

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

October 2008

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:

AUSTRALIA

BRAZIL (2)

COSTA RICA

GHANA

GUATEMALA

MALAYSIA

NEW ZEALAND

PHILIPPINES

SOUTH AFRICA

THAILAND

UNITED STATES OF AMERICA (2)

CRN - Council for Responsible Nutrition

IDF (2) - International Dairy Federation

NHF - National Health Federation

AUSTRALIA

Paragraph	Comments
3 and Footnote 2	<p>The text appears to have been corrupted. The last few words of this paragraph i.e. “, microbiological pathogens, contaminants and” should be re-inserted after “(pesticide and veterinary drug) residues” in line 5 as originally shown in the Appendix to CX/NFSDU 07/29/7.</p> <p>Footnote 2</p> <p>The word ‘inherent’ can be deleted since the intention is to cover fortified foods as well as naturally-occurring substances.</p> <p>The amended Footnote 2 no longer indicates whether the physiological effect is favourable or unfavourable, although there is an implication by insertion of ‘nutritional or’ that the physiological effect would be potentially favourable rather than harmful. The word ‘potential’ is now in square brackets.</p> <p>Australia believes that ‘potentially’ and ‘favourable’ should be explicitly retained. Also, nutritional effects should be produced only by nutrients rather than by nutrients and related substances. This is a simple classification that is easy to understand and implement. We therefore suggest the Footnote be amended to read:</p> <p>²A related substance is an inherent constituent of food (other than a nutrient) that has a [potentially] nutritional or favourable physiological effect.</p>
4	<p>Since the title has been agreed by the Committee, (Para 105, ALINORM 08/31/26), the square brackets should be removed.</p>
Unnumbered after Para 4	<p>The unnumbered paragraph commencing “These Nutritional Risk Analysis Principles” should be numbered as paragraph 5. The ideas contained in this paragraph are separate from preceding paragraph 4.</p>
5	<p>‘Expert bodies’ should be retained and the square brackets removed. Australia understands that JECFA has established reference health standards (ADI or PMTDI) for total intakes of 7 vitamins and minerals (3 vitamins; 4 minerals) that were assigned to functional classes of colour, anti-oxidant or contaminant. These values should be included within the range of potential data when deciding an appropriate reference value for upper level of intake.</p>
6	<p>The purpose of this paragraph was to link the application of nutritional risk analysis principles to the entire scope of CCNFSDU’s work including its 4th term of reference. In deciding whether the paragraph is deleted, retained or changed, CCNFSDU needs to decide whether nutritional risk analysis would be conducted by any other Codex subsidiary body and submitted to CCNFSDU for endorsement. If so, the paragraph should be retained; if not, it could be deleted. The Committee’s endorsement at its last meeting of the Annex on <i>Food Safety Assessment Of Foods Derived From Recombinant DNA Plants Modified For Nutritional Or Health Benefits</i>, exemplifies consideration of nutritional risk analysis by another Codex subsidiary body. Australia therefore supports retention of the text, and removal of the square brackets.</p>
7	<p>Australia prefers to delete the newly-inserted text in square brackets that refers to ‘one form of’ a nutritional benefit. The original intention of this paragraph was to position the term ‘benefit’ to mean ‘risk reduction’ when referring to reductions in health risk from increased nutrient/substance intake. This is the way in which the <i>ad hoc</i> Intergovernmental Task Force has used the term in the Annex mentioned in the preceding comment.</p> <p>Such usage of ‘benefit’ should be confined to situations of increased intake. The Committee’s proposed insertion extends the use of ‘benefit’ to possibly describe reductions in health risk from decreased nutrient/substance intake. This is not consistent with traditional risk analysis which generally does not use ‘benefit’ when referring to reduction in risk from</p>

Paragraph	Comments
	decreased intake of a hazard.
8	<p>Australia supports the deletion of the outer square brackets. In relation to the inner square brackets around the third dot point, we note that the Committee’s revisions have unintentionally brought the risk-increasing nutrients that coexist in the food containing a nutrient/related substance of primary interest under the banner of food constituents <i>of primary interest</i>.</p> <p>Taking as examples of phytosterols in chocolate or vitamin A in butter, the phytosterols/vitamin A would be the related substance/nutrient of primary interest whereas saturated fat in chocolate/butter would belong to the third category of nutrient. This third category relates more to the appropriateness of a fortified/enhanced food’s overall nutritional profile. Australia supports deletion of the inner brackets around the third dot point with the following amendments to clarify the current text:</p> <p>The food constituents of primary interest in nutritional risk analysis....</p> <ul style="list-style-type: none"> • nutrients <u>of primary interest</u> that may reduce...; or • related substances <u>of primary interest</u> that may increase...;or • other nutrients that increase the risk of adverse health effects that exist when also present in a food matrix with a nutrient or related substance of primary interest associated with a reduction of the risk of inadequacy or adverse health effects at lower intake.
12	The reference to footnote 4 attached to HIGHEST OBSERVED INTAKE is an error and should be deleted.
27	Australia supports retention of the text and deletion of the square brackets noting that bioavailability is also (and more likely to be) taken into account in nutrient-related hazard characterization, discussed in paragraph 22.
New Unnumbered sub-paragraph in Para 29.	<p>Australia recognises that the issue of the health risks associated with substitution of a product of overall inferior nutritional quality (e.g. calcium-fortified water in place of milk) has not been directly addressed. However, the sentence in the preceding paragraph which refers to ‘consideration of the suitability of foods containing risk-increasing nutrients for certain purposes’ could provide a suitable context to capture this idea. This section could be expanded to insert ‘or having low amounts of risk-decreasing nutrients’ to cover both possibilities.</p> <p>It could then read “..., consideration of the suitability of foods containing risk-increasing nutrients <u>or having low amounts of risk-decreasing nutrients</u> for certain purposes or...’</p>
32	Australia does not object to the inclusion of the text in square brackets.
33	Given the addition of ‘by CCNFSDU’ to the heading of Section 6, the second sentence referring to ‘by the relevant Codex subsidiary body’ should be deleted.
34	If the text in square brackets is problematic, then the sentence can be shortened by deleting ‘to ensure currency and consistency with good regulatory practice’ since the secretariat had informed the Committee that Good Regulatory Practice was not a recognised term in Codex.

BRAZIL (1)

SECTION 2 – INTRODUCTION

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

Brazil proposes to remove the brackets of the whole footnote and to maintain the text. However, it intends to maintain the brackets in the term "potential" for better discussion of the understanding of the term and of the repercussions in the application of the definition of "related substance".

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.

Brazil proposes to remove the brackets and to maintain the text.

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.

Brazil proposes to remove the brackets and to maintain the text, because the recommendations of FAO/OMS bodies must be considered on the discussion of the CCNFSDU issues.

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. }

Brazil proposes to remove the brackets and to maintain the text in order to be coherent with the title of the norm and with item 5.

