processes, maintenance, or repair of human structural components or physiological processes; “food” includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of “food” but does not include cosmetics or tobacco or substances used only as drugs.*

8. The sentence in the draft should have the following added at the end, just before the period: with the word ‘assurance’ interpreted in a manner consistent with risk assessment to mean ‘reasonable certainty of no harm’ or ‘without significant or unreasonable risk’

9. Acceptable as drafted because it repeats the descriptions in the Working Principles of Risk Analysis (WPRAs) (pp. 42-48, Procedural Manual, 13<sup>th</sup> Edition).
10. Any disparity should be reconciled only by future modification of the WPRAs because in the scope of responsibility of the CCNFSDU it is valid and desirable to consider applying the word “risk” to risk of inadequacy of intake of foods or nutritive substances, as well as to the common application to excessive intake of a substance.
11. The description of RISK should be rewritten as follows: RISK—a function of the probability, severity and persistence of an adverse health effect, consequential to a hazard(s) in foods, recognizing that inadequate amounts of nutritive substance(s) may qualify as a hazard(s). Inadequate quantities, like excessive intakes, must be judged in relation to the total diet (that is, total intake) and not in relation to simple concentrations in specific foods. Specific foods must be judged against the label claims for nutrient content, the recommended or expected intake, and in the context of how these contribute to the total dietary intake. The description of HAZARD implicitly, but not explicitly, recognizes that deficiencies may be hazardous, because it includes the phrase “or condition of” a food, and clearly a condition could be an inadequate amount of a nutritive substance, that is, to have a trivial concentration in relation to the recommended or expected quantity of food to be consumed.
12. This comment is appropriate as drafted.

#### 4. ISSUES FOR CONSIDERATION IN NUTRITIONAL RISK

13. The issue is posed appropriately in the draft.
14. The risk associated with either inadequate or excess intake must be evaluated in relation to the total intake from all sources. Individual foods may be evaluated for their contribution to the upper or lower limits of acceptable intake. Although, as indicated in the draft, the risk associated with nutritional inadequacy generally has not been evaluated by a risk assessment approach it is valid and may be useful for the CCNFSDU to articulate the advantages of doing so, and to communicate them to the FAO and WHO.
15. The present level of scientific understanding and amount of relevant data currently available would not support consideration of inhibitors and enhancers of absorption and utilization.
16. The comments are appropriate, but these considerations are more amenable to nutrition policy than to risk analysis components and techniques.
17. Risks associated with changes in dietary patterns may be addressed qualitatively, but current insights and information would not permit quantitative risk assessment.
18. The comment is appropriate as drafted.
19. This comment is appropriate as drafted.
20. This comment is appropriate and identifies major challenges that the CCNFSDU should address.

5. APPLICATION OF THE RISK ANALYSIS PROCESS TO THE WORK OF CCNFSDU

21. This comment is appropriate as drafted.
22. Some changes are needed in this and the following paragraph to make to focus of each fit within the usual definitions of Risk Assessment and Risk Management. Specifically, this paragraph should be refocused by inserting the words “the scientific limits for” after the words “determination of” in the second line. This change will keep the focus of this paragraph to the scientific procedures of risk assessment, leaving the risk management decisions on regulatory levels to be addressed in the next paragraph on Risk Management. Appropriately, this paragraph includes nutrient reference values in Risk Assessment. Such values apply to nutrients from all sources. Maximums and minimums for products are properly addressed under Risk Management, but Risk Assessment is the appropriate process to putting scientific boundaries around the decisions that risk managers may make. It is imperative that the CCNFSDU use its interest in Risk Analysis to ensure that the Risk Assessment it uses as the foundation of its Risk Management decisions on nutrients added to foods are those risk assessment that have been properly designed and performed for this purpose. That is, maximums for nutrients added to food products must be derived from “nutrient-appropriate” risk assessment. Specifically, the Tolerable Upper Intake Level (UL) method uses uncertainty factors that are derived from the specific database for each nutrient, thus avoiding nonsensical risk assessment outcomes that sometimes result from application of the Acceptable Daily Intake (ADI) or related risk assessment methods that use arbitrary default uncertainty factors. Such factors sometimes suggest UL values lower than the Recommended Dietary Allowances (RDA).
23. Appropriately, this paragraph addresses “controlling composition” in a manner that would include the setting of maximums and minimums as a part of Risk Management decisions. This should be done in a way that is bounded by the Risk Assessment process outcomes addressed in the previous paragraph.
24. This paragraph should state that the Risk Communication process and content should be tightly linked to Risk Assessment outcomes and Risk Management decisions.
25. This paragraph should acknowledge that, in the absence of relevant risk assessments by the FAO/WHO expert bodies, it might be necessary for risk managers to use risk assessments performed by regional or national authorities.
26. The draft is appropriate.
27. This comment would be more appropriately directed by replacing “assessment” with “analysis.”

