

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

**CRN comments on**

**DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS APPLICABLE TO  
CCNFSDU**

**(Draft prepared by Australia for the EWG and distributed as filename: Attachment  
1 to EWG discussion paper 2 July 2004)**

The recommended edits are generally acceptable, but CRN offers specific suggestions, as shown for each section below:

- 1) The suggested application to the CCNFSDU is appropriate.
- 2) Inclusion of all nutritional aspect is appropriate.

COMMENT: If the principles (or more detailed guidelines, if developed later) apply to the risk of inadequate intake, the total diet as well as specific foods must be considered. Moreover, consideration of overall diet also improves the evaluation of risk in relation to individual foods.

- 3) The added last sentence asserting the need for subsidiary bodies sometimes performing risk assessment is appropriate, especially considering that the current expert bodies use risk assessment methods, such as the Acceptable Intake Level (ADI) method, that are less appropriate for nutrients and other nutritive substances than the Tolerable Upper Intake Level (UL) method currently employed by the U.S. Institute of Medicine, the EC European Food Safety Authority (and formerly by the Scientific Committee on Food, and the UK Expert Group on Vitamins and Minerals. For some nutrients, customary application of the ADI method suggests limits below the levels recommended for certain age-gender groups.
- 4) The text is appropriate.
- 5) The text is appropriate.
- 6) The text is appropriate.
- 7) The text is appropriate.
- 8) The text is appropriate.
- 9) Without criteria or procedures for determining the meaning of “where practicable” this concept generally is so vague and subject to differing interpretation that it should not be used. Of course, this criticism applies to numerous Codex texts from a wide range of committees.

COMMENT: For nutrients and related materials used for their nutritive value, the FAO/WHO or their advisors need to undertake nutrient-appropriate risk assessment of the type exemplified by the Tolerable Upper Intake Level (UL) method. Otherwise, the CCNFSDU will need to create an independent subsidiary body to carry out appropriate risk assessments.

- 10) The words “or incomplete” should be deleted, because any amount or type of data may be judged “incomplete.” The included concept of “insufficient” is adequate to address this issue.
- 11) The change included is appropriate.
- 12) The text is appropriate.
- 13) The text is appropriate.
- 14) The text is appropriate.

- 15) The text is appropriate.
- 16) The text is appropriate.
- 17) The change included is appropriate.
- 18) The text is appropriate.
- 19) The text is appropriate.
- 20) The text is appropriate.
- 21) The text is appropriate.

COMMENT: The addition of “transport” is appropriate and it explicitly addresses this issue, although it would seem that transport could be included as type of “handling.”

- 22) The text is appropriate.
- 23) The text is appropriate.
- 24) It is not clear how to use risk assessment to evaluate the impact of “dietary change.”  
If any or all potential dietary changes were addressed, criteria and guidelines to prevent use of worst-case scenarios would be needed to avoid concluding that any potential change could possibly be unsafe.

COMMENT: The concept of risk assessment on potential “dietary change” may be redundant with risk assessment for individual nutrients or related substances. For example, a risk assessment on retinol addresses the potential adverse effects of a specific intake of this vitamin. Any increase or decrease in retinol intake, judged by a risk assessment in context of the remainder of the diet will amount to a risk assessment for a “dietary change.” If the term “dietary change” is included in the CCNFSDU WPRA, a careful statement of what it means, and does not mean, must be included to prevent inconsistent or even incompatible interpretations by different risk assessors and risk managers.

- 25) The text is appropriate.
- 26) The text is appropriate.
- 27) The suggested change is appropriate.
- 28) The text is appropriate, but needs elaboration per the COMMENT.

COMMENT: Dietary surveys to accurately determine the range and statistical distribution of intakes in the relevant populations are needed. Preliminary risk management activities could be the determination of whether nutrient intakes are likely to be in a range to create significant risk from either excess or inadequate intakes. Such determination is essential for priority setting to be objective.

- 29) The change is appropriate.
- 30) The text is appropriate.
- 31) The text should be modified by inserting the word “provisional” before “risk” at the end of the sentence, to read, “...reach a decision on the provisional management of risk.” This change is necessary to prevent actions taken under this provision from being established on a more permanent basis than justified by the level of evidence available.
- 32) The text is appropriate.
- 33) The change is appropriate.
- 34) The change is appropriate.
- 35) [There is no paragraph numbered 35.]

- 36) The available evidence should be reviewed on a timely basis, but the work “regularly” may imply some consistent, preset schedule. Such schedules are seldom justified. A better schedule would be “as needed” or the equivalent.
- 37) The text is appropriate.
- 38) The changed text is appropriate.
- 39) The text is appropriate.
- 40) This text should be expanded to indicate that risk communication should describe the risk management options considered, and the evidence and rationale that compelled the selected option.
- 41) This section is appropriate, but somewhat vague.