

# CODEX ALIMENTARIUS COMMISSION



**Food and Agriculture  
Organization of  
the United Nations**



**World Health  
Organization**

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**Agenda Item 5**

**CX/NFSDU 10/32/5 -Add.1  
October 2010**

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

### **CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES**

**32<sup>nd</sup> Session**

**Santiago, Chile**

**1 – 6 November 2010**

#### **PROPOSED DRAFT REVISION OF THE CODEX GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS (CAC/GL 9-1987)**

**Comments from:**

**Brazil, Chile, EU, Thailand**

**BRAZIL**

Brazil thanks for the opportunity to present the following comments on the Draft Revised General Principles for the Addition of Essential Nutrients to Foods.

**INTRODUCTION**

The *[General Principles] [Guidelines] for the Addition of Essential Nutrients to Foods* are intended to:

**Brazilian Comments**

We reaffirm our previous comment that the use of the term “Guidelines” is better than “General Principles” as it is in line with other Codex standards, like the Guidelines for Vitamin and Mineral Supplements.

- Provide guidance to those responsible for developing guidelines and legal texts pertaining to the addition of essential nutrients to foods [through the establishment of a set of principles].
- [Establish a uniform set of principles for the rational addition of essential nutrients to foods.]

**Brazilian Comments**

We suggest to maintain both bullets separately for greater clarity to the text. Thus, we suggest to delete the sentence “through the establishment of a set of principles” and to maintain the sentence “Establish a uniform set of principles for the rational addition of essential nutrients to foods”.

[• [To allow a wider choice of fortified foods] [to contribute to the improvement of health and/or the nutritional status of the population or specific population groups.]

**Brazilian Comments**

We agree to remove the square brackets from the sentences “To allow a wider choice of fortified foods” and “to contribute to the improvement of health and/or the nutritional status of the population or specific population groups”. The addition of the second sentence clarifies the purpose of allowing a wider choice of fortified foods.

[The *General Principles for the Addition of Essential Nutrients to Foods* aim at providing a framework for the addition of essential nutrients to foods for the purpose of:

- correcting a demonstrated deficiency of one or more essential nutrients in the population or specific population groups;
- contributing to meeting requirements of one or more essential nutrients and reducing the risk of their deficiency;
- contributing to the improvement of health and/or nutritional status of the population or specific population groups.]

**Brazilian Comments**

We reaffirm our agreement for the text proposed. Nevertheless, we suggest to include a new bullet related to the prevention of the indiscriminate addition of essential nutrients, as proposed below:

- *“contributing to prevent the indiscriminate addition of essential nutrients to foods thereby decreasing the risk of health hazard due to essential nutrient excesses, deficits or imbalances.”*

[The [General Principles] [Guidelines] for the Addition of Essential Nutrients to Foods [take into consideration] [are consistent and used in conjunction with] the Codex Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses (CAC Procedural Manual.

### **Brazilian Comments**

We reaffirm our previous comment that it is more appropriate to use the text “are consistent and used in conjunction with”, as this document shall be consistent with the document “Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses, Procedural Manual, Nineteenth edition.”

## **2. DESCRIPTION [DEFINITIONS]**

~~[Definitions]~~

### **Brazilian Comments**

We reaffirm our agreement for the use of the term “Definitions”.

For the purpose of these [principles] [guidelines]:

**2.2 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. [Essential nutrient includes but is not limited to vitamins and mineral nutrients.]

### **Brazilian Comments**

We agree to include the sentence “Essential nutrient includes but is not limited to vitamins and mineral nutrients”.

**2.5 Fortification [~~or enrichment~~] [which may be called enrichment]** means the addition, of one or more essential nutrients to a food, whether or not it is normally contained in the food, [for the purpose of reducing risk of inadequate intakes], including preventing or correcting a demonstrated deficiency [or a potential deficiency] of one or more nutrients in the population or specific population group(s). [Fortification may be mandatory or voluntary.]

### **Brazilian Comments**

We reaffirm our previous comment to remove the square brackets from the sentences “which may be called enrichment”, “for the purpose of reducing risk of inadequate intakes”, “or a potential deficiency” and “Fortification may be mandatory or voluntary”.

**2.7 Special purpose foods** are foods that have been designed to perform a specific function, such as to replace a meal which necessitates a content of essential nutrients which cannot be achieved except by addition, direct or indirect, of one or more of these nutrients. These foods include but are not limited to foods for special dietary use, [and also include foods intended for infants and young children].

### **Brazilian Comments**

We agree to remove the square brackets from the sentence “and also include foods intended for infants and young children”.

**[2.9 Standardization** means the addition of nutrients to a food in order to compensate for natural variations in nutrient level, [e.g., seasonal variation in nutrient content.]

**Brazilian Comments**

We reaffirm our previous comment that we agree with the item 2.9, but we understand that the inclusion of examples in definitions is not appropriate.