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 that may reduce the risk of inadequacy and those that may increase the risk of adverse health effects; or
- related substances² 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;
- {nutrients that increase the risk of adverse health effects that exist in a food matrix with a nutrient(s) or related substance(s) associated with reduction of the risk of inadequacy or adverse health effects at lower intake};}

Brazil intends to remove the first and the last brackets, maintaining the text of the first and of the second item.

In relation to the third item, Brazil requests explanations for the meaning of the sentence and examples of its application, once this item seems to overcome the proposal of the document.

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 supplements⁶, 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.}

Brazil proposes to remove the brackets and to maintain the text.

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 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.}

Brazil proposes to remove the brackets and to maintain the text.

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.

Brazil proposes to remove the brackets and to maintain the text, once the country specialists can be consulted, considering the regional differences.

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} and subsequent to any future amendments to the Codex Working Principles.

Brazil proposes to remove the brackets and to maintain the text.

BRAZIL 2

Brazil agrees with the document at step 6 and the continuity of the work by Australia. We strengthen that Brazil has already answered the CL 2007/43-NFSDU at step 5.

COSTA RICA

In general we are in agreement with the document since it reflects the characteristics and special features of risk analysis applied to nutritional matters. For this reason, we accept practically the entire text that is found in brackets and have made only some editorial observations in order to improve the Spanish version of the document. The text has been modified in the following manner:

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 referred to as "Nutritional Risk Analysis Principles") are subsidiary to and should be read in conjunction with the Working Principles.

Page 2 footnote {A related substance is an inherent constituent of food (other than a nutrient) that has a {potential}-nutritional or physiological effect.}

5. Taking into account its significant function with respect to providing scientific advice to the Codex Alimentarius Commission and its subsidiary bodies, the FAO and the WHO and their expert consultations {and expert bodies}...

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) — with respect to 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.

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 related situations that address inadequate intakes, such a reduction in risk might be referred to as {a form of} a nutritional benefit.
8. The food constituents of primary significance in nutritional risk analysis are inherent components of food and/or intentionally added to food {and are identified as:
- nutrients that may reduce the risk of inadequate nutrition and those that may increase the risk of adverse health effects; or
 - related substances 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;
 - [nutrients that increase the risk of adverse health effects that exist in a food matrix with a nutrient(s) or related substance(s) associated with reduction of the risk of inadequacy or adverse health effects at lower intake].}
27. Nutrient-related intake assessment and risk characterisation 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 recognises that nutrient-related risks are often associated with total intakes from multiple dietary sources, including fortified foods, food supplements, 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.]}
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 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.}
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 organisations {as well as national relevant expertise}, if and when justified.
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}, and subsequent to any future amendments to the Codex Working Principles.

GHANA

Section 3 – Scope and Application

Paragraph 6

The text in square brackets in paragraph 6 should be adopted; that is the square brackets in sentence: ‘[The Nutritional Risk Analysis.....that are developed by other Codex subsidiary bodies]’ should be removed and the sentence added to document as paragraph 6.

Paragraph 7, second sentence

We prefer the deletion of the text in square brackets in the following sentence: ‘In situations that address inadequate intakes, such a reduction in risk might be referred to as [one form of] a nutritional benefit.’ for text to read as follows:

‘In situations that address inadequate intakes, such a reduction in risk might be referred to as a nutritional benefit.’

Reason: The text in square brackets does not make a difference in the reasoning of the sentence so may be deleted. On the other hand, its retention implies that there are other forms of nutritional benefits.

Paragraph 8

We propose the removal of the two square brackets in paragraph 8.

We also propose the deletion of the word **‘inherent’** and the retention of the words **‘intentionally added’** in the sentence:

‘The food constituents of primary interest in nutritional risk analysis are **inherent** components of food and/or intentionally added to the food and are identified as:’

for the sentence to read as follows:

‘The food constituents of primary interest in nutritional risk analysis are components of food and/or intentionally added to the food and are identified as:’

Reason: this is because food originally may not contain related substances but related substances can be intentionally added.

3rd bullet of Para 8

We suggest the removal of the square brackets and the replacement of a semi colon at the end of sentence with a full stop.

Footnote 2

To conform to paragraph 8, we also propose that the word phrase **‘intentionally added to food’** is added to the sentence and the square brackets are removed for sentence to read as follows:

A related substance is an inherent constituent (other than a nutrient) and/or can be intentionally added to food and that has a potential nutritional or physiological effect

Paragraph 27

We prefer the addition of the text in the last sentence ‘It may also take into account the bioavailability and stability of nutrients and related substances in the foods consumed’ to other sentences in the paragraph and hence the removal of the square brackets.

Paragraph 29

We prefer the addition of the text in the last sentence ‘Nutritional risk management.....overall risk reduction.’ to other sentences in the paragraph and hence the removal of the square brackets.

Paragraph 32 reinforces the earlier statement in Paragraph 5.

We propose the removal of the square brackets and maintaining the words ‘as well as national relevant experience’ in the sentence as this gives flexibility in choice of risk assessors.

GUATEMALA

Comments from Guatemala			Justification
Page	Original text	Modifications	
77	[Principles of nutritional risk analysis and guidelines for the application of such analysis in the work of the Committee on Nutrition and Foods for Special Dietary Uses]	Delete brackets and approve text.	Determine title and description of the document's contents.
77 Foot of page 2	[A related substance is an inherent constituent of food (other than a nutrient) that has a [potential] nutritional or physiological effect.	Delete brackets and approve text.	Define related substance.
77 Foot of page 2	[potential]	Delete brackets and approve text.	Not all related substances have a nutritional effect or physiological
78 Point 5	[and expert groups]	Delete text.	It is deemed implicit that the joint expert consultants may also be expert groups.
78 Point 6	[The principles of nutritional risk analysis have been established to orient...]	Delete brackets and approve text.	Determine and clarify the scope of the document.
78 Point 7	[a form of]	Delete text.	For a correct composition.
78 Point 8	[and is characterised as follows...]	Delete brackets and approve text.	Determine the characteristics of the food constituents that are most important for the nutritional risk analysis, that is nutrients or related substances.
		Delete the following word: [and is characterised as follows...]	For a more concrete translation of the English version.
78 Point 8	[nutrients that increase the risk of adverse health effects that exist...]	Delete text.	The characteristics are described in the two previous points, and for this reason, the last point is unnecessary.
81 Point 24	Nutrient reference standards that may be used to characterise nutrient-related hazards	Nutrient reference standards that may be used to characterise nutrient-related hazards related to excessive	For a more precise translation of the English version.

	related to excessive intakes include upper levels of intake.	intakes <u>include upper levels of intake.</u>	
	The FAO and WHO have published some globally relevant reference standards related to upper levels of intake.	The FAO and WHO have published some globally relevant reference standards that are globally relevant related to <u>upper levels of intake.</u>	For a more precise translation of the version in English.
	In addition, the establishment of international upper levels of intake and highest observed intake that build on recommendations may be considered in the future.	In addition, the establishment of <u>upper levels of intake and highest observed intake</u> that build on recommendations may be considered in the future.	For a more precise translation of the version in English.
82 Point 27	[It may also take into account the bioavailability and stability of nutrients and related substances in the foods consumed].	Delete brackets and approve text.	The risks may also be associated with the bioavailability and stability.
82 Point 29	[Nutritional risk management decisions should take into account the actual impact...].	Delete brackets and approve text.	The information is relevant as a complement to the previous text.
82 Point 32	However, this does not exclude the choice of alternative sources of advice, such as appropriate international expert groups or organisations [or related national experts], when justified.	Delete the word approved, delete brackets and approve text. However, this does not exclude the choice of alternative sources of advice, such as international expert groups or organisations or <u>related national relevant experts</u> , when justified.	For a more precise translation of the version in English. Determine the advisory voice of national experts also.
83 Point 34	[good regulatory practice]	Delete brackets and approve text. Delete the word “regulatory” and change it to “regulation”: <u>good regulation practice</u>	The word regulation is more appropriate in this case, since it determines the rules or norms to which someone or something must adjust.