6. CONCLUSION AND FUTURE CONSIDERATIONS

28. This paragraph is appropriate.

29. By addressing risk assessment as a component of its Risk Analysis performed under its Risk Management Mandate, the CCNFSDU should insist that all risk assessment methods and outcomes to be considered are defined and designed appropriate for nutrients and nutrition issues. It must avoid utilizing risk assessments that are performed with inappropriate methods, such as the ADI method. See paragraph 22, above.
30. The comment is appropriate—specific risk assessment policy is needed. See comments in paragraphs 22 and 29.
31. The comment is appropriate—implementation guidelines are needed to ensure that Risk Management decisions are consistent with the scientific outcomes of Risk Assessment.
32. This comment should be elaborated to include the acknowledgement that while the CCFH examples provide general guidance on both, the CCNFSDU will need to develop specific guidance and examples.
33. This comment is appropriate as far as it goes. It should state also that the CCNFSDU should take analogous actions.
34. This comment is appropriate, but should continue to suggest that the CCNFSDU take similar actions.
35. This comment is not useful.
36. This comment is not useful because the JECFA approach to risk assessment is not appropriate for nutrients and nutritional safety. See comments in paragraphs 22 and 29.

#### 7. INVITATION TO COMMENT

37. The focus of the invitation for the EWG to comment is appropriately focused on nutritional risk.
38. The adapted version of the WPRA is appropriate and should be further developed, as necessary.

### RESPNSE TO QUESTIONS

#### Core terms

1. The terms are logically compatible with a nutritional perspective but are not generally considered to include such considerations. Therefore it is necessary to explicitly state that the terms do include nutritional risk.
2. Yes, a definition of nutritional risk is needed.
3. Suggested definition:  
 NUTRITIONAL RISK—a function of the probability, severity and permanence of adverse health effects resulting from excess or inadequate intakes of nutrients or other food ingredients with nutritive effects, recognizing that nutritional risk is related to total intakes from all sources and therefore assumptions of dietary pattern must be made in order to related nutritional risk to a specific food.
4. The definition offered in the previous paragraph is an expansion of the more general definition of risk.

5. The term NUTRITIONAL HAZARD should be defined in a manner consistent with the general definition of “hazard” and the suggested definition of Nutritional Risk offered in paragraph 3, above. Thus, the following definition is suggested:  
NUTRITIONAL HAZARD—a nutritional characteristic of a food with the potential to cause an adverse health effect, depending on the quantities and characteristics of other foods in the overall diet.
6. The amended and new definitions should not apply generally, but mainly within the context of CCNFSDU. Consideration should be given of whether to suggest them to the CCFL.

### **Application to risk analysis**

7. The scope of nutritional risk assessment should include the identification of and guidelines for application of UL or similar values for nutrients and other nutritive components of foods. To accommodate the application of risk assessment concepts to inadequate intakes, the CCNFSDU WPRA could define an “LL” (Tolerable Lower Intake Level) that is exactly analogous to the UL. An LL identified by a risk assessment procedure could be higher than an RDA, which is established in relation requirements rather than safely adequate intakes. The LL definition as an advisory intake would refocus nutrition policy away from the Recommended Dietary Allowance (RDA), which, by its statistical definition, is not adequate for 2.3 percent of the population even if it is based on the most appropriate nutrient function.
8. The scope of nutritional risk management activities should immediately include the identification of maximum values for nutrients and other nutritive ingredients added to food products. This application is comparatively straightforward through utilization of risk assessment outcomes. The needed subsequent application to the identification of minimum values will require additional consideration and concept development to be certain that nutritional risk assessment is appropriately defined and structured in relation to inadequate intakes of nutrients and other nutritive ingredients.
9. The Principles of Risk Analysis for the CCNFSDU should be based on the WPRA, and thus the draft modification provided is an excellent start. Comments on the amended version offered are provided in a separate document.
10. The process should extend to include the development of guidelines, but development of the principles should have priority.