**3. BASIC PRINCIPLES**

~~{3.1 Essential nutrients may be added, to foods for the purpose of:~~

~~3.1.1 restoration;~~

~~3.1.2 nutritional equivalence of substitute foods;~~

~~3.1.3 fortification [or enrichment];~~

~~3.1.4 ensuring the appropriate nutrient composition of a special purpose food;,-~~

~~{3.1.5 to allow a wider choice of fortified foods}~~

[3.1 Essential nutrients may be added to foods for the purpose of restoration, nutritional equivalence of substitute foods, fortification and ensuring the appropriate nutrient composition of a special purpose food. The following basic principles are generally applicable to both mandatory and voluntary fortification.]

**Brazilian Comments**

We agree to remove the square brackets from the item 3.1.

**3.2 (modified 6.1) Fortification** The mandatory and voluntary addition of essential nutrients to foods should be the responsibility of in accordance with food law and other policies established by national authorities since and take into account the kinds and amounts of essential nutrients to be added, and foods to be fortified, will depend upon the particular nutritional problems to be corrected, the characteristics of the target populations, and the food consumption patterns of the area.

**Brazilian Comments**

We agree with the new text proposed for item 3.2.

**3.2.1 (New)** [Mandatory nutrient addition occurs when governments require food manufacturers to add specified essential nutrients to particular foods or categories of foods.]

**3.2.2 (New)** [Voluntary nutrient addition is when a food manufacturer chooses to add specified nutrients to particular foods or food categories.]

**Brazilian Comments**

We agree with the new texts proposed for items 3.2.1 and 3.2.2.

**3.3 (Former 3.2)** The [addition of an] essential nutrient should be [scientifically and nutritionally justified and be] present at a level which will not result in either an excessive or an insignificant intake of the added essential nutrient, considering amounts from other sources in the diet. [Upper levels of intake based on scientific risk assessment may be used to identify the need for any restrictions on the types of foods to be fortified.]

**Brazilian Comments**

We agree to remove the square brackets from the item 3.3.

**3.5** (new) [The sources of the essential nutrient may be either natural or synthetic and their selection should be based on considerations such as safety and bioavailability. In addition, purity criteria should take into account FAO/WHO standards, or if FAO/WHO standards are not available, international Pharmacopoeias or recognized international standards. In the absence of criteria from these sources, national legislation may be used.]

#### **Brazilian Comments**

We agree to remove the square brackets from the item 3.5.

**3.6** (Former 3.4) The essential nutrient should be sufficiently stable in the food under customary conditions of packaging, storage, distribution and use.

#### **Brazilian Comments**

We agree with the item 3.6.

**3.8** (Former 3.6) The essential nutrient should not impart undesirable characteristics to the food (e.g. colour, taste, flavour, texture, cooking properties) and should not unduly shorten shelf-life.

#### **Brazilian Comments**

In relation to the item 3.8, we reaffirm our previous comment and suggest to remove the phrase “and should not unduly shorten shelf-life”. We understand that to ensure the amount of some vitamins in the final product may be necessary to short the shelf-life, considering the instability of vitamins in some food matrix.

**3.10** (Former 3.8) Addition of essential nutrients to foods should not be used to mislead or deceive the consumer, [including by presentation or labelling practices], as to the nutritional merit [or the health benefit] of the food.

#### **Brazilian Comments**

We agree to remove the square brackets and with the new text proposed for the item 3.10.

[3.13 Monitoring total intakes of the added nutrients in population(s) by national authorities is essential particularly to assess the extent to which public health needs are being addressed and to ensure that a risk of excessive intakes is absent.]

OR

[3.13 National authorities should give highest priority to monitoring total nutrient intakes and the relative contributions from all dietary sources for those nutrients that are most likely to pose a risk of inadequate or excessive intakes for the population(s).]

#### **Brazilian Comments**

We agree with the second proposal of the item 3.13, because we understand that it is more feasible.

## **4. [NUTRIENT] ADDITION [OF ESSENTIAL NUTRIENTS] FOR PURPOSES OF RESTORATION**

**4.1** Where the food has been identified as a significant [contributor to intake source] of energy and/or essential nutrients in the [population group(s) food supply], and particularly where there is demonstrated evidence of public health need, restoration of the essential nutrients of concern lost during processing, storage or handling should be strongly recommended.

**4.2** A food should be considered a significant [contributor to intake source] of an essential nutrient if the edible portion of the food prior to processing, storage or handling contains the essential nutrient in amounts equal to or greater than 10% of the recommended nutrient intake [or INL<sub>98</sub>] in a reasonable daily intake [of the food] (or in the case of an essential nutrient for which there is no recommended intake, 10% of the average daily intake [of the nutrient]).

### **Brazilian Comments**

We suggest to delete the square brackets from “OF ESSENTIAL NUTRIENTS” to be consistent with the scope and title of the document.

We suggest to use the terms “source” and “food supply”, considering that the purpose is to restore lost of nutrients during processing, storage or handling of the food and not only handle public health concerns.

