

## CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of  
the United Nations



World Health  
Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: [codex@fao.org](mailto:codex@fao.org) - [www.codexalimentarius.net](http://www.codexalimentarius.net)

Agenda Item 6

CX/NFSDU 12/34/9-Add.1

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

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

**Thirty-fourth Session**

**Bad Soden am Taunus, Germany**

**3 – 7 December 2012**

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

*(Comments at Step 3)*

**Comments from:**

**BRAZIL**

**PHILIPPINES**

**IADSA -International Alliance of Dietary/Food Supplement Associations**

**ICBA - International Council of Beverages Associations**

**BRAZIL****GENERAL COMMENTS**

Brazil thanks for the opportunity to present the following comments on the CX/NFSDU 12/34/9 - Work to Amend the Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987).

**SPECIFIC COMMENTS**

**Appendix A: Draft Revised General Principles for the Addition of Essential Nutrients to Foods, version of September , 2012 for distribution for comments at Step 3**

**Table 3: Proposed Draft Revised Text - Clean Version:**

**Table 3: Proposed Revised Text from Table 2 – Clean Version**

**INTRODUCTION**

*(Revised)* The [General Principles] for the Addition of Essential Nutrients to Foods (the Principles) are intended to provide guidance to National Authorities responsible for developing guidelines and legal texts through the establishment of a set of principles that serve as a basis for the rational and safe addition of essential nutrients to foods.

**Brazilian Comments:**

We agree with the paragraph proposed for the Introduction of the document. We agree to remove the square brackets from “General Principles”.

(new) The Principles take into consideration provisions in 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), where applicable.

**Brazilian Comments:**

We agree with the text proposed.

(new) The Principles are applicable, as appropriate, to both mandatory and voluntary addition of essential nutrients unless otherwise indicated.

**Brazilian Comments:**

We agree with the text proposed. Nevertheless, we consider that it is more appropriate to place the text in the Section 1 – Scope.

(new) National authorities may also consult FAO/WHO publications for further guidance on nutrient addition.

**Brazilian Comments:**

We agree with the text proposed.

**1. SCOPE**

These Principles apply to the addition of essential nutrients to foods, not including vitamin and mineral food supplements<sup>1</sup>.

**Table 3: Proposed Revised Text from Table 2 – Clean Version**

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

## **2. DEFINITIONS**

For the purpose of these Principles:

### **Brazilian Comments:**

For purposes of clarity, we consider important to define the terms “Upper Level of Intake”, because it is used throughout the current draft, and also “Recommended Nutrient Intake”, “NRV” or “Individual Nutrient Level 98 (INL<sub>98</sub>)” according to the decision for the items 4.2.2 and 4.3.2.

As some of these terms are already defined in the “General Principles for Establishing Nutrient Reference Values of Vitamins and Minerals for the General Population”, we suggest including a footnote crossreferencing it when they appear in this document.

**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 life and which cannot be synthesized in adequate amounts by the body.

### **Brazilian Comments:**

We agree with the proposed text.

**2.3 (former 2.4) *Substitute food*** is a food which is designed to resemble a common food in appearance and texture, [flavour and odour] and is intended to be used as a complete or partial replacement for the food it resembles, [e.g., plant protein-based beverages as a replacement for milk.]

### **Brazilian Comments:**

Brazil suggests excluding the terms in square brackets “flavour and odour”. In Brazil, we have been observing that some foods are designed to resemble a common food and intended to be used as a complete or partial replacement for it, regardless the addition of flavours or odours. So, we understand that the definition of substitute food should be comprehensive.

Brazil also suggests excluding the example “e.g., plant protein-based beverages as a replacement for milk”, as it is not appropriate and the definition should be self-explanatory.

**2.4 (former 2.3) *Nutritional equivalence*** means the addition of one or more essential nutrient to a substitute food to achieve a similar nutritive value to its counterpart in terms of quantity and quality of protein and in terms of kinds, quantity and bioavailability of essential nutrients.

### **Brazilian Comments:**

Brazil agrees with the proposed text.

