codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 5 **CX/NFSDU 08/30/5-Add.1**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
30th Session

Cape Town, South Africa, 3 - 7 November 2008

DRAFT NUTRITIONAL RISK ANALYSIS PRINCIPLES AND GUIDELINES FOR APPLICATION TO THE WORK OF THE COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

- ***Comments at Step 6 of the Procedure*** -

Comments from:

ARGENTINA
UNITED STATES OF AMERICA
IADSA - International Alliance of Dietary/Food Supplement Associations

ARGENTINA

SPECIFIC COMMENTS

SECTION 2

Paragraph 3

The committee proposes to keep the definition of "refined substances" in square brackets, given that it is not understood which substances are referred to. And to keep the phrase "refined substances" within square brackets throughout the document, until its scope has been clarified.

Reference 2 at the foot of the page

The statement in Paragraph 3 of this section is reiterated.

At the same time, we find it convenient to take the "new definition" into consideration and not to speak of a "possible" nutritional or physiological effect

Paragraph 4

This committee agrees to eliminate the square brackets from the paragraph

Paragraph 5

This committee agrees to eliminate the square brackets and to change the term between brackets from "organs" to "groups", given that this would be the correct translation of the text in English.

SECTION 3

Paragraph 6

This committee agrees to eliminate the square brackets from the paragraph

Paragraph 7

The committee believes that the square brackets should be removed, given that the phrase "a form of" is correct in this context.

Paragraph 8

The committee suggests the effects of clarifying this point to modify the paragraph as follows:

"The object of nutritional risk analysis shall be the nutrients and [refined substances] which are food constituents inherent in the food, or intentionally added"

And to eliminate the rest of the paragraph between square brackets and the explanation of the characterization of the same, given that they are confusing.

Paragraph 10

The committee proposes the modification of the paragraph as follows:

"The nutritional risk analysis must be quantitative, although the application of a focus based on qualitative risk analysis ... may be used in elaborating the texts in the Codex...:";

And observes that in the 3rd, item there appears a reference 3 which does not seem to relate to what is listed at the foot of the page.

SECTION 4

Paragraph 12

The committee believes that the first paragraph should mention both insufficient ingestion and excessive ingestion in the following manner: "However, other definitions of the terms... have been modified to make reference to insufficient or excessive ingestion as a factor in nutritional risk...".

SECTION 5

Paragraph 17

The committee proposes the following change to the paragraph "The specific information ... about nutritional problems shall include, among other things:..."

And in relation to the third point, the sentence "the pertinent exposure paths" is confusing, given that we consider when working with foods that the exposure path in this case is oral (ingestion).

Paragraph 22

The committee believes that in the evaluation of nutritional risk, bioavailability should always be taken into consideration. For this reason, we propose replacing "... can be taken into consideration" with "...must be taken into consideration...".

Paragraph 27

This committee is of the opinion that the square brackets must be eliminated, given that it is useful to rely on data on bioavailability and stability of the nutrients as prior information for evaluation of ingestion and characterization of the risks associated with nutrients. And we propose replacing "may be taken into consideration" by "must be taken into consideration".

Paragraph 29

The committee proposes eliminating the square brackets.

Paragraph 32

The committee has agreed to eliminate the square brackets and change the term "pertinent" to "appropriate", as this is the correct translation of the text in this context.

Paragraph 34

The committee does not clearly understand what is referred to by "Good Practices of Regulation" and so the square brackets should be kept.

UNITED STATES OF AMERICA

I. GENERAL COMMENTS

The United States notes the substantial progress made on this Codex text. Our comments mainly focus on bracketed text. We also offer a few other edits intended for clarification.

II. SPECIFIC COMMENTS

SECTION 2--INTRODUCTION

3. Codex nutritional risk analysis addresses nutrients[1] and related substances[2] and the risk to health from their inadequate and/or excessive intake. Nutritional risk analysis applies the same general approach as traditional food safety risk analysis to consideration of excessive intakes of nutrients and related substances. However, unlike many constituents of food that are the subject of traditional food safety risk analysis such as food additives, chemical (pesticide and veterinary drug) residues**, microbiological pathogens, contaminants and** inherent constituents such as allergens**,** nutrients and related substances are inherent constituents that are biologically essential (in the case of essential nutrients) or in other ways potentially favourable to health. Nutritional risk analysis therefore adds a new dimension to traditional risk analysis by also considering risks directly posed by inadequate intakes.~~, microbiological pathogens, contaminants and~~

> Comment: The United States agrees with comments from the Australian delegation that certain text in para 3 appears to have been corrupted. The repositioning of the text "microbiological pathogens, contaminants and" is proposed to restore text to that shown in CX/NFSDU 07/29/7, which was agreed upon at the last session.
>
> In addition, in the third sentence we suggest that a semi-colon be placed after "allergens" (instead of a comma) to separate independent clauses.