We’d also like to ask for clarifications of the rationale for the limit of 10% of the recommended nutrient intake in a reasonable daily intake of the food (or in the case of an essential nutrient for which there is no recommended intake, 10% of the average daily intake of the nutrient) set in the item 4.2. We point out that the Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) sets conditions for foods to bear nutrition claims of source and high content of nutrients.

## **5. [NUTRIENT] ADDITION [OF ESSENTIAL NUTRIENTS] FOR PURPOSES OF NUTRITIONAL EQUIVALENCE**

**5.1** Where a substitute food is intended to replace a food which has been identified as a significant [contributor to intake source] of energy and/or essential nutrients in the [population group(s) food supply], and particularly where there is demonstrated evidence of public health need, nutritional equivalence in terms of the essential nutrients of concern should be strongly recommended.

**5.2** A food being substituted or partially substituted should be considered a significant [contributor source] of an essential nutrient if a serving or portion or 100 kcal of the food contains the essential nutrient in amounts equal to or greater than 5% [or INL<sub>98</sub>] of the recommended nutrient intake.

### **Brazilian Comments**

We suggest to delete the square brackets from “OF ESSENTIAL NUTRIENTS” to be consistent with the scope and title of the document.

We ask for clarifications about the references used to set the criteria proposed in item 5.2, particularly the limit of 5% of the recommended nutrient intake per serving or portion or 100 kcal of the food to consider a food as a significant contributor of an essential nutrient. We point out that the Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) sets conditions for foods to bear nutrition claims of source and high content of nutrients.

**5.3** Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this nutrient need not be equivalent.

## **6. NUTRIENT ADDITION FOR PURPOSES OF FORTIFICATION**

6.1.1 (*former 6.2.1*) There should be a demonstrated [public health] need for increasing the intake of an essential nutrient in one or more population groups [through fortification]. This need may be demonstrated by ~~may be in the form of~~ actual clinical or subclinical evidence of deficiency, estimates indicating ~~low~~ inadequate or potentially inadequate levels of intake of nutrients or possible deficiencies likely to develop because of changes taking place in food habits. Mandatory fortification is appropriate in

addressing serious public health needs such as clinical deficiency whereas voluntary fortification may be appropriate in addressing lower order risk of inadequate nutrient intakes.

**Brazilian Comments**

We suggest to delete the sentence “such as clinical deficiency” from the last sentence, because subclinical evidence of deficiency may also be considered relevant by the national authorities to require food manufacturers to add specified essential nutrients to particular foods or categories of foods.

We suggest to delete the square brackets from “public health”.

6.1.4 (*former 6.2.4*) The amount of the essential nutrient added to the food, should be sufficient to [address the public health need] [correct or prevent the deficiency] when the food is consumed in normal amounts by the population at risk.

**Brazilian Comments**

We agree to delete the square brackets from the item 6.1.4.

6.1.5 (*former 6.2.5*) The amount of the essential nutrient added to a food, should not result in excessive [total] intakes [of the nutrient from the fortified food when combined with other dietary sources] [by individuals with a high intake of a fortified food].

**Brazilian Comments**

We agree to delete the square brackets from the item 6.1.5.

[6.1.6 (*former 3.7*) Technology and processing facilities should be available to permit the addition of the essential nutrient [to a food] in a satisfactory manner.]

**Brazilian Comments**

We agree to delete the square brackets from the item 6.1.6.

[6.1.7 (*former 3.9*) The additional cost [of mandatory addition of essential nutrients to foods] should be reasonable for the intended consumer.]

**Brazilian Comments**

We agree to delete the square brackets from the item 6.1.7.

[6.2 (6.3 in previous draft; this entire section is renumbered consequently) The following conditions should be fulfilled in the case of fortification programs that are voluntary:

6.2.1 Foods which may be fortified:

6.2.1.1 The intake of the food (s) which may be fortified should be stable and the lower and upper levels of intake should be known.

6.2.1.2 Certain foods should be excluded from voluntary fortification because of their ubiquity in the food supply and thus the potential for exposure to high intakes associated with a risk of adverse health effects.

**OR**

[6.2.1.2 Certain foods may not be appropriate for voluntary fortification, e.g., foods with the potential to result in exposure to high intakes associated with a risk of adverse health effects.]

**Brazilian Comments**

We agree with the first text proposed for the item 6.2.1.2, but we suggest to delete the sentence “their ubiquity in the food supply and thus”, because the main issue to be considered is the association between the high intakes and the risk of adverse health effects.

[6.2.1.3 Consideration should be given to the nutrient profile of the food before fortification to ensure that nutritionally appropriate foods are selected for fortification.]

[6.2.1.4 Foods with nutrient profiles associated with a risk of adverse health effects as a consequence of a high content of risk-increasing nutrients, as demonstrated by scientific evidence, should be excluded from fortification.]