### **If retained, Proposed revised definition for option 3):**

**2.5 *Fortification*** means the addition of one or more essential nutrients to a food [whether or not it is normally contained in the food].

**Table 3: Proposed Revised Text from Table 2 – Clean Version****Brazilian Comments:**

We agree with the proposed text. Brazil supports retaining the definition for fortification in the document as it is used in many countries to designate the addition of nutrients to a food.

**2.8 Restoration** means the addition to a food of essential nutrient(s) in amounts to replace those lost during the course of good manufacturing practice, or during normal storage and handling procedures, [or in order to compensate for natural variations in essential nutrients.]

**Brazilian Comments:**

We agree with the proposed text and suggests excluding the square brackets from “or in order to compensate for natural variations in essential nutrients”.

**2.6 (new) Mandatory nutrient addition** is when National Authorities require food manufacturers to add specified essential nutrients to particular foods or food categories.

**Brazilian Comments:**

We agree with the proposed text.

**2.7 (new) Voluntary nutrient addition** is when National Authorities permit food manufacturers to add specified essential nutrients to particular foods or food categories

**Brazilian Comments:**

We agree with the proposed text.

**2.9 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 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 suggest excluding the item 2.9 as we consider that the principle established in section 4.4 (Nutrient addition to Special Purpose Foods) is already covered by the fundamental principles, so it could be deleted. Thus, the definition for special purpose foods is not necessary.

**2.11 (new) Population** refers to a national population or specific population group(s) as appropriate.

**Brazilian Comments:**

We agree with the proposed text.

**Table 3: Proposed Revised Text from Table 2 – Clean Version****3.0 PRINCIPLES****3.1 (New) Fundamental Principles**

3.1.1 Essential nutrients may be appropriately added to foods for the purpose of:

- contributing to correcting a demonstrated deficiency or [inadequate intakes] of one or more essential nutrients in the population;
- contributing to meeting [requirements] of one or more essential nutrients and reducing the risk of [inadequate intakes and/or] deficiency;
- contributing to the maintenance or improvement of health and/or nutritional status of the population and/or
- maintaining or improving the nutritional quality of foods;

**Brazilian Comments:**

We agree with the proposed text and suggests excluding the square brackets from the first and second bullets.

3.1.3 (New) National authorities should determine whether [nutrient addition] should be mandatory or voluntary [This decision may be based on severity and extent of public health need as demonstrated by scientific evidence. The kinds and amounts of essential nutrients to be added and the food vehicle chosen will depend upon the particular nutritional problems to be corrected or prevented, the characteristics of the target populations, and their food consumption patterns.

**Brazilian Comments:**

We agree with the proposed text, because it provides sufficient guidance on level of demonstration of public health need required to support mandatory versus that required for voluntary addition of essential nutrients. Thus, we suggest removing the square brackets.

3.1.4 The addition of essential nutrients to foods should be in accordance with food law and other policies established by national authorities. When provision is made in national food standards, regulations or guidelines for the addition of essential nutrients to foods, specific provisions should be included identifying the foods, the essential nutrients required or permitted to be added and where appropriate the minimum and maximum levels at which they should be present.

**Brazilian Comments:**

We agree with the proposed text.

3.1.5 (Former 3.8 with additions) Addition of essential nutrients to foods should not be used to mislead or deceive the consumer

**Brazilian Comments:**

We agree with the proposed text.

**3.2 (New) Selection of Nutrients and Determination of amounts**

**3.2.1 Former 3.2 with modifications (also considered to cover former 6.2.5):** The [amount of an added] or [addition of an] essential nutrient should be [scientifically and nutritionally justified] [in line with one or more of the purposes stated in 3.1.1] and not result in either an excessive intake or, for the target

**Table 3: Proposed Revised Text from Table 2 – Clean Version**

population, an insignificant intake of [the added] essential nutrient[s], considering [total intakes] from all [relevant] sources [including food supplements], [Upper Levels of intake and identification of special subpopulations at risk]. [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:**

With regard to the text proposed, Brazil suggests the following edits:

- To use the term “amount of an added” instead of “addition of an”;
- To delete the square brackets from the following texts: “scientifically and nutritionally justified”, “in line with one or more of the purposes stated in 3.1.1”, “the added”, “total intakes”, “relevant”, “including food supplements”, “Upper Levels of intake and identification of special subpopulations at risk” and “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”.

