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codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 5

ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

*Thirty-first Session,
International Conference Centre, Geneva, Switzerland, 30 June – 4 July 2008*

COMMENTS ON PROPOSED DRAFT STANDARDS AND RELATED TEXTS SUBMITTED AT STEP 5

(Comments submitted as before 1 June 2008)

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING/ COMITÉ DU CODEX SUR LES MÉTHODES D'ANALYSE ET D'ÉCHANTILLONAGE/ COMITE DEL CODEX SOBRE MÉTODOS DE ANÁLISIS Y TOMA DE MUESTRAS (CCMAS)

Proposed Draft Guidelines on Analytical Terminology (ALINORM 08/31/23, para. 51 and Appendix V)

AUSTRALIA

Australia commends the work conducted by the United States and the great deal of progress made on this paper but would respectfully like to see the abbreviations for Limit of Detection and Limit of Quantitation retained as LOD and LOQ, respectively and not L_D and L_Q as proposed. The terms LOD and LOQ are widely used by analytical laboratories in Australia and we believe that the proposed abbreviations, L_D and L_Q , will add a great deal of confusion to the reporting of these terms.

Furthermore, Australia notes that the OECD document GUIDANCE DOCUMENT ON PESTICIDE RESIDUE ANALYTICAL METHODS 13 August 2007 referred to in Appendix V uses the abbreviations LOD and LOQ and supports the inclusion of the definitions in this document as an alternative to that proposed. In addition, the IUPAC document NOMENCLATURE IN EVALUATION OF ANALYTICAL METHODS, Pure and Applied Chemistry 1995 67,1699-1723 applies the following for L_D viz. Minimum Detectable Value; Detection Limit and for L_Q Minimum Quantifiable Value; Quantification Limit further adding to the ambiguity of these terms.

Australia also notes that the EURACHEM Guide THE FITNESS FOR PURPOSE OF ANALYTICAL METHODS 1998 use LOD and LOQ as abbreviations for Limit of detection and Limit of Quantitation, respectively.

UNITED STATES OF AMERICA

The United States strongly supports the adoption of the Proposed Draft Guidelines on Analytical Terminology at Step 5 by the Codex Alimentarius Commission.

CODEX COMMITTEE ON MILK AND MILK PRODUCTS
COMITE DU CODEX SUR LE LAIT ET LES PRODUITS LAITIERS
COMITE DEL CODEX SOBRE LA LECHE Y LOS PRODUCTOS LACTEOS (CCMMP)

**Proposed Draft Amendment to the Codex Standard for Fermented Milks (CODEX STAN 243-2003),
Pertaining to Drinks Based on Fermented Milk (ALINORM 08/31/30, para. 48 and Appendix IV)**

EGYPT

2 – Proposed draft amendment to Codex Standard for Fermented milk (Codex Stan 243-2003), pertaining to drinks based on Fermented milk (Appendix VI) at step 5.

- EOS supports changing the title to be “drinks based on fermented milk” in order to differential these products from those already covered in the existing standard.
- EOS suggests inserting whey and permeate as other dairy ingredients in 2.4 (description), and to replace “drinks based on fermented milk containing a minimum of 40% m/m fermented milk” with “drinks based on fermented milk contain a protein content corresponding to a min. of 50% fermented milk, thereby emphasizing that, although fermented milk is the key ingredient in these products, there is no analytical method available for their determination”.

IRAN

1. Drinks based on fermented milks

1.1. Section 2.4: Drinks based on fermented milks

- It has been noted that replacing language of “dairy ingredients” with “fermented milk” brings two advantages; namely, (1) “emphasizing that fermented milk is the key ingredients”, and (2) “no analytical method is available for determination of dairy ingredients” (page 5 of report). The first explanation seems logical, but how again it would be possible to assess the amount of fermented milk in final product? It is clear that dairy ingredients are part of fermented milk.