Footnote 2. [A related substance is an inherent constituent of food (other than a nutrient) that has a ~~[~~potential~~] nutritional or~~ **favourable** physiological effect.]

Comment: The United States proposes the above edits to footnote 2 to define a related substance as having a "potential favourable physiological effect", which is consistent with text agreed upon in para 3, line 3 (i.e., "potentially favourable to health"). The U.S. believes it would be confusing to refer to related substances that are not nutrients as having "nutritional effects".

4. The ~~[~~*Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses*~~]~~ presented in this document (hereafter cited as "Nutritional Risk Analysis Principles") are subsidiary to and should be read in conjunction with the Working Principles.

Comment: The United States supports the deletion of brackets in the above text, given that this title was agreed upon at the last session (ALINORM 08/31/26, para 105).

These Nutritional Risk Analysis Principles are framed within the three-component structure of the Working Principles, but with an added initial step to formally recognize Problem Formulation as an important preliminary risk management activity.

Comment: The United States believes that this should be a separately numbered paragraph as is shown in CX/NFSDU 07/29/7, August 2007.

5. 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 other sources of scientific advice such as appropriate international expert groups or organizations if and when justified.

Comment: The first sentence identifies primary source(s) of nutritional risk assessment advice to Codex. The United States recommends deleting the reference to "expert bodies." Presently there is no FAO/WHO expert body that serves as a primary source of scientific advice on nutritional risk assessment to Codex or that has nutritional risk assessment in its terms of reference. While the Joint Expert Committee on Food Additives (JECFA) has established Acceptable Daily Intakes (ADIs) for certain nutrient compounds that have food additive functional effects, there are differences in the objectives and process for establishing food additive ADIs compared to those for establishing levels of upper intake for nutrients.

If in the future FAO/WHO establishes an expert body with terms of reference to conduct nutritional risk assessment, the Committee could consider amending this Codex text to add "expert bodies" then.

SECTION 3-- SCOPE AND APPLICATION

6. ~~[~~The Nutritional Risk Analysis Principles are established to guide the Codex Alimentarius Commission and its subsidiary bodies - primarily but not exclusively the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) - in applying nutritional risk analysis to their work. This guidance potentially extends beyond CCNFSDU since the Committee is also mandated, in accordance with its 4th term of reference, "to consider, amend if necessary, and endorse provisions on nutritional aspects" of foods including those resulting from application of nutritional risk analysis that are developed by other Codex subsidiary bodies. ~~]~~

Comment: The United States supports retention of this text and deletion of the square brackets in order to clarify that this guidance may extend to the work of other Codex committees as reflected in CCNFSDU's fourth term of reference. As a recent example, the Committee endorsed at its last session the Annex on *Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits.*

7. Nutritional risk analysis considers the risk of adverse health effects from inadequate and/or excessive intakes of nutrients and related substances, and the predicted reduction in risk from proposed management strategies. ~~In situations that address inadequate intakes,~~ **S**uch a reduction in risk might **also** be referred to as ~~[one form of]~~ a nutritional benefit.

Comment:

The United States offers the above edits for the Committee's consideration, which may more clearly express the intent.

8. The food constituents ~~of primary interest~~ in nutritional risk analysis are inherent components of food and/or intentionally added to food ~~[~~and are identified as:

• nutrients **of primary interest** that may reduce the risk of inadequacy and those that may increase the risk of adverse health effects; or

• related substances[2] **of primary interest** that may increase the risk of adverse health effects at excessive intake and may also reduce the risk of other adverse health effects at lower intake; **or**

• ~~[~~**other** nutrients that increase the risk of adverse health effects ~~that exist~~ **when also present** in a food matrix with a nutrient(s) or related substance(s) **of primary interest** ~~associated with reduction of the risk of inadequacy or adverse health effects at lower intake];]~~.

Comment: The United States supports the above edits which were proposed by the Australian delegation, with the subsequent deletion of both sets of square brackets.

SECTION 4--DEFINITIONS

12.

Highest observed intake[4] – **The highest observed intake is derived only when no adverse health effects have been identified. It is** the highest level of intake observed or administered as reported within a stud**y**(ies) of acceptable quality. ~~It is derived only when no adverse health effects have been identified.~~

Comment: As noted above, the Committee may wish to reverse the order of these sentences to be consistent with the text in p. 85 of the footnote 4 reference (i.e., the report of a 2005 joint FAO/WHO technical workshop on nutrient risk assessment) and to place emphasis in the first sentence on appropriate circumstances in which a "highest observed intake" may be considered.