**3.2.2** (new) The Upper Level of Intake should be used to assess potential exposure to excessive intakes of essential nutrients and to estimate safe limits of addition, [including considerations of populations at risk of excessive intake]. [This exposure assessment should also help to identify the need for any restrictions on the types of foods to which nutrients should be added.]

**Brazilian Comments:**

We agree to retain the proposed text and we suggest excluding the square brackets.

**3.2.3** (new) Potential change to population intakes should be estimated as part of the decision making about nutrient addition [to evaluate safety and adequacy]. Assessment of potential exposure could be made through a dietary modelling approach of scenarios using data on population intakes, proposed amounts of an essential nutrient in a target food and daily intake reference values for adequacy and for safety.”

**Brazilian Comments:**

We agree to retain the proposed text and we suggest excluding the square brackets.

*Alternative for 3.2.2 and 3.2.3: [National authorities may establish maximum limits for the addition of essential nutrients to foods to reduce any potential risks for adverse effects on health. Maximum limits for the addition of essential nutrients to foods should be based on the following criteria:*

*(i) Upper Level of Intake (UL) of essential nutrients established by scientific risk assessment based on generally accepted scientific data, taking into consideration, as appropriate, the varying degrees of sensitivity of different consumer groups;*

*(ii) the daily intake of essential nutrients from other dietary sources.*

*When the maximum levels are set, due account may be taken of the reference intake values of essential nutrients for the population. When maximum amounts are close to the Upper Level of Intake (UL) restrictions of foods to which nutrients may be added should take account of the contribution of individual foods to the overall diet of the population in general or of sub-groups of the population.]*

**Table 3: Proposed Revised Text from Table 2 – Clean Version**

**3.2.4** (new) Where an Upper Level of Intake is not available, [National authorities may consider] the scientific evidence to support the safe addition of an essential nutrient [should be considered], including [demonstration of an upper level or a range of intake that is unlikely to result in adverse health effects] [or the potential relevance of Highest Observed Intake]<sup>1</sup>.

footnote 1: **Highest observed intake** – the highest level of intake observed or administered as reported within a stud(ies) of acceptable quality. It is derived only when no adverse health effects have been identified. (appropriate source to be cited.)

**Brazilian Comments:**

With regard to the proposed text, we suggest the following edits:

- to delete “National authorities may consider” and “demonstration of an upper level or a range of intake that is unlikely to result in adverse health effects”. We believe that these texts are not necessary.
- To remove the square brackets from “should be considered” and “or the potential relevance of Highest Observed Intake”.

**[3.2.5** (new) The severity of the adverse effect on which the Upper Level of Intake (UL) is based should be reviewed to inform restrictions on the addition of essential nutrients to foods.]

**Brazilian Comments:**

We agree with the text, so we suggest excluding the square brackets.

**3.2.6** *Former 3.3* The [amount of an essential nutrient added] / [addition of an essential nutrient] to a food should not result in an adverse effect on the metabolism of any other nutrient.

**Brazilian Comments:**

We agree with the text and suggest the use of the sentence “amount of an essential nutrient added” instead of “addition of an essential nutrient”.

**3.2.7** (new) National authorities may establish minimum limits for the addition of essential nutrient to foods. [Minimum amounts for the addition of essential nutrients to foods should take into account the conditions of use for a source of claim in the Guidelines for use of nutrition and health claims (CAC/GL 23-1997)]. [The minimum amount of addition of an essential nutrient should take into account the intended purpose, and all other sources of the essential nutrient in the diet, including food supplements.]

**Brazilian Comments:**

We prefer the sentence “The minimum amount of addition of an essential nutrient should take into account the intended purpose”, and all other sources of the essential nutrient in the diet, including food supplements”, because it is more comprehensive as it considers important criteria to establish the minimum amount of addition other than the conditions of use for a source of claim in the Guidelines for use of nutrition and health claims (CAC/GL 23-1997).