- Fermented milk constitutes dairy ingredients, additional potable water as permitted additives (CODEX STAN 243-2003). This expression allows, for example, a drink based on fermented milk to be made of basic fermented milk comprising additives. Therefore, the provision of [minimum 40 or 50%] would be confusing, because it does not really shows that a drink with 40 or 50% fermented milk contains how many percent dairy- and nondairy ingredients (for quantitative emphasis on dairy part compared with nondairy compartment), and dairy proportion might be less than two mentioned minimum levels. It is proposing that at least the word “plain” be added before “fermented milk”, avoiding any additives usage in fermented milk used for production of drink based in that. Also, it should be clarified whether water is deemed as a dairy- or nondairy ingredient, because it is not an additive in nature, but an indigenous component of fermented milk.

- Replacing the language of “dairy ingredients” with “fermented milk” could be somehow problematic, since it is not clearly apparent that minimum of 40 or 50% fermented milk should be considered in final product (as a composition) or it is expressed as an incoming (inlet) fermented milk (as a formulation proportion) through the mixing in manufacturing process. If the first assumption is true, how can we determine the percentage of fermented milk as a composition in final drink based on fermented milk (as questioned previously)? Only the dairy ingredient portion is determinable. If second assumption be made, it would not feasible from mass balance standpoint; because the content of dry matter in incoming fermented milk, which is impossible to be declared in this standard as a fix amount, noticeably affects the contribution of fermented milk (from dairy dry matter viewpoint) in final product. For instance, a drink made from 50% of yogurt with dry matter content of 11% would have less dairy dry matter contribution in produced drink based on fermented milk compared with those made from 40% of yogurt comprising 13% dry matter content (for production of definite amount of final drink). In other word, proportion of applied fermented milk in the formulation of drink based in fermented milk (end product) is not an exact indication of dairy dry matter contribution, which is quantitatively important. In conclusion, in order to avoid mentioned misunderstandings, we propose following statement to be used: “Drinks based in fermented milk contain a minimum of 50% (W/W) dairy ingredients in final product, based on dry matter” (not wet basis). This provision seems to be suitable enough, since regardless of emphasizing on dairy ingredients as the main components (50% level), could comprise most of the drinks based on fermented milks worldwide, from dairy dry matter ingredients point of view. It means that, for example, in a drink with 6% of total dry matter, at least 3% must be dry dairy ingredients, i.e., milk SNF and milk fat (except water), which is quite feasible. By using proposed statement, the inconformity of existing standard regarding “minimum of 40%” with the definition of “composite milk products” (CODEX STAN 206-1999) would be also dissipated and there would be no need for delete of “composite milk product” in section 2.4 from the description, as had been proposed by some delegations.

1.2. Section 3.2: Permitted ingredients

- The bullets “potable water” and “milk and milk products” seems to be not correctly placed in this section, because these constituents have been regarded as raw materials in section 3.1 of CODEX STAN 243-2003. This categorization might arise from the idea that total/some portion of potable water and some part of milk/milk product might be added after fermentation. However, these portions can not be classified in permitted ingredients, as the word “permitted” in this standard (CODEX STAN 243-2003) does not mean materials which are used in main initial formulation before fermentation, but indicates those apart from principal components (basic milk and potable water). This is why, for example, the statement of “starter culture of harmless microorganisms” has been placed in permitted ingredients section (section 3.2) rather than raw material one (section 3.1 in CODEX STAN 243-2003), although it must be basically and inevitably added before fermentation. The two mentioned bullets can be deleted and deemed as raw materials, though be added before or after fermentation. In these two cases, what is different is only the sequence of dry matter standardization (before or after fermentation).

- In some drinks based in fermented milks, such as Iranian yogurt drink (Doogh), carbon dioxide is added as a multifunctional component, for (1) giving wriggling sensation in mouth, (2) retarding possible growth or activity of contaminant/invasive microorganisms, and (3) increasing titrable acidity and decreasing pH value. In section 3.2, no-where addition of this gas has been mentioned, which should be specified for example as “carbon dioxide added by fermentation or cold injection”.

- In some countries, sodium salt might be commonly replaced by potassium salt in order to decrease the risk of blood pressure. The latter component has not been stated in the standard, which seems important to be added.