MALAYSIA

Section 2 – Introduction

Paragraph 5

Malaysia proposes to amend the second sentence of the paragraph 5 by inserting the phrase „recognized by Codex,“ between the words „organizations“ and „if“. The amended paragraph 5 shall read as follows:

“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, if and when justified, such as appropriate international expert groups or organizations recognized by codex”

This preapproval by codex is important to ensure that the international expert groups selected are able to provide independent and unbiased scientific advice. This concern is also documented in paragraph 102 of the Alinorm 08/31/26:

“The Representative of FAO indicated that WHO/FAO should be the primary if not only source of scientific advice to CCNFSDU, and that international expert groups might not provide independent and unbiased scientific advice.”

NEW ZEALAND

New Zealand believes that excellent progress was made on the draft text at the 29th session of the CCNFSDU in November 2007 and New Zealand supports the advancement of this text for adoption at Step 5 by the 31st session of the Codex Alimentarius Commission.

New Zealand does have a few specific comments to make on the text that will be discussed at the next meeting of the CCNFSDU as follows:

The definition of related substance (as found in **footnote 2**) could be simplified as follows:

A related substance is a constituent of food (other than a nutrient) that has the potential to have a beneficial nutritional or physiological effect.

New Zealand considers it important that the effect of any added related substance should be linked to a potential beneficial effect and that this needs to be clear in the definition.

Under **para 4** the square brackets around the title can be removed as there has been agreement on the title.

New Zealand supports retaining the text in **para 6** which would provide guidance for other subsidiary bodies of Codex in the use of nutritional risk analysis principles. The experience of the recent work on the Biotech Taskforce and its work on the Annex of Food Safety Assessment of Foods derived from Recombinant DNA plants modified for Nutritional or Health Benefits is evidence of such appropriate use.

Para 8 New Zealand supports the deletion of the outer and inner square brackets with the inclusion of the word “related substances” at the beginning of the third dot point. The dot point would then read:

*Nutrients **or related substances** that increase the risk of adverse health effects that exist in a food matrix with a nutrient (s) or related substance(s) associated with reduction of risk of inadequacy or adverse health effects at lower intake:*

Para 27 New Zealand supports deletion of the square brackets and the retention of the text recognizing that the issue of bioavailability is important in a number of areas

New Zealand supports the deletion of the square brackets in **para 29** and the retention of the new text.

New Zealand can support the retention of the text in square brackets in **para 32**.

The reference of good regulatory practice in **para 34** is a concept that New Zealand supports reference to in this paragraph.

PHILIPPINES

SECTION 2 – INTRODUCTION

The Philippines proposes the following amendments:

> Item no. 3: Change the words “inherent constituents” to “intrinsic components” as

follows:

“...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 ~~inherent constituents~~ intrinsic components such as allergens, nutrients and related substances are inherent constituents that are biologically essential ...”

Rationale: the words “inherent constituents” are subsequently mentioned twice in the sentence. The first “inherent constituents” is proposed to be changed to “intrinsic components” to avoid redundancy.

> Item no. 4: Retain the statement, delete the square brackets.

> Item no. 5: Move the phrase “expert bodies” after FAO and WHO, hence, read as follows:

5. Consistent with their important role in providing scientific advice to the Codex Alimentarius Commission and its subsidiary bodies, FAO and WHO expert bodies 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.

> Footnote 2: Retain the entire statement, delete the square brackets.

SECTION 3- SCOPE AND APPLICATION

> Item nos. 6 and 7: Retain the paragraph and phrase respectively, delete the square brackets.

> Item no. 8, bullet no. 3: Delete 3rd bullet. The notion is already specified on the above first two bullets.

SECTION 5 – PRINCIPLES FOR NUTRITIONAL RISK ANALYSIS

> Item no. 27: Retain the statement, delete the square brackets

> Item no. 29, 2nd Paragraph : Retain the paragraph with some amendment adding the words “undesirable effects” and deleting the words “and to ensure overall risk reduction,” as follows:

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

Rationale: The first paragraph refers to risk management decision while the second paragraph refers to factors to be considered to arrive at appropriate risk management decisions, thus, we propose to retain the paragraph.

> Item no. 34: Retain the words “good regulatory practice,” delete square brackets. This is to make sure that Nutritional Risk Analysis Principles is in harmony with good regulatory practice.

Further, for consistency with the process flow of risk analysis i.e. risk assessment, risk management and risk communication mentioned in the draft guidelines. The Philippines proposes the rearrangement of the guidelines specifically Sections 5, 6 and 7, in the following sequence:

Section 5 – Principles for Nutritional Risk Analysis

A. Nutritional Risk Assessment

a. Selection of Risk Assessor by CCNFSDU

B. Nutritional Risk Management

a. Preliminary Nutritional Risk Management Activities

C. Nutritional Risk Communication

Section 6 - Review Process

Thus, with the above proposed sequence, the current item numbers will automatically be changed as follows:

CURRENT ITEM NUMBERS:

PROPOSED:

SECTION 5- Principles for Nutritional Risk Analysis Same SECTION 5 and title

Item number 30, being a risk assessment principle ~~will become~~ item no. 14

A. Nutritional Risk Assessment, item nos. 18-27 ~~will become~~ item nos. 15-24

a. Selection of Risk Assessor by CCNFSDU, item nos. 25-32-33 ~~will become~~ item nos. 25-26

B. Nutritional Risk Management, item nos. 28-29. ~~will become~~ item nos. 27-

(Note: item no. 30 was earlier proposed to become item no. 14) 28

a. Preliminary Nutritional Risk Management Activities, item nos. 14-17 ~~will become~~ item nos. 29-32

C. Nutritional Risk Communication, item no. 31 ~~will become~~ item no. 33

SECTION 7 – Review Process, item no. 34 ~~will become~~ SECTION 6, retain its item no. 34

SOUTH AFRICA**1. Footnote 2, paragraph 3**

Removal of brackets and deletion of {[potential] nutritional or} and the definition to read as follows:

A related substance is an inherent constituent of food (other than a nutrient) that has a physiological effect.

2. Paragraph 4

Removal of brackets to include the title as:

Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses.