**Table 3: Proposed Revised Text from Table 2 – Clean Version****3.3 (New) Selection of Foods**

**3.3.1** (new) [Certain foods may have to be excluded from voluntary nutrient addition 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 in non-target populations.]

Or

[The selection of appropriate foods to which essential nutrients may be added is best determined at national/regional/local level taking into account dietary habits, socioeconomic situations and the need to avoid any risks to health.]

Or

[The selection of food(s) to which to add an essential nutrient(s) should primarily be based on achieving appropriate purposes of nutrient addition as identified in 3.1.1.]

**Brazilian Comments:**

We agree with the first text proposed with some amendments as suggested below:

“Certain foods may have to be excluded from voluntary nutrient addition 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 ~~in non-target populations.~~ in the population.”

We suggest replacing “in non-target populations” for “in the population”, because the definition included in the section 2 for “population” encompasses national population or specific population group(s) as appropriate.

**3.3.2** (new) The selection of appropriate foods [or categories of foods] to which essential nutrients [may] / [may not] be added should take into account the nutritional value of the foods and is best determined by National Authorities.

**Brazilian Comments:**

We agree with the proposed text and suggest excluding the square brackets from “or categories of foods” and “may”.

[In addition, essential nutrients should not be added to alcoholic beverages and unprocessed foods, including, but not limited to, fruit, vegetables, meat, poultry and fish.] (Note: With this option, new 3.3.4 and 3.3.5 would be deleted.)

**[3.3.4** (new) Essential nutrients should not be added to unprocessed foods, including, but not limited to, fruit, vegetables, meat, poultry and fish.]

**[3.3.5** (new) Essential nutrients should not be added to alcoholic beverages.]

**Brazilian Comments:**

We prefer to retain the items 3.3.4 and 3.3.5 and exclude the second sentence from the item 3.3.2.



**Table 3: Proposed Revised Text from Table 2 – Clean Version****3.4 (new) Technological aspects**

3.4.1 (new) The sources of the added 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 [in the following order]: FAO/WHO standards, international Pharmacopoeias or recognized international standards, or national legislation.

**Brazilian Comments:**

We agree with the proposed text. Nevertheless, we suggest excluding the text “in the following order”, because we understand that if the national legislation establishes purity criteria, it should be the first reference in the country.

3.4.2 *Former 3.4 with modifications* The added essential nutrient should be sufficiently stable in the food under customary conditions of processing, packaging, storage, distribution and use.

**Brazilian Comments:**

We agree with the proposed text.

3.4.3 *Former 3.6* The added essential nutrient should [have minimal impact on the original food characteristics] / [not impart undesirable characteristics to the food] (e.g. colour, taste, flavour, texture, cooking properties) and should not unduly shorten shelf-life.

**Brazilian Comments:**

We suggest using the text “have minimal impact on the original food characteristics”, considering that in some cases the addition of nutrients may impart some unavoidable changes in the food.

3.4.4 *Former 3.7* Technology and processing facilities should be available to permit the [standardized] addition of the essential nutrient to a food in a manner to ensure nutrient [bio]availability, consistency, distribution and stability.

**Brazilian Comments:**

We agree with the text, so we suggest excluding the square brackets.

**3.5 Monitoring**

3.5.1 (new) [It is important that National authorities] / [National authorities should] monitor population intakes from all sources including the essential nutrients added to foods to assess the extent to which [the selected public health need or other purpose for addition] *or* [the purposes identified in 3.1.1] is addressed and to ensure that any risk of excessive intakes is minimized.

**Brazilian Comments:**

Brazil suggests the following edits to the item:

- To use the sentence “It is important that National authorities” instead of “National authorities should”. We think that the activity of monitoring depends on several

**Table 3: Proposed Revised Text from Table 2 – Clean Version**

factors, as budget, priorities and national policies. Thus, it is more appropriate to express it as something important to do rather than an obligation.