- In the last bullet, the definition/mean of plain fermented milk is not precisely clear. It seems requiring more consideration.

1.3. Section 3.3: Composition

- In many drinks based on fermented milks (as has been previously stated by IDF), including Iranian yogurt drink (Doogh), the minimum milk protein amount is much lower than the provision of 2.7%. For example, in Doogh, The minimum level of protein content is about 0.8% (overestimating, about 1%) according to Iranian national standard. Also, the viable counts of starter microorganisms might fall below the amounts specified in CODEX STAN 243-2003 due to low pH values of product and relatively high storage period. In Probiotic products, meeting this provision in such acidic products is almost impossible. Therefore, the mentioned minimum levels require precise amendments after careful considerations and even local investigations.

* A general comment

- Because of coronary heart diseases issue, partial replacement of milk fat with vegetable oils provides a good possible care and is justifiable, as might be regular in some countries. However, according to composite milk product definition (CODEX STAN 206-1999), the constituents not derived from milk would not be intended to take the place in part or in whole of any milk constituents. Considering drinks based on fermented milks are composite milks (CODEX STAN 243-2003; drinks based on fermented milks), this dietary replacement would be banned. I think this subject at least needs more consideration and discussion among the delegations.

JAPAN

We would like to support the adoption of the proposed draft amendment with “40%” at Step 5, because it fully reflects the characteristics of the drinks based on fermented milk on the market. Variety of drinks based on fermented milk which contain a minimum of 40% of fermented milk have been on the world market for a long time, and those products value have been well recognized.

LIBYAN ARAB JAMAHIRIYA

All food additives listed under sections Emulsifiers, Flavour Enhancer and Stabilizers and Thickeners of the ALINORM 08/31/11 Appendix VI should be halal or from plant origin and should be declared on the label according to Codex General Guidelines for the Use of the Term “HALAL” CAC/GL 24-1997.

MALAYSIA

Malaysia supports the adoption of the Proposed draft Amendment to the Codex *Standard for Fermented Milks* (CODEX STAN 243-2003) pertaining to Drinks based on Fermented Milk at Step 5 by the 31st Session of the Codex Alimentarius Commission. Malaysia is of the view that the proposed minimum content of fermented milk be discussed by the 9th Session of the Codex Committee on Milk and Milk Products for further progress of this work, and the proposed draft amendment to be adopted at Step 8 by the 33rd Session of the Codex Alimentarius Commission in 2010.

PERU

Sobre el capítulo 4 Aditivos Alimentarios, en lo que preservantes se refiere, el Codex estima que no está tecnológicamente justificado el uso de preservantes. Al respecto, se consultó a expertos en la materia, como resultado concluyó que se puede permitir el uso de preservantes en leches fermentadas, bebidas basadas en leches fermentadas y en aquellas tratadas térmicamente. Tal es así que en el Perú como en la mayoría de países en vías de desarrollo se viene utilizando preservantes autorizados por el Codex en alimentos desde hace mucho tiempo para los mencionados productos, dado que se tienen serias dificultades en el mantenimiento de la cadena de frío.

Concientes de que estos productos son una fuente importante de calcio y nutrientes en general, quizá más importante que su uso como alimento reparador de la flora intestinal, se recomienda permitir el uso de preservantes, en niveles que no oculten buenas prácticas de manufactura, lo cual es perfectamente factible.

En los demás puntos descritos en la enmienda, expresamos nuestra conformidad.

UNITED STATES OF AMERICA

The United States strongly supports the adoption of the Proposed Draft Amendment to the Codex Standard for Fermented Milk Pertaining to Drinks at Step 5 by the Codex Alimentarius Commission.

URUGUAY

3) Propuesta de enmienda “la Norma del Codex para Leches fermentadas “(CODEX STAN 243-2003) para la incorporación de Bebidas a base de leche fermentadas renombradas por el Comité (ver para. 48 y Apéndice IV)

Comentarios: El Subcomité de Leche y Productos Lácteos de Uruguay está de acuerdo con lo recomendado. Cualquier cambio o enmienda debería ser discutida nuevamente.