3. Paragraph 5

Removal of brackets to include expert bodies and read as follows:

and expert bodies

Reason: So that other external bodies can be consulted.

4. Paragraph 8:

Removal of all brackets and paragraph to read as follows and second brackets deleted:

The food constituents of primary interest in Nutritional Risk Analysis are inherent components and/or intentionally added to food and are identified as: nutrients to reduce the risk of inadequacy and those that may increase risk of adverse health effects; or related substances that may increase of risk of adverse health effects at excessive intake and may also reduce the risk of other adverse health effects at lower intake.

Deletion of third point.

[nutrients that increase the risk of adverse that exist in food matrix with nutrient(s) or related substance(s) associated with reduction of the risk of inadequacy or adverse health effects at lower intake];]

Reason: Already covered by the two points above.

5. Paragraph 27

Removal of brackets for inclusion of following sentence:

It may also take into account the bioavailability and stability of nutrients and related substances in the food consumed.

THAILAND

I General Comments

We are of the opinion that Nutritional Risk Analysis Principles could be applied in dealing with nutrient deficiencies, possible hazards from over consumption of nutrients or certain food ingredients, and from imbalance of nutrient intakes in various setting. Regarding provision of scientific advise to CAC particularly to CCNFSDU and CCFL, and member countries Thailand would suggest that FAO and WHO should perform this function through the Joint FAO/WHO Expert Committee on Nutrition. Since this Committee is at present not existed, it is recommended that FAO/WHO create this steering committee. The issues requested to this Committee should be requested and prioritized by the CAC and related Committees.

II Specific Comments

1) Section 2 – Introduction

- paragraph 3

For this paragraph and all the contexts of the document, the term “related substance” should be replaced with the term “other substance”. Accordingly, the term “other than nutrient” could be excluded from the definition of the term “other substance” mentioned in footnote 2. Footnote 2 would now read as follows:

”A An related other substance is an inherent a constituent of food (other than a nutrient) that has may have the a potential to have a beneficial nutritional or physiological effect.”

- paragraph 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”

The phrase “if and when justified” mentioned at the end of the paragraph 5 and 32, should be clarified and elaborated what it means.

2) Section 3 – Scope and Application

- paragraph 6

The square bracket should be removed from paragraph 6, because the development of Principles for Nutritional Risk Analysis could be implemented comprehensively in Codex works.

As a result, this paragraph 6, somehow, may not comply with the title of the document. We, therefore, propose that the title should be amended to read “Proposed Draft Principles for Nutritional Risk Analysis for Application in the Framework of the Codex Alimentarius” which is one of the options in CX/FSDU 07/29/7 APPENDIX paragraph 4.

- paragraph 8

The square bracket should be removed from this paragraph. To be clear and to avoid confusion, the first bullet should be separated into 2 bullets. Moreover, the example of “nutrients” mentioned in every bullet should be provided for a clearer understanding. The paragraph should then read as follows:

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

- nutrients that may reduce the risk of inadequacy and those that may increase the risk of adverse health effects; or
- nutrients that may increase the risk of adverse health effects; or
- related other substances 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;
- [nutrients that increase the risk of adverse health effects that exist in a food matrix with a nutrient(s) or related other substance(s) associated with reduction of the risk of inadequacy or adverse health effects at lower intake];].

UNITED STATES OF AMERICA (at Step 5)

We believe that excellent progress was made on the preparation of this draft text in the 29th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses, and support the Committee’s advancement of this text for adoption at Step 5 by the 31st Session of the Codex Alimentarius Commission.

UNITED STATES OF AMERICA (at Step 6)

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 nutrients¹ and related substances² 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.

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~~ **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 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. Such a reduction in risk might also be referred to as 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 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 substances² **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 **when also present** in a food matrix with a nutrient(s) or related substance(s) **of primary interest**

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 intake⁴ – 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 study(ies) of acceptable quality.

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 supplements¹, 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 **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.

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 advances in nutritional risk assessment and 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.

CRN - Council for Responsible Nutrition

SECTION 2—INTRODUCTION

Paragraph 3.

- There is a mistake at the end of Paragraph 3; it should end with “inadequate intakes.” Later in this comment, CRN will point out the disadvantages of immediately trying to replace the usual approach to nutritional benefits (avoidance of the adverse effects of inadequate intakes by assuring at least a level equivalent to the Recommended Dietary Allowance) with a risk assessment approach. While a risk-based approach is logically feasible, it should not detract from the more urgent task of using risk assessment outcomes as the basis of maximums for nutrients and related substances in products within the frame of reference for the CCNFSDU. The urgent need to complete all work, including the setting of Codex standards, is related to the insistence by some governments that they are not able to base national regulatory maximums for vitamins and minerals in supplement products until Codex has gone beyond the mere sanctioning of the setting of such maximums on risk assessment (per the Guidelines on Vitamin and Mineral Food Supplements, adopted by the Commission in 2005) and Codex itself has identified internationally accepted ULs and maximums.

- paragraph 3 line 5, needs a “,(comma sign)” after word “residues”.

- Footnote 1 to Paragraph 3 is acceptable as drafted.

- Footnote 2 to Paragraph 3 should have all square brackets removed.

Paragraph 5. The square brackets should be removed.

SECTION 3—SCOPE AND APPLICATION

Paragraph 6. This paragraph is appropriate as drafted, and therefore the square brackets should be removed.

Paragraph 7. The words within the square brackets (“one form of”) should be deleted because they are logically unnecessary. An inadequate intake of a nutrient or related substance automatically imposes some form of risk—of deficiency disease, inadequate nutrient reserves, depressed function, or unacceptable likelihood of one or more of these adverse effects. Avoidance of any or all of these undesirable consequences of inadequate intake should be seen as “nutritional benefit.”

Paragraph 8. The concepts included are appropriate, but the third bullet wording is confusing and the intent and provisions are not clear. The following suggested wording for the third bullet may be more understandable, and the point is not included in the first two:

- [nutrients or related substances that exist in a food matrix at levels that may increase the risk of adverse health effects but are also associated with risk of inadequacy or adverse health effects at lower intake;]

Paragraph 10. Although all the points in this paragraph describe worthwhile objective, it is not clear how a qualitative approach can contribute to their accomplishment. CRN recommends that this paragraph is addressed in detail in a special working group meeting just prior to the next CCCNFSDU meeting. Unless this paragraph can be made clear and objective, with a transparent meaning, CRN recommends that it be deleted in its entirety.

SECTION 4—DEFINITIONS

Paragraph 12.

Nutritional risk: The words “and persistence” should be inserted after “severity.”

Nutrient-related hazard: While this definition is correct, it is not useful because all nutrients and related substances are, at least conceptually, included. Rewording would be helpful if made consistent with a reworked Paragraph 8. As is, this definition is neither helpful nor harmful.

Nutrient-related hazard identification: This definition is not useful; it merely repeats the words in the term in context of foods. Deletion of this definition would make the document more succinct and not eliminate any meaning.

Highest level of intake: This definition is correct, and is much needed to help assure proper interpretation of the absence of a UL for many nutrients and related substances. [Does this mean “upper level of intake” or “highest observed intake” in the Definition?]