[6.2.1.5 Essential nutrients should not be added to unprocessed foods, including, but not limited to, fruit, vegetables, meat, poultry and fish.]

[6.2.1.6 Essential nutrients should not be added to beverages containing more than 1.2% by volume of alcohol.]

### **Brazilian Comments**

We reaffirm our previous agreement for the new sentences proposed for the items 6.2.1.3 to 6.2.1.6, but we understand that the item 6.2.1.4 should also be considered in the mandatory fortification.

In relation to the item 6.3.1.6, we ask for clarifications about the criteria used to exclude only beverages containing more than 1,2% by volume of alcohol. According to Brazilian legislation, beverages containing more than 0,5% by volume of alcohol are considered alcoholic and the fortification of these beverages are not allowed.

#### 6.2.2 Selection of essential nutrients that may be added:

6.2.2.1 The severity of the adverse effect on which the Upper Intake Level (UL) is based should be reviewed by national authorities and should inform restrictions on essential nutrients permitted to be added to foods on a voluntary basis.

#### 6.2.3 Determination of amounts of essential nutrients that may be added:

6.2.3.1 Minimum and/or maximum limits on the addition of essential nutrients to foods may be established by national authorities based on information on the level to achieve a health benefit without the risk of resulting in an adverse effect on health or on the metabolism of any nutrient.

6.2.3.2 The amount of the essential nutrient added to the food, should be sufficient for the purpose of contributing to meeting requirements of one or more essential nutrients and reducing the risk of their deficiency when the food is consumed in normal amounts by the population.

6.2.3.3 The amount of the essential nutrient added to a food, should not result in excessive intakes by individuals with a potentially high intake of a fortified food.

6.2.3.4 Intake data and a careful modelling approach by national authorities should be used to provide evidence to ensure that the exposure to the essential nutrient in question is within the Upper Level of Intake where this is available.

6.2.3.5 The Upper Level of Intake should be used to assess exposure to excessive intakes and to estimate safe limits of addition for essential nutrients.

6.2.3.6 Where an Upper Level of Intake is not available, the scientific evidence to support the safe addition of an essential nutrient should include:



a) demonstration of an upper level or a range of intake that is unlikely to result in adverse health effects, and b) intake data and a careful modelling approach adopted by national authorities should be used to provide evidence to ensure that aggregate exposure to the essential nutrient in question is within acceptable limits.]

### **Brazilian Comments**

We agree to delete the square brackets from the items 6.2.2 to 6.2.3.6.

## **7. NUTRIENT ADDITION TO SPECIAL PURPOSE FOODS**

7.1 Nutrients may be added to special purpose foods, including foods for special dietary uses, to ensure an appropriate and adequate nutrient content [based on the principles in this guidance wherever applicable]. Where appropriate, such addition should be made with due regard to the nutrient density of such foods.

### **Brazilian Comments**

We agree to delete the square brackets from the item 7.1.

We suggest to use the term “essential nutrients” in the items 6 and 7 to be consistent with the title and scope of the document.

## **CHILE**

(IN ORIGINAL LANGUAGE)

<p>1. Pertinencia y actualidad. Evaluar si el texto propuesto aporta con medidas sanitarias orientadas a impactar sobre problema. El problema se presenta como perfil de riesgo en la introducción.</p>	<p>Este documento es pertinente, va con las políticas ministeriales, en términos de contar con principios para la adición de nutrientes a los alimentos, en términos de necesidades poblacionales, pone límites a los excesos y a los mínimos para comunicar la adición.</p> <p>Cuando contemos con la encuesta nacional de consumo alimentario podremos conocer más de nuestra realidad país y por ende aplicar estos principios a cabalidad, tanto en términos de promover como de limitar las adiciones.</p>
<p>Otro punto de vista, es realizar una estimación respecto si la norma mejorará o empeorará el flujo de intercambio internacional de este tipo de alimentos, en mediano y largo plazo.</p>	<p>La norma contribuye a regular la adición de nutrientes y sienta bases comunes lo que de todas maneras facilitará las decisiones nacionales y facilitará el entendimiento entre países para respetar diferencias, pero también para contar con factores científicos comunes al respecto.</p>
<p>2. Examinar si las medidas propuestas en el anteproyecto son factibles de aplicar por los países en desarrollo. La mirada puede hacerse desde el punto de vista de la complejidad técnica, de las</p>	<p>Es factible de implementar, en la medida que los Principios son orientaciones que deben ser adoptadas por los distintos gobiernos en la realidad local y considerando, primeramente, los estudios e información disponible de su población. Por otro lado hoy Chile está en condiciones de medir estos nutrientes y en colaboración con la industria puede acceder a la información de adición y de contenidos</p>