Se hace especial énfasis en la Sección 2.4 de Bebidas a base de Leches Fermentadas que se apoya que estas presentan un contenido mínimo del 50% (m/m) de leche fermentada para cumplir con la definición de leche compuesta, según lo especifica la Norma General para el Uso de Términos Lecheros (CODEX STAN 206-1999) y para asegurar que el contenido principal sea la leche fermentada. El comité noto que se hay varias interpretaciones de la definición.

Por tal motivo, apoya que siga entre corchetes el contenido mínimo de leches fermentadas en la Sección 2.4 de Bebidas a base de leche fermentada, tal cual esta en el Apéndice IV, y ser nuevamente discutido en la novena reunión del Comité de Leche y Productos Lácteos.

**CODEX COMMITTEE ON NUTRITION AND FOOD FOR SPECIAL DIETARY USES
COMITÉ DU CODEX SUR LA NUTRITION ET
LES ALIMENTS DIÉTÉTIQUES OU DE RÉGIME
COMITÉ DEL CODEX SOBRE NUTICIÓN Y
ALIMENTOS PARA REGÍMENES ESPECIALES (CCNFSDU)**

Proposed Draft Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses (ALINORM 08/31/26 para. 121 and Appendix VI).

BRAZIL**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.

GUATEMALA

Comentarios Guatemala			Justificación
Página	Texto original	Modificaciones	
77	[Principios de análisis de riesgos nutricionales y directrices para su aplicación en la labor del Comité sobre Nutrición y Alimentos para Regímenes Especiales]	Eliminar corchetes y aprobar texto.	Determina título y descripción del contenido del documento.
77 Pie de página 2	[Una sustancia afín es un constituyente inherente de los alimentos (distinto de un nutriente) que tiene un [posible] efecto nutricional o fisiológico.	Eliminar corchetes y aprobar texto.	Define lo que es una sustancia afín.
77 Pie de página 2	[posible]	Eliminar corchetes y aprobar texto.	No todas las sustancias afines tienen un efecto nutricional o fisiológico.
78 Punto 5	[y órganos expertos]	Eliminar texto.	Se encuentra implícito que las consultas conjuntas de expertos pueden ser órganos de expertos también.
78 Punto 6	[Los principios de análisis de riesgos nutricionales se han establecido para orientar...]	Eliminar corchetes y aprobar texto.	Determina y aclara el alcance del documento.
78 Punto 7	[una forma de]	Eliminar texto.	Para una correcta redacción.
78 Punto 8	[y se caracterizan como sigue...]	Eliminar corchetes y aprobar texto.	Determina las características de los constituyentes alimentarios más importantes para el análisis de riesgo nutricional, ya sean nutrientes o sustancias afines.
		Eliminar la palabra sigue: [y se caracterizan como...]	Para una traducción más concreta de la versión en inglés.

