

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
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**Agenda Item 7**

**CX/NFSDU 07/29/7-Add.1**  
**October 2007**

## **JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES**  
**29<sup>th</sup> Session**

**Bad Neuenahr-Ahrweiler, 12 - 16 November 2007**

**APPLICATION OF RISK ANALYSIS PRINCIPLES BY THE COMMITTEE ON  
NUTRITION AND FOODS FOR SPECIAL DIETARY USES**

*- Comments at Step 3 of the Procedure -*

### **Comments from:**

**United States of America**  
**WSRO - World Sugar Research Organisation**

## United States of America

### I. General Comments

The United States only recently received the draft principles document that will be discussed at the 29<sup>th</sup> CCNFSDU session (CX/NFSDU 07/29/7). Consequently, the U.S. offers a few preliminary comments at this time, but anticipates offering additional comments later. The U.S. expresses its appreciation to the Government of Australia for their work in preparing this draft document, taking into consideration comments from the Electronic Working Group. The U.S. is pleased with the progress made on this agenda item.

The United States supports the development of overarching principles for nutritional risk analysis, based on consideration of the Codex Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius (Codex Alimentarius Commission Procedural Manual, 16<sup>th</sup> Edition, page 103). The development of such a document is consistent with the Commission's request, at its 26<sup>th</sup> session, that relevant Codex committees develop or complete specific guidelines on risk analysis in their respective area, for inclusion in the Procedural Manual, as recommended in the Commission's Action Plan (*para 147, ALINORM 03/41*).

The United States further notes the complexity of risk assessment of nutrients and related substances as is addressed in the FAO/WHO report, *A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances. Report of a Joint FAO/WHO Technical Workshop on Nutrient Risk Assessment (May 2005)*. Thus, the U.S. supports references to this report, as appropriate, in the drafting of these principles.

### II. Specific Comments

#### Title and Scope

**Comment:** With regard to the two options for the title identified in Recommendation #4 p. 2 and para 4 p.3, the United States looks forward to an exchange of views at the CCNFSDU session. We note past and current CCNFSDU work to develop Codex provisions aimed at mitigating nutritional risk, and note the 4<sup>th</sup> term of reference of this Committee which is to “to consider, amend if necessary, and endorse provisions on nutritional aspects proposed for inclusion in Codex standards, guidelines and related texts.” Accordingly, we believe it appropriate for CCNFSDU to have a role in matters related to nutritional risk within the framework of the Codex Alimentarius, and for these general principles to reflect that role.

Para 6: The U.S. suggests the following edits:

“Consistent with their important role in providing scientific advice to the Codex Alimentarius Commission and its subsidiary bodies, FAO and WHO and their joint expert consultations [and expert bodies] are acknowledged as the primary source of nutritional risk assessment advice to Codex Alimentarius. This role, however, does not preclude the choice of alternative sources of scientific advice such as appropriate international expert groups or organizations if and when justified.”

**Comment:** The U.S. suggests placing “expert bodies” in brackets and request clarification about what other expert bodies the above text is referring to besides JEFCA. The U.S. suggests deleting specific reference to JEFCA because it is our understanding that the current terms of reference for JECFA do not include nutrient risk assessment.

<http://www.who.int/ipcs/food/jecfa/about/en/index4.html>

Para 13

“Nutritional risk analysis does not apply to consideration of traditional food safety risks in the context of assessing food additives, chemical residues, microbiological pathogens, contaminants or allergens, including when the food constituent could be also regarded as a nutrient or related substance. It also

does not apply to the general aspects of food labelling that manage risks related to food's storage, preparation and use.”

**Comment:** Paragraph 13 seems unclear as written. The U.S. suggests that it be deleted. It does not appear necessary since “nutritional risk” is defined in paragraph 15.

#### Para 33

“[The Policy of the Codex Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups (CCFA Policy) in this Procedural Manual outlines an approach that could serve as a model for FAO/WHO in their risk assessment role to provide international estimates of total intake of nutrients or related substances as appropriate and as required. Based on this example, information for nutritional risk assessment could be collected through centralized data calls by FAO/WHO to Codex member countries for relevant dietary intake assessments such as baseline and previously devised scenario intakes. These data could then be evaluated noting the variability in approaches and assumptions that might have been used by contributors throughout the world.]”