capacidades de laboratorio instaladas y del costo económico, entre otros aspectos.	finales.
3. Que no sea una repetición de otras normas ya existentes.	También se están desarrollando Principios Generales en términos de presencia de nutrientes críticos: una vez completados ambos, es posible que sea uno solo documento, quizás con dos partes.
4. En el caso que haya falencias, como ejemplo aspectos que faltan o existen, pero están insuficientemente tratados, proponer la forma cómo se podría mejorar o complementar con aportes nacionales y regionales.	No procede
5. Introducción	Concordamos con el concepto de principios, que es más amplio y no directrices que es más específico.
6. Objetivo y ámbito de aplicación	Proponemos eliminar de los objetivos la frase “para permitir que exista una mayor variedad de alimentos enriquecidos” dado que estos principios no pretenden estimular la adición ni fortificación voluntaria de alimentos. Preferimos que el propósito se redacte en forma punteada, ya que clarifica mejor su contenido. En el ámbito de aplicación estamos de acuerdo.
7. Definiciones	El concepto enriquecimiento y fortificación es lo mismo, por lo que sugerimos que dejar “enriquecimiento también denominado fortificación” y dejar el párrafo completo retirando corchetes dejando a las autoridades nacionales las políticas locales (aceptando el tercer párrafo 2.5). En densidad de nutrientes 2.8 corregir unidad de kilojoules. Aceptamos nuevo párrafo 3.3 para sustituir al 3.4, 3.5 y 3.7 referente a las fuentes de nutrientes en términos de seguridad y biodisponibilidad. Párrafo 6.2.1 en relación a demostrar la necesidad de incrementar la ingesta de nutrientes, optamos por dejar el primer párrafo que habla de pruebas clínicas o subclínicas, pero que no diferencia la adición voluntaria de la obligatoria, la que responde a decisiones y estudios nacionales. Párrafo 6.3.1.2 consideramos necesario dejar los dos párrafo alternativos en relación al listado de alimentos que no debieran ser fortificados, tanto por su ubicuidad en la cadena alimenticia como por sus características esenciales (golosinas).
<b>8. Propuesta de posición nacional</b>	Se apoya documento en su contenido general y en su fondo, pero sin ampliar el ámbito de aplicación, para evitar el exceso de alimentos

enriquecidos.
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## **EU**

The European Union (EU) would like to express its gratitude to Canada, Chile and New Zealand for preparing the proposed Draft revision of the Codex General Principles for the Addition of Essential Nutrients to Foods.

The EU still considers that the initiative of revising the General Principles creates an opportunity to review the totality of the document. Such a revision is important in the context of the socio-economic changes and the life styles of the population that have led to changes in the energy and nutrient requirements of various groups of the population and to intakes of certain vitamins and minerals for these groups that would be below those recommended. In addition, there has been considerable progress in scientific knowledge concerning intakes of some nutrients that are necessary for maintaining optimal health and well-being. In light of the above, the EU has the following general comments on the consultation document.

### **GENERAL COMMENTS**

#### **Introduction**

The EU welcomes the modifications to the overall structure of the document, in particular the laying down of general provisions stating the intentions of the General Principles in the Introduction. The EU welcomes the introduction of other general principles (such as the purpose of allowing a wider choice of fortified foods) in this introductory section.

The EU also welcomes the insertion of the reasons for the addition of essential nutrients to foods in the introductory section of the General Principles. In light of such a revision and additions to the introductory section, the EU considers that it is not necessary to maintain certain definitions (i.e. definitions of nutritional equivalence, substitute food, fortification, restoration, etc) and basic principles (i.e. restoration, nutritional equivalence of substitute food, etc) in the General Principles. The EU considers that a decrease in the number of definitions and basic principles would simplify and clarify the General Principles.

#### **Mandatory versus Voluntary Fortification**

The EU questions the necessity to specify that fortification may be mandatory or voluntary, and the need to set specific criteria and conditions to be fulfilled for mandatory and voluntary fortification. The EU considers that mandatory fortification should remain the responsibility of the national authorities as they are in the best position to address specific public health concerns at local level. The EU considers the General Principles should focus on voluntary fortification.

#### **Conditions for Voluntary Fortification**

The EU does not consider it necessary to define detailed conditions which should be fulfilled in the case of voluntary fortification or enrichment of foods.

The EU believes that specific provisions, such as those related to the selection of foods which may be fortified and essential nutrients which may be added should not be set at international level. These would be best determined, when necessary, at regional/national/local level taking into account dietary habits, socioeconomic situations and the need to avoid any risks to health.

Furthermore, the Codex Guidelines for Vitamin and Mineral Food Supplements (CAC/GL 55-2005) already provide for the basic principles of a risk-based approach to set minimum and maximum amounts of vitamins and minerals contained in food supplements. The EU considers that the same principles

should apply to foods to which essential nutrients have been added and does not consider it necessary to establish detailed criteria and conditions to be followed to determine amounts of essential nutrients that may be added to foods.

## **THAILAND**

### **TITLE:**

### **Comment**

To be consistent and in accordance with the contexts of the document that including principles and guidelines. We are of the opinions that the title of the document should be “General Principles and Guidelines”.