Comentarios Guatemala			Justificación
Página	Texto original	Modificaciones	
78 Punto 8	[nutrientes que aumentan el riesgo de efectos nocivos para la salud que existen...]	Eliminar texto.	Las características se describen en los dos puntos anteriores, por lo que no es necesario éste último.
81 Punto 24	Las normas de referencia sobre nutrientes que se pueden aplicar para caracterizar los peligros asociados a los nutrientes provocados por una ingesta excesiva incluyen las ingestas máximas.	Las normas de referencia sobre nutrientes que se pueden aplicar para caracterizar los peligros asociados a los nutrientes provocados por una ingesta excesiva incluyen <u>niveles superiores de ingesta</u> .	Para una traducción más concreta de la versión en inglés.
	La FAO y la OMS han publicado algunas normas de referencia de aplicación mundial relativas a las ingestas máximas.	La FAO y la OMS han publicado algunas normas de referencia de aplicación mundial relativas a <u>niveles superiores de ingesta</u> .	Para una traducción más concreta de la versión en inglés.
	Además, en el futuro se podrá considerar el establecimiento de ingestas máximas e ingestas máximas observadas a nivel internacional que complementen las recomendaciones existentes.	Además, en el futuro se podrá considerar el establecimiento de <u>niveles superiores de ingesta y nivel máximo de ingesta</u> observadas a nivel internacional que complementen las recomendaciones existentes.	Para una traducción más concreta de la versión en inglés.
82 Punto 27	[También puede tener en cuenta la biodisponibilidad y estabilidad de los nutrientes y sustancias afines en los alimentos consumidos].	Eliminar corchetes y aprobar texto.	Los riesgos también pueden estar asociados a la biodisponibilidad y estabilidad.
82 Punto 29	[En la adopción de decisiones sobre gestión de riesgos nutricionales debería tenerse en cuenta el efecto real...].	Eliminar corchetes y aprobar texto.	La información tiene relevancia como complemento del texto anterior.
82 Punto 32	Sin embargo, ello no excluye la elección de otras fuentes de asesoramiento, como organizaciones o grupos de expertos internacionales apropiados [o expertos nacionales pertinentes], cuando ello esté justificado.	Eliminar la palabra aprobados, eliminar corchetes y aprobar texto. Sin embargo, ello no excluye la elección de otras fuentes de asesoramiento, como organizaciones o grupos de <u>expertos internacionales o expertos nacionales pertinentes</u> , cuando ello esté justificado.	Para una traducción más concreta de la versión en inglés. Determina el asesoramiento de expertos nacionales también.
83 Punto 34	[buenas prácticas de reglamentación]	Eliminar corchetes y aprobar texto. Eliminar la palabra reglamentación y cambiarla por regulación: <u>buenas prácticas de regulación</u>	La palabra regulación es más apropiada en este caso, ya que determina las reglas o normas a que debe ajustarse alguien o algo.

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 of 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.

UNITED STATES OF AMERICA

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.

COUNCIL FOR RESPONSIBLE NUTRITION (CRN)

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.

INTERNATIONAL DAIRY FEDERATION (IDF)

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 CCNFSDU

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

NATIONAL HEALTH FEDERATION (NHF)

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 direction 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 nutrients² and related substances³ 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 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.
4. The [*Nutritional Risk Analysis Principles for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses // Application of Risk Analysis Principles by the Committee on Nutrition and Foods for Special Dietary Uses OR Principles for Nutritional Risk Analysis for Application in the Framework of the Codex Alimentarius*] presented in this document (hereafter cited as “Nutritional 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 activity.
6. 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 including, but not limited to, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) are acknowledged as a primary source of nutritional risk assessment advice to Codex Alimentarius. This role however, does not preclude the choice of alternative sources of scientific advice such as appropriate international expert groups or organizations if and when justified.

SECTION 3 – SCOPE AND APPLICATION

7. The Nutritional 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.

² 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.

³ A related substance is an inherent constituent of food (other than a nutrient) that has a potentially favorable impact on health.

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 risk from proposed management strategies. In situations that address inadequate intakes, such a reduction in risk might be referred to as a nutritional benefit.
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 that may reduce the risk of inadequacy (e.g. vitamins, minerals, amino acids, essential fatty acids, plant extracts, probiotics) and those that may increase the risk of adverse health effects (e.g. trans fatty acids and some vitamins at excessive intake); or
 - related substances² (e.g. some non-vitamin A carotenoids [comment: this is not a good example as non-vitamin A [pro-vitamin A substances such as beta-carotene are clearly 'nutrients'. A better example of a 'related substance' might be fibre or silver, where the nutritional status has not been agreed by authoritative bodies]) that may increase the risk of adverse health effects at excessive intake and may also reduce the risk of other adverse health effects at low intake.
10. Other food constituents of interest in nutritional risk analysis include:
 - nutrients that increase the risk of adverse health effects (e.g. saturated fatty acids) and that coexist in a food matrix with a nutrient(s) or related substance(s) of primary interest associated with reduction of the risk of inadequacy or adverse health effects at low intake;
 - [nutrients that increase the risk of adverse health effects in a food potentially eligible to carry a health claim].
11. 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 (e.g. minimum and/or maximum levels of nutrients and optional ingredients in infant formula).
12. 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 potentially eligible to bear a health claim];
 - managing risks by labelling advice in relation to consumption of foods of certain nutrient-related⁴ 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).
13. Nutritional risk analysis does not apply to consideration of traditional food safety risks in the context of assessing food additives, chemical residues, microbiological pathogens, contaminants or allergens, including when the food constituent could be also regarded as a nutrient or related substance. It also does not apply to the general aspects of food labelling that manage risks related to a food's storage, preparation and use.