Bioavailability: The definition given is appropriate, but additional explanation, including constraints on interpretation, will need to be given for it to be useful in making regulatory and policy decisions. Without this additional information, the definition is not needed and should be deleted.

Homeostatic mechanism: The definition is appropriate but not any more useful than defining “cell,” “organ,” or “physiology.” There is no apparent need for this definition in the document, and it should be deleted.

SECTION 5—PRINCIPLES FOR NUTRITIONAL RISK ANALYSIS

Paragraph 13. The description of three components is appropriate, but the practical meaning of “particular emphasis” on Problem Formulation is not clear. How does “particular emphasis” differ from simply stating that Problem Formulation should be the first step in preliminary risk management?

Paragraph 16.

- Third bullet on nutritional risk assessment policy. The term is not defined in this document and the consequences of its absence are not addressed. If nutritional risk assessment policy is cited as needed for the decision to perform a risk assessment, the term should be defined or at least described. CRN suggests that this bulleted item is not needed, unless the entirety of paragraph 16 is seen as the policy.

Paragraph 17.

- Third bullet on route(s) of exposure. This item is misleading. The term “route of exposure” generally means one of the following: oral, inhalation, intravenous, etc. For nutritional risk assessment, the oral

route of exposure should be the automatic assumption. If the intent of this item is to specify source of exposure, e.g., ordinary foods, fortified foods, supplements, and the like, the term “source of exposure” would be better.

- Fourth bullet on health endpoints. The phrase “to be considered” should be deleted. Of course, the decision on the health endpoints to be considered should be dictated by the purpose and available data.

Paragraph 20. The second sentence is misleading and only partly true: a nutrient-related hazard may be the excessive intake of any nutrient or related substance, regardless of whether that excessive intake occurred (1) independently and not in association with any other change, (2) by accompanying risk-increasing nutrients in a food vehicle, or (3) by accompanying risk-decreasing nutrients in a food vehicle. The second sentence should be deleted or expanded to make all three of the points listed in the previous sentence of this comment.

Paragraph 21. In addition to the current text, CRN recommends the addition of a second sentence: “In recognition of the differences in these technologies and approaches, it should be recognized that a direct ratio or comparison of the risks related to excessive intake and those related to inadequate intake may not be logical or feasible.”

Paragraph 22. In addition to the current text, CRN recommends the addition of a second sentence: “It should be recognized that for some nutrients bioavailability may be influenced as much or more by other dietary components than by the inherent characteristics of the nutrient source.”

Paragraph 27. The final sentence is accurate and may be useful. The square brackets should be removed.

Paragraph 29. The first sentence should have the following phrase added: “, but the quantitative approach should be used where the available data make this feasible.” The second square-bracketed section of Paragraph 29 should be deleted. It is much too open-ended and speculative through use of the words “or likely,” “anticipate,” and “possible.” As written, this sentence would give the risk manager the license to make almost any decision on a speculative basis.

Paragraph 30. There is a major discontinuity between the policy statement made here and the discussion in Paragraph 16. Since these differences are not easy to reconcile, CRN recommends that the working group suggested under Paragraph 10 also address this issue and develop a recommendation before the next CCNFSDU meeting.

Paragraph 32. This paragraph will be acceptable if the square brackets are deleted.

IDF (at Step 5) - International Dairy Federation

General comments

- Foods are complex combinations of nutrients and it is not always possible to predict the effect of foods on health based on their content of one or two nutrients. Food patterns, food groups and individual foods, the food matrix, and individual nutrient requirements, and the physiological status of the consumer, all have an impact on health responses. IDF’s concern is that these principles will isolate nutrients and not give due consideration to the synergistic aspects of foods and nutrients or the aspect of total diet.

- The term ‘excessive’ is used in the document without an appropriate definition or discussion of the alleged consequences of such “excesses”.

- There appears to be no criteria established for the qualitative or quantitative evidence necessary to arrive at a credible risk assessment.

Specific comments per section:

Section 2. Introduction

Para 3: Editorial comment: 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, 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, in addition to risks of microbiological pathogens and contaminants. ~~and~~

Section 3 Scope and application

Paragraph 8, third bullet in square brackets:

[nutrients that increase the risk of adverse health effects that exist in a food matrix with a nutrient(s) or related substance(s) associated with reduction of the risk of inadequacy or adverse health effects at lower intake];].

IDF would like to emphasise the importance of the food matrix with regard to nutritional risk analysis and is in favour of keeping this paragraph in the text.

Section 4. Definitions

Paragraph 12: The definitions of ‘Nutritional risk’, ‘Nutrient-related hazard’, and ‘Nutrient-related hazard characterisation’ mirror the classical risk assessment definitions and refer to inadequate or excessive intake of a nutrient or related substance. ‘Inadequate’ and ‘excessive’ are used without an appropriate definition or discussion of the alleged consequences of such “excesses”. In addition to these definitional issues, IDF would like to stress the importance of the overall dietary intake when performing a nutritional risk analysis and request that this be considered during the determination of the definitions.

Section 5. Principles for Nutritional Risk Analysis

Paragraph 26-27 Nutrient-related intake assessment and risk characterisation:

For traditional risk assessment: the tools and types of data available to assess the risk from chemicals are well established as integral parts of the risk assessment process. However, for Nutritional Risk Assessment (benefit assessment) human dose-response curves are mostly not available for foods and scarce for single nutrients¹. Intake assessment is a crucial tool, but detailed, reliable data on food intakes are often not available. IDF would like to emphasise that derivation of reliable exposure data requires consideration of food variability, matrix effects on bioavailability, and interaction between components.

Paragraph 29 2nd paragraph in square brackets: ‘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.’

IDF agrees that creating a set of principles that can be adopted by countries for their own use in food legislation may have merit, but trying to adopt the framework for global issues unrealistically assumes that different populations all have the same types of diets and have the same nutrient requirements. Differences between populations should be taken into account when nutritional risk management decisions are taken. However, whilst supporting this paragraph in principle, data requirements in relation to predicting consumer behaviour should be kept realistic in terms of availability and should not be restrictive to innovation.

Section 6. Selection of Risk Assessor by CCFNSDU

Paragraph 32: Because of different populations with different dietary patterns, IDF considers it very important to include other sources of scientific advice and national relevant expertise in addition to FAO/WHO as the primary risk assessor.