**Comment:** The U.S. notes that Recommendation # 3 in the discussion paper is for the Committee to provide guidance on the further development of the text in paragraph 33 which is currently in brackets. The U.S. believes the Committee should also consider whether this paragraph should be deleted, after CCNFSDU has had the opportunity to fully consider its purpose, assumptions, and implications.

For example, the Committee may wish to consider what is meant by the “provision of international estimates of total intake of nutrients or related substances”, and whether these data would be needed to accomplish the work of the CCNFSDU—with specific examples of high priority needs. If these needs can be documented, the Committee may further consider whether this is now feasible, considering among other things the specific means by which this would be accomplished by FAO/WHO, the resources that would be required by FAO/WHO and member countries, and the complexity of dietary intake assessment as identified in the report of the 2005 Joint FAO/WHO Technical Workshop on Nutrient Risk Assessment.

In addition, the U.S. believes there are important differences in approaches to risk assessment (including assessment of dietary intake) of nutrients compared to the approach for contaminants identified in the reference for para 33. While the U.S. does not support referencing the Codex policy for exposure assessment of contaminants and toxins in this principles document—the U.S. would support consideration of additional references to the 2005 FAO/WHO nutrient risk assessment workshop report in this document, as appropriate.

### **WSRO - World Sugar Research Organisation**

It is the opinion of the World Sugar Research Organisation (WSRO) that the proposed draft principles for nutritional risk analysis to be applied by the CCNFSDU are drawn too optimistically and do not adequately consider a number of issues that need to be addressed before considering the feasibility of adopting such principles in relation to the nutrient content of individual food products. Further consideration is advised before advancing to Step 5.

Foremost it should be clearly stated in any principles that nutritional risk analysis will be based on direct scientific evidence from human data, from peer reviewed articles or validated scientific reports, showing exposure and effect. Scientific advice provided by FAO, WHO and associated expert bodies should be presented in a clear and transparent manner and considered in the light of any other relevant evidence available.

Nutritional risk analysis may be practical for use for those vitamins and minerals where a toxic level has been clearly defined. However they cannot be applied to some nutrients, particularly macronutrients, and other substances where any possible toxic level is unknown. In some cases no data yet exists on adverse effects unambiguously associated with high levels of consumption of some of these types of nutrients or substances. Clear scientific evidence of a safe dietary Upper Level of intake (UL) must be available before nutritional risk analysis can be carried out. Even if a dietary UL can be defined, the translation of this information into suitable permitted upper levels in individual foods to be traded internationally, presents extreme difficulties, because of the very wide range of intakes likely to occur in different populations.

It should also be noted that the definition of a safe upper level of intake in the diet for a macronutrient is not synonymous with any suggested dietary guideline for that macronutrient. Dietary guidelines are conventionally recommended average intakes levels, or average upper limits, for populations. Nutrient risk analysis must address the safety of individuals, not populations. It must consider both the risks of overconsumption of a particular nutrient and the consequences of any attempts to limit consumption. These consequences may include risks associated with inadequate dietary intake and other unintended consequences from changes in dietary habits.

As currently drafted, the proposed nutritional risk analysis principles apply the same general approach as traditional food safety risk analysis for non-nutrients. It is assumed that it should be possible to set permitted levels of nutrients and other substances in products using calculations based on an acceptable daily intake level (ADI), together with data on dietary patterns. All the necessary dietary data may not be available for many countries, bearing in mind that many sources of nutrients in less developed countries may not be purchased from retail outlets but generated by domestic agriculture. Clearly, it would not be possible to apply this approach to macronutrients for which a toxic level is not known or if the dietary habits affecting consumption of the macronutrient vary widely within and between populations. One or both of these limitations is likely to apply to most macronutrients.

Since an aim of Codex Alimentarius is to ensure fair trade practises in international food trade, further consideration is advised on how nutritional risk analysis might be applied to food products. It may not be possible to define a level of a nutrient in a particular food that would, in itself, increase the risk of adverse health effects. For some macronutrients no evidence has been found for an upper level of dietary intake so an upper level within a particular food product may also be impossible to set.