SECTION 5- PRINCIPLES FOR NUTRITIONAL RISK ANALYSIS

27. Nutrient-related intake assessment and risk characterization should be applied within a total diet context. Where feasible, it would typically involve the evaluation of the distribution of habitual total daily intakes for the target population(s). This approach recognizes that nutrient-related risks are often associated with total intakes from multiple dietary sources, including fortified foods, food supplements[1], and in the case of certain minerals, water. ~~[~~It may also take into account the bioavailability and stability of nutrients and related substances in the foods consumed.~~]~~

Comment: The United States supports retaining the last sentence and deletion of the brackets.

29. Nutritional risk management can be effected through quantitative measures or qualitative guidance elaborated in Codex texts. Such risk management could involve decisions about nutrient composition, consideration of the suitability of foods ~~containing risk-increasing nutrients~~ **for meeting nutritional needs** for certain purposes or (sub)populations, labelling advice intended to mitigate nutritional risks to public health, and formulation of relevant general principles.

~~[Nutritional risk management decisions should take into account, the actual, or likely, impact on consumers' behaviour, such as dietary patterns and preparation practices, which are cultural habits, in order to anticipate possible product substitutions and to ensure an overall risk reduction.]~~

Comment: The United States suggests the above edits to the first paragraph in lieu of retaining the second paragraph. This document is intended to provide general principles for the work of CCNFSDU rather than specific guidance to governments in the conduct of their own nutritional risk analyses. In the latter case, additional factors may be considered, and the

assessment of impacts on behaviors and/or dietary patterns at the national or regional level may be more feasible—although still challenging.

SECTION 6 – SELECTION OF RISK ASSESSOR BY CCNFSDU

32. Consistent with their important role in providing scientific advice to Codex Alimentarius and its subsidiary bodies, FAO and WHO are acknowledged as the primary source of nutritional risk assessment advice to Codex Alimentarius. However, this role does not preclude the choice of other sources of advice such as appropriate international expert groups or organizations ~~[~~as well as national relevant expertise~~,~~] if and when justified.

Comment: With the qualifying text of "if and when justified", the United States supports retaining the bracketed text and removal of the brackets.

SECTION 7 – REVIEW PROCESS

34. These Nutritional Risk Analysis Principles should be reviewed by CCNFSDU at appropriate intervals after implementation to ensure currency and consistency with ~~[good regulatory practice]~~ **advances in nutritional risk assessment** and ~~subsequent to~~ any future amendments to the Codex Working Principles.

Comment: The United States offers the above edits for the Committee's consideration, consistent with the reference in paragraph 22 to recognizing scientific advances in nutritional risk assessment.

IADSA - International Alliance of Dietary/Food Supplement Associations

SECTION 2 – INTRODUCTION

The final sentence of paragraph 3 is incomplete.

SECTION 3 – SCOPE AND APPLICATION

The English text in paragraph 8 is difficult to follow, particularly the section in square brackets, with the result that the meaning of this paragraph is not clear.

In IADSA's view, the word 'qualitative' should be inserted before 'nutritional' in paragraph 9, so that the sentence reads, "Where appropriate, the application of quantitative <u>and qualitative</u> nutritional risk analysis may guide decision making…"

There is a bracket missing at the end of the fourth bullet point in section 10. Additionally, in IADSA's view, the concept of "risk-risk analysis" requires further explanation/clarification.

SECTION 4 – DEFINITIONS

In paragraph 12, 'Upper level of intake' is defined as 'the maximum level of habitual intake from all sources of a nutrient……'. In IADSA's view the definition should refer to lifetime/chronic exposures.

SECTION 5 – PRINCIPLES FOR NUTRITIONAL RISK ANALYSIS

IADSA commends the wording of this section, in particular the emphasis given to the initial step of Problem Formulation as a key preliminary risk management activity.

PRELIMINARY NUTRITIONAL RISK MANAGEMENT ACTIVITIES

The final bullet point of paragraph 17, 'Specific information to be gathered for nutritional problem formulation may include:' reads 'the health endpoints to be considered'. In IADSA's view, consideration should be given to expanding this bullet point to address assessment of both risks and benefits, and/or to include specific health metrics, not only of health but also of economic/social benefit, such as Disability Adjusted Life Years (DALYs) and Quality Adjusted Life Years (QUALYs) e.g. a fitter older population; healthy life expectancy.