¹ Reference: EFSA's 6th Scientific Colloquium Report - Risk-benefit analysis of foods: methods and approaches. ISBN 978-92-9199-031-3 Publication date: July 2007

IDF (at step 6) - International Dairy Federation

General comments

- Concerning the field of nutrition, the notion of risk is related to combined factors (way of life, individual physiology, heredity, age, balance of diet...) and considering these different factors, it could be hazardous to apply nutritional risk analysis without proper judgment to Codex standards.
- It is important to emphasise that the nutritional risk is related to the global intake of energy and nutrients, but in most cases not to a particular food. Nutritional risk analysis needs to take into account social and cultural aspects, as well as availability and food prices. IDF acknowledges that there are some occasions where for individuals nutritional risk can be attributed to a single food, for example food containing food allergens or gluten.
- Foods are complex combinations of nutrients and except for cases in which the risk can be attributed to a single food it is difficult to predict the effect of foods on health based on their content of one or two nutrients/components. Food patterns, food groups and individual foods, the food matrix, individual nutrient requirements, and the physiological status of the consumer, all have an impact on health responses. The IDF's concern is that the proposed principles will isolate nutrients and not give due consideration to the synergistic aspects and bioavailability of foods and nutrients or the aspect of total diet.
- The terms 'inadequate' and 'excessive' intake need to be defined as appropriate, and the consequences of such inadequate or excessive intake need to be clarified.
- There appears to be no criteria established for the qualitative or quantitative evidence necessary to arrive at a credible risk assessment.

Specific comments per section:

Section 2. Introduction

Paragraph 3:

Editorial comment:

“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 and inherent constituents such as allergens, nutrients and related substances are ~~inherent constituents that are~~ either biologically essential (in the case of essential nutrients) or in other ways potentially favourable to health. Therefore nutritional risk analysis therefore adds a new dimension to traditional risk analysis. That is, it also considers by also considering risks directly posed by inadequate or excessive intakes, in addition to risks of potentially harmful components, such as microbiological pathogens and other contaminants. And”

Section 3 Scope and Application

Paragraph 7:

IDF proposes to add the following sentence at the end of the paragraph: “...a nutritional benefit, provided that there is no consequence on the intake of other nutrients, which may result in adverse health effects.”

Paragraph 8:

- first bullet:

The sentence does not take into account the relation between a nutrient and its intake, as has been done in the 2nd bullet. IDF therefore proposes the following wording (same wording as the second bullet):

“ nutrients that may reduce the risk of inadequacy at lower intake and those that may increase the risk of adverse health effects at excessive intake”

- third bullet in square brackets:

[nutrients that increase the risk of adverse health effects that exist in a food matrix with a nutrient(s) or related substance(s) associated with reduction of the risk of inadequacy or adverse health effects at lower intake];].

IDF would like to emphasise the importance of the food matrix and the concept of nutrient density/richness with regard to nutritional risk analysis and is in favour of keeping this paragraph in the text.

Paragraph 9:

The application of quantitative nutritional risk analysis data should not lead to a systematic modification of the quantity of different nutrients in food, which constitute the basis of consumers' intake, to obtain a "balanced food" because the nutritional objective should be to obtain a balanced diet.

Paragraph 10:

- First bullet:

IDF would like to ask for clarification of this bullet. Is the objective to elaborate principles to establish the nutritional composition of different foods, for example to which nutrients can be added? It is IDF's opinion that unless carefully considered this may have a negative effect on a balanced diet. Given the different diets of different populations in different countries around the world, any international guidelines would be required to be suitably broad.

Section 4. Definitions

Paragraph 12:

The definitions of 'Nutritional risk', 'Nutrient-related hazard', and 'Nutrient-related hazard characterisation' mirror the classical risk assessment definitions and refer to inadequate or excessive intake of a nutrient or related substance. 'Inadequate' and 'excessive' are used without an appropriate definition or discussion of the alleged consequences of such "excesses". In addition to these definitional issues, IDF would like to stress the importance of the overall dietary intake when performing a nutritional risk analysis and request that this be considered during the determination of the definitions.

Section 5. Principles for Nutritional Risk Analysis

Paragraph 19:

Scientific data and medical literature should be revisited regularly, in particular in the field of nutrition, where new data are regularly released.

Paragraph 22:

It is important to take the bioavailability of nutrients into account. IDF proposes to replace "it may..." by "it should" or "it is appropriate..." in the second sentence of this paragraph.

Paragraph 23: (editorial)

It would be useful to give the FAO/WHO document references and date of publication.

Paragraph 26-27:

For traditional risk assessment the tools and types of data available to assess the risk from chemicals are well established as integral parts of the risk assessment process. However, for Nutritional Risk Assessment (benefit assessment) human dose-response curves are mostly not available for foods and scarce for single nutrients². Intake assessment is a crucial tool, but detailed, reliable and up to date data on food intakes are often not available. IDF would like to emphasise that derivation of reliable exposure data requires consideration of food variability, matrix effects on bioavailability, and interaction between components.

² Reference: EFSA's 6th Scientific Colloquium Report - Risk-benefit analysis of foods: methods and approaches. ISBN 978-92-9199-031-3 Publication date: July 2007

Paragraph 29:

2nd Paragraph in square brackets:

‘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.’

IDF agrees that creating a set of principles that can be adopted by countries for their own use in food legislation may have merit, but trying to adopt the framework for global issues unrealistically assumes that different populations all have the same types of diets and have the same nutrient requirements. Differences between populations should be taken into account when nutritional risk management decisions are taken. However, whilst supporting this paragraph in principle, data requirements in relation to predicting consumer behaviour should be kept realistic and should not be restrictive to innovation.

Section 6. Selection of Risk Assessor by CCFNSDU

Paragraph 32:

Because of different populations with different dietary patterns, IDF considers it very important to include other sources of scientific advice and national relevant expertise in addition to FAO/WHO as the primary risk assessor.

NHF - National Health Federation

SECTION 1 – BACKGROUND

1. The *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* (hereafter cited as “Working Principles”) has established general guidance on risk analysis to Codex Alimentarius. These Working Principles were adopted in 2003 and published in this Procedural Manual.
2. The objective of the Working 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”. By its reference to health aspects in addition to food safety, the objective provides clearer scope for risk analysis to apply to nutritional matters that are within the mandate of the Codex Alimentarius Commission and its subsidiary bodies.

SECTION 2 – INTRODUCTION

3. Codex nutritional risk analysis addresses nutrients³ and related substances⁴ and the attendant 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 also inherent constituents of food that are biologically essential (in the case of essential nutrients) or in other ways potentially favourable to

³ Nutrient is defined by Codex *General Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 09-1987) to mean:

Any substance normally consumed as a constituent of food:

- (a) which provides energy; or
- (b) which is needed for growth and development and maintenance of healthy life; or
- (c) a deficit of which will cause characteristic biochemical or physiological changes to occur.

Essential nutrient means any substance normally consumed as a constituent of food which is needed for growth and development and the maintenance of healthy life and which cannot be synthesized in adequate amounts by the body.

⁴ A related substance is an inherent constituent of food (other than a nutrient) that has a potentially favourable impact on health.

health. Nutritional risk analysis therefore adds a new dimension to traditional risk analysis by also considering risks directly posed by inadequate intakes.

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

COMMENT BY NHF: This step would actually be risk assessment and not risk management, given the stage of the process at which it is conducted.

6. Consistent with their important role in providing scientific advice to Codex Alimentarius 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. For purposes of this document, “scientific” shall mean logical and based upon the scientific method, but there shall be no consequences if the advice rendered by the primary source of nutritional risk assessment to Codex Alimentarius is not scientific.