- To use the sentence “the selected public health need or other purpose for addition” instead of “the purposes identified in 3.1.1”. We think that the first sentence is more objective.

3.5.2 (new) Monitoring of total nutrient intakes should use the same approach as used in deciding the nutrient addition.

**Brazilian Comments:**

We agree with the text.

**4.0 [Principles for] Types of Nutrient Addition****Brazilian Comments:**

We agree with the new title, so we suggest excluding the square brackets.

**4.1 (new) Addition of Essential Nutrients [to Address a Demonstrated Public Health Need] [and Mandatory Addition]****Brazilian Comments:**

We think that the sentences “to Address a Demonstrated Public Health Need” “and Mandatory Addition” should be retained in the title based on the principle set in the item 3.1.1. This item establishes that the decision about the mandatory or voluntary addition should be determined by national authorities and may be based on severity and extent of public health need. Thus, we understand that either voluntary or mandatory addition can be used to address a demonstrated public health need.

4.1.1 *Former 6.2.1* There should be a demonstrated public health need for increasing the intake of an essential nutrient in one or more populations [which may be accomplished by mandatory addition of essential nutrients. A demonstrated public health need, however, may also be addressed through voluntary addition.] This need may be demonstrated by clinical evidence of deficiency, subclinical evidence of deficiency, [suboptimal nutritional status], [evidence from valid biochemical indicators], estimates indicating inadequate intake of nutrients, estimates indicating potentially inadequate intakes of nutrients, and/or by estimates of possible deficiencies because of changes in food habits.

**Brazilian Comments:**

We suggest excluding the sentence “A demonstrated public health need, however, may also be addressed through voluntary addition” from the text, because we understand that this statement is already covered by the items 3.1.1, 3.1.3 e 3.2.1.

4.1.2 *Former 6.2.2* The food(s) selected as a vehicle for the added essential nutrient(s) should be consumed by the population at risk [of inadequate intake].

**Brazilian Comments:**

We agree with the proposed text.

**Table 3: Proposed Revised Text from Table 2 – Clean Version**

4.1.3. The amount of the essential nutrient added to the food should aim to be sufficient to meet the public health need.

**Brazilian Comments:**

We agree with the proposed text.

[Switch order with 4.1.3]:

4.1.4.*Former 6.2.3* The intake of the food selected as a vehicle should be stable and uniform and the [amount of the food consumed by the lower and upper percentiles of the population] should be known.

**Brazilian Comments:**

We agree with the proposed text.

4.1.5 *Former 3.9 revised* The cost effectiveness of the addition of essential nutrients to foods for the intended consumer should be considered.

**Brazilian Comments:**

We agree with the proposed text.

**4.2 Nutrient Addition for Purposes of Restoration**

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

**Brazilian Comments:**

We prefer the use of “contributor to intake” instead of “source”. We think that in this case the restoration is strongly recommended, so we suggest excluding the square brackets from the word “recommended”.

4.2.2 *Former 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 [daily intake reference value]/ [recommended nutrient intake]/ [NRV]/ [INL 98] in a reasonable daily [intake] / [consumption] of the food (or in the case of an essential nutrient for which there is no [daily intake reference value]/ [recommended nutrient intake]/ [NRV]/ [INL 98] 10% of the average daily intake of the nutrient).

[Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this nutrient need not be restored.]

**4.3 Nutrient Addition for Purposes of Nutritional Equivalence**

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

**Table 3: Proposed Revised Text from Table 2 – Clean Version****Brazilian Comments:**

We prefer the use of “contributor to intake” instead of “source”.

We suggest excluding the square brackets from “recommended” and “population”.

4.3.2 *Former 5.2* A food being substituted or partially substituted should be considered a significant contributor to intake 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% of the [recommended nutrient intake]/[NRV]/ [INL 98].

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

**Brazilian Comments:**

We would like to point out that the sentence “Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this need not be equivalent” is equivalent to the item 4.3.3. We think that this statement should be written in a separate item.

4.3.3 *Former 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.

**Brazilian Comments:**

We agree with the proposed text.