### **INTRODUCTION**

The ~~General Principles~~ and ~~Guidelines~~ for the Addition of Essential Nutrients to Foods are intended to:

- Provide guidance to those responsible for developing guidelines and legal texts pertaining to the addition of essential nutrients to foods ~~through the establishment of a set of principles~~.
- ~~Establish a uniform set of principles for the rational addition of essential nutrients to foods.~~
- Maintain or improve the overall nutritional quality of foods.
- Prevent the indiscriminate addition of essential nutrients to foods thereby decreasing the risk of health hazard due to essential nutrient excesses, deficits or imbalances. This will also help to prevent practices which may mislead or deceive the consumer.
- Facilitate acceptance in international trade of foods which contain added essential nutrients.
- [• ~~To allow a wider choice of fortified foods] [to contribute to the improvement of health and/or the nutritional status of the population or specific population groups.]~~

~~The~~ *General Principles and Guidelines for the Addition of Essential Nutrients to Foods* aim at providing a framework for the addition of essential nutrients to foods for the purpose of:

- correcting a demonstrated deficiency of one or more essential nutrients in the population or specific population groups;
- contributing to meeting requirements of one or more essential nutrients and reducing the risk of their deficiency;
- contributing to the improvement of health and/or nutritional status of the population or specific population groups.]

~~The~~ ~~General Principles~~ and ~~Guidelines~~ for the Addition of Essential Nutrients to Foods ~~take into consideration~~ are consistent and used in conjunction with the Codex Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses (CAC Procedural Manual).

### **Comment**

#### **- The first paragraph**

The second bullet should be deleted and replaced by an additional clause at the end of the 1<sup>st</sup> bullet.

- The sequence of the first and second paragraph should be reordered. Since, a format of the document should initial with purpose and principle respectively.
- The sixth bullet should be deleted, since it is replicated with the third bullet of the second paragraph.
- We agree in principle with the third paragraph according to the Codex Nutritional Risk Analysis Principles and Guidelines for the Work of the CCNFSDU as well as support the use of the text “are consistent and used in conjunction with”

## 1. SCOPE

These ~~principles~~ and ~~guidelines~~ are intended to apply to all foods to which essential nutrients are added, not including vitamin and mineral food supplements<sup>1</sup>.

## 2. ~~DEFINITIONS~~

For the purpose of these ~~principles~~ and ~~guidelines~~:

**2.2 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. ~~Essential\_nutrient~~ includes but is not limited to vitamins and mineral nutrients~~.~~

### Comment

We agree to remove a square bracket from this section.

**2.5 Fortification** ~~which may be called enrichment~~ means the addition, of one or more essential nutrients to a food, whether or not it is normally contained in the food, ~~for the purpose of reducing risk of inadequate intakes~~, including preventing or correcting a demonstrated deficiency ~~for a potential deficiency~~ of one or more nutrients in the population or specific population group(s). ~~Fortification may be mandatory or voluntary.~~

### Comment

- We agree to remove a square bracket from “which may be called enrichment” and “Fortification may be mandatory or voluntary”.
- We are of the opinions that the phrase “[for the purpose of reducing risk of inadequate intakes]” should be deleted, since it is already mentioned in introduction.
- Since, it is unnecessary to emphasize on deficiency, so we agree to delete the phrase “[or a potential deficiency]”.

**2.7 Special purpose foods** are foods that have been designed to perform a specific function, such as to replace a meal which necessitates a content of essential nutrients which cannot be achieved except by addition, direct or indirect, of one or more of these nutrients. These foods include but are not limited to foods for special dietary use, ~~and also include foods intended for infants and young children.~~

### Comment

Since a scope of the document applies to all food, therefore the phrase “[and also include foods intended for infants and young children].” should be deleted.

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<sup>1</sup> Codex Guidelines for Vitamin and Mineral Food Supplements (CAC/GL 55-2005)

~~2.9 Standardization means the addition of nutrients to a food in order to compensate for natural variations in nutrient level, [e.g., seasonal variation in nutrient content.]~~

**Comment**

We are of an opinion that a definition of “standardization” should be deleted, as it is unnecessary and there is no reference to this term in the document.

**3. BASIC PRINCIPLES**

~~3.1 Essential nutrients may be added to foods for the purpose of restoration, nutritional equivalence of substitute foods, fortification and ensuring the appropriate nutrient composition of a special purpose food. The following basic principles are generally applicable to both mandatory and voluntary fortification.~~

**Comment**

We agree to remove a square bracket from this section.

~~3.2.1 (New) Mandatory nutrient addition occurs when governments require food manufacturers to add specified essential nutrients to particular foods or categories of foods.~~

**Comment**

We agree to remove a square bracket from this section.

~~3.2.2 (New) Voluntary nutrient addition is when a food manufacturer chooses to add specified essential nutrients to particular foods or food categories.~~

**Comment**

- We agree to remove a square bracket from this section.