COMMENT BY NHF: NHF recommends retaining the reference to “expert bodies” regardless of whether or not they currently exist, because they could still be usefully created and used by FAO/WHO in the future without the time-consuming need to amend this Codex text.

SECTION 3 – SCOPE AND APPLICATION

7. [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.]

COMMENT BY NHF: NHF notes that the language stricken above was too unspecific and broad, allowing mandates to be passed without proper review by the most interested committee.

8. 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 risks resulting from management efforts to mitigate those risks. In situations that address inadequate intakes, such a reduction in risk might be referred to as one form of a nutritional benefit. **Likewise, mismanagement of risk factors by this Committee contributing factor to malnutrition, disease, and death.**

COMMENT BY NHF: NHF recommends the deletion of the brackets and the inclusion of the additional sentence so as to discourage, in the latter instance, the occurrence of any such eventuality.

9. 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 (e.g., vitamins, minerals) that may reduce the risk of inadequacy and those (e.g., trans-fatty acids) that may increase the risk of adverse health effects; or
 - related substances⁴ 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-; whether directly or in a food matrix.
 - ~~[nutrients that increase the risk of adverse health effects that exist in a food matrix with a nutrient(s) or related substance(s) associated with reduction of the risk of inadequacy or adverse health effects at lower intake];]~~

COMMENT BY NHF: The NHF recommends to the Committee that representative, parenthetical examples be used as set forth above in order to aid readers in following the Committee's intent. In addition, the final bullet point is unnecessary with the changes suggested to the middle bullet point above.

10. Where appropriate, the application of quantitative nutritional risk analysis may guide decision making on quantitative content provisions for nutrients and related substances in certain Codex texts.
11. Nutritional risk analysis should be as quantitative as possible, although a qualitative risk-based approach drawing on the principles of nutritional risk analysis could assist the development of Codex texts in such situations as:
 - formulating general principles related to nutritional composition (e.g. principles for the addition of nutrients to foods);
 - formulating general principles for assessing or managing risks related to foods for which a nutrition or health claim has been requested;
 - managing risks by labelling advice in relation to consumption of foods of certain nutrient-related⁵ composition, including foods for special dietary use; and
 - advising on risk-risk analysis (e.g. risk associated with a significantly reduced or entirely avoided consumption of a nutritious, staple food in response to a dietary hazard such as a contaminant present in that food).

SECTION 4 – DEFINITIONS

12. The *Definitions of Risk Analysis Terms Related to Food Safety* in this Procedural Manual provide suitable generic definitions of risk analysis, risk assessment, risk management, risk communication and risk assessment policy. When applied in a nutritional risk analysis context, these high-level risk analysis terms should be prefaced by “nutritional” and their existing definitions appropriately adapted by replacement of relevant existing terms and definitions with those listed below.
13. However, other *Definitions of Risk Analysis Terms Related to Food Safety* have been modified to reference inadequate intake as a nutritional risk factor. Some new terms also have been defined to provide further clarity. The modified or newly developed subsidiary definitions are as follows:

Nutritional risk –

A function of the [scientifically-proven](#) probability of an adverse health effect associated with inadequate or excessive intake of a nutrient or related substance and the [scientifically-proven](#) severity of that effect, consequential to a nutrient-related hazard(s) in food.

Adverse health effect⁶ -

A [scientifically--proven](#) change in the morphology, physiology, growth, development, reproduction or life span of an organism, system, or (sub)population that results in an [unacceptable](#) impairment of functional capacity, an [unacceptable](#) impairment of the capacity to compensate for additional stress, or an [unacceptable](#) increase in susceptibility to other [harmful](#) influences.

COMMENT BY NHF: The introduction of the concept of “scientifically-proven” in this and subsequent definitions tracks exactly the science-based risk analysis approach adopted by this Committee. The addition of the term “unacceptable” also eliminates de minimus, or negligible, impairments that would not rise to actionable levels.

⁵ For the purpose of these Nutritional Principles, the descriptive term ‘nutrient-related’ refers to one or more nutrients and/or related substances, as the case may be.

⁶ Report of a joint FAO/WHO technical workshop 2005. A model for establishing upper levels of intake for nutrients and related substances, WHO, 2006.

Nutrient-related hazard⁵

A nutrient or related substance in food that has the potential to cause an [scientifically--proven](#) adverse health effect depending on inadequate or excessive levels of intake.

Nutrient-related hazard identification –

The [scientific](#) identification of a nutrient-related hazard in a particular food or group of foods.

Nutrient-related hazard characterization –

The qualitative and/or quantitative [scientific](#) evaluation of the nature of the adverse health effects [directly](#) associated with a nutrient-related hazard.

Dose response assessment –

The [scientific](#) determination of the relationship between the magnitude of intake of (or exposure to) (i.e. dose) a nutrient or related substance and the severity and/or frequency of [directly](#) associated adverse health effects (i.e. response).

Upper level of intake –

The maximum level of habitual intake from all sources of a nutrient or related substance [scientifically-proven judged](#) to be unlikely to lead to adverse health effects in humans.

Highest observed intake –

The highest level of intake observed or administered as reported within a stud(ies) of acceptable quality. It is derived only when no adverse health effects have been identified [in direct association with the nutrient intake](#).

Intake (~~Exposure~~)-assessment –

The [scientific](#) qualitative and/or quantitative evaluation of the likely intake of a nutrient or related substance from food as well as intake from other relevant sources such as food supplements.

COMMENT BY NHF: Elsewhere in this document, this term is simply referred to as intake assessment. In order to be consistent, the term “exposure” should be deleted.

Nutrient-related risk characterization –

The [scientifically](#) qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of ~~known or potential~~ [scientifically--proven](#) adverse health effects in a given population based on nutrient-related hazard identification, nutrient-related hazard characterization and intake assessment.

Bioavailability⁷

The proportion of the ingested nutrient or related substance that is absorbed and utilised through normal metabolic pathways. Bioavailability is influenced by [environmental factors](#), dietary factors such as chemical form, interactions with other nutrients and food components, ~~and~~ food processing/preparation~~;~~ and host-related intestinal and systemic factors.

Homeostatic Mechanism⁶

A mechanism effected through a system of controls activated by negative feedback that allows the maintenance of normal body functions in the presence of a variable nutrition environment.

SECTION 5 – PRINCIPLES FOR NUTRITIONAL RISK ANALYSIS

14. Nutritional risk analysis comprises three components: risk assessment, risk management and risk communication. Particular emphasis is given to an initial step of Problem Formulation as a key preliminary risk management activity.

⁷ Gibson R.S. The role of diet- and host-related factors in nutrient bioavailability and thus in nutrient-based dietary requirement estimates. Food and Nutrition Bulletin 2007;28(suppl):S77-100.

PRELIMINARY NUTRITIONAL RISK MANAGEMENT ACTIVITIES

15. Preliminary nutritional risk management activities should have regard to the particular sections in the Working Principles titled the General Aspects of Risk Analysis, and Risk Assessment Policy.