SECTION 4 – DEFINITIONS

14. 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.

⁴ 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.

15. 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 probability of an adverse health effect associated with inadequate or excessive intake of a nutrient or related substance and the severity of that effect, consequential to a nutrient-related hazard(s) in food.

Adverse health effect⁵ – A change in the morphology, physiology, growth, development, reproduction or life span of an organism, system, or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences.

Nutrient-related hazard³ – A nutrient or related substance in food that has the potential to cause an adverse health effect depending on inadequate or excessive level of intake.

Nutrient-related hazard identification – The identification of a nutrient-related hazard in a particular food or group of foods.

Nutrient-related hazard characterization – The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with a nutrient-related hazard.

Dose response assessment – The 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 associated adverse health effects (i.e. response).

Upper level of intake⁴ – the maximum level of intake from all sources of a nutrient or related substance judged to be unlikely to lead to adverse health effects in a given population or sub-population of humans.

[The word “habitual” should be deleted because from a regulatory perspective the word “habitual” has no meaning as it is an imprecise term that does not describe a quantitative amount. Given that the CCNFSDU has decided that upper limits will be based on scientific risk assessment, any reference in the definitions to words such as “habitual” or “quantities” are therefore both unnecessary and inappropriate, because upper limits will be specified separately for each nutrient.]

Highest observed intake⁴ – 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.

Intake (Exposure) assessment – The qualitative and/or quantitative evaluation of the actual or likely intake in a given population or sub-population of a nutrient or related substance from food as well as intake from other relevant sources such as food supplements.

Nutrient-related risk characterization – The qualitative and/or quantitative attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on nutrient-related hazard identification, nutrient-related hazard characterization and intake assessment.

Bioavailability⁶ – The proportion of the ingested nutrient or related substance that is absorbed and utilised through normal metabolic pathways. Bioavailability is influenced by dietary factors such as chemical form, interactions with other nutrients and food components, and food processing/preparation; and host-related intestinal and systemic factors. It is normally established through human studies or in relevant animal models.

Homeostatic mechanism⁴ – A mechanism effected through a system of controls activated by negative feedback that allow the maintenance of normal body functions in the presence of a variable nutrition environment.

SECTION 5 – PRINCIPLES FOR NUTRITIONAL RISK ANALYSIS

16. These Nutritional Principles build on and respect the Codex Working Principles.

⁵ *A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances*. Report of a joint FAO/WHO technical workshop 2005, WHO, 2006.

⁶ 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.

17. 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.

PRELIMINARY NUTRITIONAL RISK MANAGEMENT ACTIVITIES

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

Nutritional Problem Formulation⁴

19. 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.

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

- the priority it should be accorded;
- whether the risk is equivalent for, or varies between, different forms or species of a given nutrient;
- the many years of safe use by virtue of the nutrient form's presence in foods and/or food supplements consumed by humans
- 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.

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

- a detailed inventory of prior knowledge, including but not limited to the different nutrient forms and species as well as the length of time of their consumption by humans;
- identification of the (sub)populations 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 considered.