- To be consistent with section 3.2.1, we propose that the word “essential” should be added prior “nutrients”.

~~3.3 (Former 3.2) The addition of an essential nutrient should be scientifically and nutritionally justified and be present at a level which will not result in either an excessive or an insignificant intake of the added essential nutrient, considering amounts from other sources in the diet. Upper levels of intake based on scientific risk assessment may be used to identify the need for any restrictions on the types of foods to be fortified.~~

**Comment**

We agree to remove all square brackets from this section.

~~3.5 (new) The sources of the essential nutrient may be either natural or synthetic and their selection should be based on considerations such as safety and bioavailability. In addition, purity criteria should take into account FAO/WHO standards, or if FAO/WHO standards are not available, international Pharmacopoeias or recognized international standards. In the absence of criteria from these sources, national legislation may be used.~~

**Comment**

We agree to remove a square bracket from this section.

**3.10** (Former 3.8) Addition of essential nutrients to foods should not be used to mislead or deceive the consumer, ~~including by presentation or labelling practices,~~ as to the nutritional merit ~~for the health benefit~~ of the food.

**Comment**

We agree that a square bracket should be removed from “including by presentation or labelling practices” and “or the health benefit”.

~~{3.9 The additional cost of addition [of essential nutrients to foods] should be reasonable for the intended consumer.}~~ applicable to mandatory fortification; moved to section 6.21 as 6.21.7

~~**3.13** Monitoring total intakes of the added nutrients in population(s) by national authorities is essential particularly to assess the extent to which public health needs are being addressed and to ensure that a risk of excessive intakes is absent.~~

OR

~~**3.13** National authorities should give highest priority to monitoring total nutrient intakes and the relative contributions from all dietary sources for those nutrients that are most likely to pose a risk of inadequate or excessive intakes for the population(s).~~

**Comment**

We are of the opinions that Option 1 should be retained, as it is more specific and practical, meanwhile, option 2 would be impractical in many cases.

**4. ~~[NUTRIENT]~~ ADDITION ~~[OF ESSENTIAL NUTRIENTS]~~ FOR PURPOSES OF RESTORATION**

**Comment**

We agree that the title should be “ADDITION OF ESSENTIAL NUTRIENTS FOR PURPOSES OF RESTORATION”

**4.1** Where the food has been identified as a significant ~~contributor to intake~~ of energy and/or essential nutrients in the ~~population group(s)~~, and particularly where there is demonstrated evidence of public health need, restoration of the essential nutrients of concern lost during processing, storage or handling should be strongly recommended.

**4.2** A food should be considered a significant ~~contributor to intake~~ of an essential nutrient if the edible portion of the food prior to processing, storage or handling contains the essential nutrient in amounts equal to or greater than 10% of the recommended nutrient intake ~~or NRVs~~ ~~for INL<sub>95</sub>~~ in a reasonable daily intake ~~of the food~~ (or in the case of an essential nutrient for which there is no recommended intake, 10% of the average daily intake ~~of the nutrient~~).

**Comment**

- The square brackets should be deleted from 4.1 and 4.2 .

- To be consistent with current situations and works of CCNFSDU in establishing NRVs for vitamin and mineral and NRVs-NCD, we agree to add “NRVs” after “recommended nutrient intake”. The phrase would then read: “recommended nutrient intake or NRVs”.

## 5. ~~NUTRIENT~~ ADDITION ~~OF ESSENTIAL NUTRIENTS~~ FOR PURPOSES OF NUTRITIONAL EQUIVALENCE

5.1 Where a substitute food is intended to replace a food which has been identified as a significant contributor to intake of energy and/or essential nutrients in the population group(s), and particularly where there is demonstrated evidence of public health need, nutritional equivalence in terms of the essential nutrients of concern should be strongly recommended.

5.2 A food being substituted or partially substituted should be considered a significant contributor of an essential nutrient if a serving or portion or 100 kcal of the food contains the essential nutrient in amounts equal to or greater than 5% ~~or NRVs for INL<sub>95</sub>~~ of the recommended nutrient intake.

### Comment

- The square brackets should be deleted from 5.1 and 5.2.
- To be consistent with current situations and works of CCNFSDU in establishing NRVs for vitamin and mineral and NRVs-NCD, we agree to add “NRVs” after “recommended nutrient intake”. The phrase would then read: “recommended nutrient intake or NRVs”

## 6. ~~NUTRIENT~~ ADDITION OF ESSENTIAL NUTRIENTS FOR PURPOSES OF FORTIFICATION

~~6.1 [move to section 3.2] Mandatory fortification should be the responsibility of national authorities since the kinds and amounts of essential nutrients to be added, and foods to be fortified, will depend upon the particular nutritional problems to be corrected, the characteristics of the target populations, and the food consumption patterns of the area.]~~

6.1 (former 6.2) The following conditions should be fulfilled [when fortifying foods][for any fortification programme]:

### Comment

We agree to remove a square bracket from “when fortifying foods”.