Nutritional Problem Formulation⁶

16. Nutritional Problem Formulation is necessary to identify the purpose of a nutritional risk assessment and is a key component of preliminary nutritional risk management activity because it fosters interactions between risk managers and risk assessors to help ensure common understanding of the problem and the purpose of the risk assessment.

17. Such considerations should include whether a nutritional risk assessment is needed and if so:

- the priority it should be accorded;
- who should conduct and be involved in the nutritional risk assessment, nutritional risk management and nutritional risk communication processes;
- the need for development of nutritional risk assessment policy;
- how the nutritional risk assessment will provide the information necessary to support the nutritional risk management decision;
- whether sufficient data are available to embark on an evaluation of nutritional risks to given populations or subpopulations;
- what level of resources are available; and
- the timeline for completing the assessment.

18. Specific information to be gathered for nutritional problem formulation may include:

- A detailed inventory of prior knowledge;
- Identification of the (sub)population to be the focus for the risk assessment, geographical areas or consumer settings to be covered;
- Relevant route(s) of exposure; and
- The health endpoints to be checked.

NUTRITIONAL RISK ASSESSMENT

19. The risk assessment section of the Codex *Working Principles for Risk Assessment* is generally applicable to nutritional risk assessment. Additional nutritional risk assessment principles to consider within the Codex framework are identified below.

Nutrient-Related Hazard Identification and Hazard Characterization

20. These two steps are often globally relevant because they are based on available scientific and medical literature that contribute data from diverse population groups. This global relevance for characterization of hazard does not, however, preclude the possibility of a subpopulation-specific hazard. The implications of any subpopulation-specific hazard should not necessarily be factored into population-wide risk management decisions as label warnings may be sufficient. Accordingly, risks associated with inadequate intake may be incurred if risk management decisions are based on the assumption that the whole population is as sensitive as the most sensitive group.

21. Nutritional risk assessment should take into consideration the nutrient-related hazard(s) posed by both inadequate and excessive intakes. This may include consideration of hazard(s) posed by excessive intakes of accompanying risk-increasing nutrients in the food vehicle(s) under consideration as well as assessment of both risks and benefits in different subpopulations.

22. Nutrient-related hazard identification and characterization should recognize current methodological differences in assessment of nutritional risk of inadequate and excessive intakes, and scientific advances in these methodologies.
23. Nutrient-related hazard characterization should take into account homeostatic mechanisms for essential nutrients, and limitations in the capacity for homeostatic adaptations. It may also take into account bioavailability including factors affecting the bioavailability of nutrients and related substances such as different chemical forms.
24. Nutrient reference standards that may be used to characterize nutrient-related hazard(s) related to adequacy include measures of average requirement. Some globally applicable nutrient reference standards for average requirement have been published by FAO/WHO. Official regional and national nutrient reference standards are also available and have been periodically updated to reflect scientific advances. These are more likely to relate to nutrients than to related substances. ~~however~~ However, very few reference standards developed from a systematic review of the evidence ~~that exists~~ for inadequate or suboptimal levels of intake of related substances.
25. Nutrient reference standards that may be used to characterize nutrient-related hazard(s) related to excessive intakes include upper levels of intake. Some globally applicable reference standards of upper level of intake have been published by FAO/WHO. In addition, the establishment of international upper levels of intake and highest observed intake that build on recommendations⁴ may be considered in the future. Some

periodically-updated nutrient reference standards are available from regional and national authorities. For some related substances, such standards developed from a systematic review of the evidence are available only in the peer-reviewed scientific literature.

26. The assessment of inadequate and excessive levels of intake of particular nutrients and related substances should take into account the availability of all such scientifically determined reference sources, as appropriate. When using such reference standards for nutrient and related substances in nutritional risk assessment, the basis for their derivation should be explicitly described.

Nutrient-Related Intake Assessment and Risk Characterization

27. These two steps are generally specific to the (sub)population(s) under consideration for risk assessment. The ideal standard for risk assessment is to examine individual nutritional needs and tolerances. The compromised standard is to examine populations relevant to Codex consideration ~~are~~ populations at large in Codex member countries or these countries' particular subpopulation groups defined according to physiological parameters such as age or state of health.
28. Nutrient-related intake assessment and risk characterization should be applied within a total diet health context. Where feasible, it would typically involve the evaluation of the distribution of usual 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, 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.~~ as well as the higher nutrient needs required from human exposure to environmental toxins and pollutants.

COMMENT BY NHF: The NHF supports deleting the brackets around the last sentence and retaining such wording so long as the additional language is included to ensure a proper balance in risk assessment.

29. Nutrient-related hazard identification and characterization should take into account the totality of available evidence, including evidence from peer reviewed studies, relevant reports and medical records. Hazard identification should be specific to given chemical forms or species of nutrient and relevant to stated target populations, in full acknowledgement that each person has unique and ever-changing nutritional needs and tolerances.⁸

⁸ European Food Safety Authority (EFSA) Colloquium 6 Summary Report: *Risk-benefit analysis of foods: methods and approaches*, 13-14 July 2006, Parma, Italy. 156 pp.

30. In order to make direct comparisons between the risk and benefits associated with nutrient intakes as well as making meaningful and scientifically valid communications of nutrient risks and benefits, the Committee may deem it necessary to develop a common scale of measurement for both risks and benefit (e.g. using Disability Adjusted Life Years [DALYs] or Quality Adjusted Life Years [QUALYs])⁷

COMMENT BY NHF: The NHF recommends these two above additional paragraphs so as to clarify nutrient-related hazard identification and characterization considerations. This will enable more accurate appraisals.

NUTRITIONAL RISK MANAGEMENT

31. The risk management section of the Codex *Working Principles for Risk Management* is generally applicable to nutritional risk management. Additional nutritional risk management principles to consider within the Codex framework are identified below.
32. 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 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.]
33. Nutritional risk assessment policy should be articulated as appropriate for the selected risk assessor prior to the conduct of the nutritional risk assessment.

NUTRITIONAL RISK COMMUNICATION

34. The risk communication section of the Codex *Working Principles for Risk Communication* is generally applicable to nutritional risk communication.

SECTION 6 – SELECTION OF RISK ASSESSOR BY CCFNSDU

35. 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 alternative sources of advice such as appropriate international expert groups or organizations [as well as national and industry relevant expertise,] if and when justified.

COMMENT BY NHF: Government is not the sole source of valuable advice in this field and the Draft Principles should reflect this fact. Otherwise, why do we have INGOs at these Codex meetings?

36. All requests for risk assessment advice should be accompanied by terms of reference and where appropriate risk analysis policy to provide guidance to the risk assessor. These parameters should be established by the relevant Codex subsidiary body.

SECTION 7 – REVIEW PROCESS

37. These Nutritional Risk Analysis Principles should be reviewed by CCFNSDU at appropriate regular intervals after implementation to ensure currency and consistency with [good regulatory practice]advances in nutritional risk assessment, general nutritional data, and subsequent to any future amendments to the Codex Working Principles.

COMMENT BY NHF: The NHF supports the United States' suggestion as to this wording, with two small additions thereto.