NUTRITIONAL RISK ASSESSMENT

22. The Codex *Working Principles for Risk Assessment* are 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

23. 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 (sub)population-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.
24. 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.
25. Nutrient-related hazard identification and characterization should recognize current methodological differences in assessment of nutritional risk of inadequate and excessive intakes, scientific advances in these methodologies, and identification of nutrients where hazards vary significantly between different chemical forms.
26. 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 of different chemical forms of nutrients and bioavailability including factors affecting the bioavailability of nutrients and related substances such as different chemical forms.
27. 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. If appropriate FAO/WHO standards are not available, appropriate international Pharmacopoeias or recognized international standards should be taken into account.
28. 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 upper⁴ 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 but these may not be relevant to all populations and geographic regions.
29. 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 bases for their derivation should be considered.

Nutrient-Related Intake Assessment and Risk Characterization

30. These two steps are generally specific to the (sub)population(s) under consideration for risk assessment. The populations relevant to Codex consideration are populations at large in Codex member countries or particular subpopulation groups in these countries defined according to physiological parameters such as age, gender, life stage or state of health.
31. Nutrient-related intake assessment should consider the composition and types of foods and relevant food supplements⁷ consumed by the target population(s). It may also take into account, the bioavailability of nutrients (and their distinct chemical forms where variations in risk are known to occur) and related substances in the foods consumed.

⁷ Codex *Guidelines for Vitamin and Mineral Food Supplements* (CAC/GL 55 – 2005) define food supplements as sources in concentrated forms of those nutrients or related substances alone or in combinations, marketed in forms such as capsules, tablets, powders solutions, etc., that are designed to be taken in measured small unit quantities but are not in

32. Nutrient-related intake assessment and risk characterization should be applied within a total diet context. Where feasible, it would typically involve the evaluation of the distribution of habitual total daily intakes for the target population(s). This approach recognizes that nutrient-related risks are often associated with total intakes from multiple dietary sources, including fortified foods, food supplements, and in the case of certain minerals, water.
33. RECOMMEND DELETION OF THIS BRACKETED PARAGRAPH AS IT IS IN THE VIEW OF THE NHF NOT RELEVANT TO THE REQUIREMENTS FOR NUTRIENT RISK ANALYSIS. Recommend insertion of NEW 33 as follows: Nutrient-related risk characterization should take into account the totality of available evidence, including but not limited to existing data from the peer-reviewed literature, relevant reports and medical records which confirms the safety of given higher levels of intake. Such an approach serves to test the validity of the risk characterization model used by comparison with known safe exposures to humans. It thus prevents inclusion of excessive safety margins which may lead to the imposition of overly stringent maximum safe levels that may otherwise give rise to additional risks of inadequate intake if risk management policies are based on these levels.
34. 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, it may be 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

NUTRITIONAL RISK MANAGEMENT

35. The Codex *Working Principles for Risk Management* are generally applicable to nutritional risk management. Additional nutritional risk management principles to consider within the Codex framework are identified below.
36. Nutritional risk management can be effected through quantitative measures or qualitative guidance elaborated in Codex texts or in relevant peer-reviewed journals. 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.
37. 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

38. The Codex *Working Principles for Risk Communication* are generally applicable to nutritional risk communication.

SECTION 6 – SELECTION OF RISK ASSESSOR

39. Consistent with their important role in providing scientific advice to Codex Alimentarius and its subsidiary bodies, FAO and WHO are acknowledged as a 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 if and when justified.
40. All requests for risk assessment advice should be accompanied by terms of reference and where appropriate risk assessment policy to provide guidance to the risk assessor. These parameters should be established by the relevant Codex subsidiary body.

SECTION 7 – REVIEW PROCESS

41. These Nutritional Principles should be reviewed by CCFNSDU 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.

a conventional food form and whose purpose is to supplement the intake of nutrients or related substances from the diet.

⁷ 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.

**CODEX COMMITTEE ON PESTICIDE RESIDUES IN FOODS
COMITÉ DU CODEX SUR LES RÉSIDUS DE PESTICIDES
COMITÉ DEL CODEX SOBRE RESIDUOS DE PLAGUICIDAS (CCPR)**

Proposed Draft Maximum Residue Limits at Step 5 (ALINORM 08/31/24, APPENDIX IV)

AUSTRALIA

Australia supports the adoption of the proposed draft MRLs listed in Appendix IV at Step 5.