~~6.2.1 There should be a demonstrated need for increasing the intake of an essential nutrient in one or more population groups. This may be in the form of actual clinical or subclinical evidence of deficiency, estimates indicating low levels of intake of nutrients or possible deficiencies likely to develop because of changes taking place in food habits.~~

6.1.1 (former 6.2.1) There should be a demonstrated public health need for increasing the intake of an essential nutrient in one or more population groups through fortification. This need may be demonstrated by actual clinical, ~~or~~ subclinical and dysfunction evidence of deficiency, estimates indicating inadequate or potentially inadequate levels of intake of nutrients or possible deficiencies likely to develop because of changes taking place in food habits. Mandatory fortification is appropriate in addressing serious public health needs ~~such as clinical deficiency~~ whereas voluntary fortification may be appropriate in addressing lower order risk of inadequate nutrient intakes.

### Comment

- We agree to remove a square bracket from “public health” and “through fortification”.
- We would like to propose to add “and dysfunction” after “subclinical” in the second sentence. The sentence would then read:



This need may be demonstrated by actual clinical, ~~or~~ subclinical and dysfunction evidence of deficiency, estimates indicating inadequate or potentially inadequate levels of intake of nutrients or possible deficiencies likely to develop because of changes taking place in food habits.

- We are of an opinion that “such as clinical deficiency” in the last sentence should be removed, as it is already mentioned in the second sentence.

6.1.4 (former 6.2.4) The amount of the essential nutrient added to the food, should be sufficient to ~~address the public health need~~ ~~[correct or prevent the deficiency]~~ when the food is consumed in normal amounts by the population at risk.

#### **Comment**

We agree that a square bracket should be removed from “address the public health need”, meanwhile “correct or prevent the deficiency” should be deleted.

6.1.5 (former 6.2.5) The amount of the essential nutrient added to a food, should not result in excessive ~~total~~ intakes ~~of~~ the nutrient from the fortified food when combined with other dietary sources ~~by individuals~~ general population and population group with a high intake of a fortified food.

#### **Comment**

- We agree to remove all square brackets in this section.

- We propose to replace the word “individuals” with “general population and population group”.

“6.1.5 (former 6.2.5) The amount of the essential nutrient added to a food, should not result in excessive ~~total~~ intakes ~~of~~ the nutrient from the fortified food when combined with other dietary sources ~~by individuals~~ general population and population group with a high intake of a fortified food.”

~~6.1.6 (former 3.7) Technology and processing facilities should be available to permit the addition of the essential nutrient [to a food] in a satisfactory manner.~~

#### **Comment**

Section 6.1.6 should be deleted, as it is replicated with section 3.9.

~~6.1.7 (former 3.9) The additional cost ~~of~~ mandatory addition of essential nutrients to foods ~~]~~ should be reasonable for the intended consumer.~~

#### **Comment**

We agree to remove a square bracket from this section.

6.2 (6.3 in previous draft; this entire section is renumbered consequently) The following conditions should be fulfilled in the case of fortification programs that are voluntary:

#### **Comment**

Section 6.2, we found that both conditions for foods which may be fortified and may not be appropriate for fortification are combined and mentioned in this section. To be clear and understanding, we would like to propose that inclusion and exclusion criteria of foods for fortification should be generated instead of providing combined conditions for the 2 mentioned food categories.

6.2.1.6 Essential nutrients should not be added to beverages containing more than 1.2% by volume of alcohol.]

**Comment**

In principle, essential nutrients should not be added in alcoholic beverages. Furthermore, there should be scientific evidence to support the establishment of alcohol level at 1.2%.

**6.2.2 Selection of essential nutrients that may be added:**

6.2.2.1 The severity of the adverse effect on which the Upper Intake Level (UL) is based should be reviewed by national authorities and should inform restrictions on essential nutrients permitted to be added to foods on a voluntary basis.

**Comment**

- We are of the opinions that there should be criteria for selection of nutrient based on essential nutrient intake, because low or inadequate intake will cause public health problem.

- In adding other essential nutrients, Upper Intake Level (UL), cost effectiveness and cost benefit should be concerned and reviewed by national authorities .

6.2.3.3 The amount of the essential nutrient added to a food, should not result in excessive intakes by ~~individuals~~ general population and population group with a potentially high intake of a fortified food.

**Comment :**

We propose to replace the word “individuals” with “general population and population group”

**7. ~~NUTRIENT~~ ADDITION OF ESSENTIAL NUTRIENTS TO SPECIAL PURPOSE FOODS**

**7.1** Nutrients may be added to special purpose foods, including foods for special dietary uses, to ensure an appropriate and adequate nutrient content ~~based on the principles in this guidance wherever applicable~~. Where appropriate, such addition should be made with due regard to the nutrient density of such foods.

**Comment**

We agree to remove a square bracket from “based on the principles in this guidance wherever applicable”.