**4.4 Nutrient addition to Special Purpose Foods**

**4.4.1 *Former 7.1*** [Essential] nutrients may be added to special purpose foods, including foods for special dietary uses, to ensure an appropriate and adequate nutrient content [for their intended use] [based on the principles in this guidance wherever applicable]. Where appropriate, such addition should be made with due regard to the nutrient [composition] of such foods. [Consideration should be given to the target population and their nutrient requirements based on general reference intakes such as RNIs.]

*Alternative:* [Essential] nutrients may be added to special purpose foods to ensure an appropriate and adequate nutrient content [for their intended use] Consideration should be given to the nutrient requirements [of the target population] based on [relevant] [daily intake reference values].

**Brazilian Comments:**

We understand that this section is not necessary because the principle is already covered by the fundamental principles.

**PHILIPPINES**

<b>Draft Revised General Principles for Addition of Essential Nutrient to Foods</b>	<b>PHILIPPINE POSITION</b>
<b>INTRODUCTION</b> <i>(Revised) The [General Principles] for the Addition of Essential Nutrients to Foods</i>	The Philippines supports the revised introduction with the retention of the bracketed text to wit: “The General Principles for the Addition of Essential Nutrients to Foods are intended to provide guidance to National

<p>(the Principles) are intended to provide guidance to National Authorities responsible for developing guidelines and legal texts through the establishment of a set of principles that serve as a basis for the rational and safe addition of essential nutrients to foods.</p>	<p>Authorities responsible for developing guidelines and legal texts through the establishment of a set of principles that serve as a basis for the rational and safe addition of essential nutrients to foods”</p>
<p>(new) The Principles take into consideration provisions in 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), where applicable.</p>	
<p>(new) The Principles are applicable, as appropriate, to both mandatory and voluntary addition of essential nutrients unless otherwise indicated.</p>	<p>The Philippines supports this new statement in the Introduction.</p>
<p>(new) National authorities may also consult FAO/WHO publications for further guidance on nutrient addition.</p>	<p>The Philippine supports this new statement, since DOH-DA follow FAO-WHO Guidelines where available in their policy objectives.</p>
<p><b>1. SCOPE</b></p> <p>These Principles apply to the addition of essential nutrients to foods, not including vitamin and mineral food supplements<sup>1</sup>.</p> <p>1 See the Codex <i>Guidelines for Vitamin and Mineral Food Supplements</i> (CAC/GL-55-2005)</p>	
<p><b>2. DEFINITIONS</b></p> <p>For the purpose of these Principles:</p>	
<p><b>2.2 Essential nutrient</b> means any substance normally consumed as a constituent of food which is needed for growth and development and the maintenance of life and which cannot be synthesized in adequate amounts by the body.</p>	
<p><b>2.3 (former 2.4) Substitute food</b> is a food which is designed to resemble a common food in appearance and texture, [flavour and odour] and is intended to be used as a complete or partial replacement for the food it resembles, [e.g., plant protein-based beverages as a replacement for milk.]</p>	
<p><b>2.4 (former 2.3) Nutritional equivalence</b> means the addition of one or more essential nutrient to a substitute food to achieve a similar nutritive value to its counterpart in terms of quantity and quality of protein and in terms of kinds, quantity and bioavailability of essential nutrients</p>	

<p><b>If retained, Proposed revised definition for option 3):</b></p> <p><b>2.5 Fortification</b> means the addition of one or more essential nutrients to a food [whether or not it is normally contained in the food].</p>	<p>The Philippines supports retaining the definition of fortification sans the texts inside the bracket.</p> <p>We are of the opinion that retention of the term “fortification” in the definition has scientific basis. Fortification is widely accepted in both developed and developing countries worldwide (FAO Technical Consultation on Food Fortification Technologies and Quality Control, 1995). Fortification is also the term used in the WHO Nutrition Guidelines on Food Fortification with Micronutrients. This was also the basis of the Philippine legislation and regulations.</p>
<p><b>2.8 Restoration</b> means the addition to a food of essential nutrient(s) in amounts to replace those lost during the course of good manufacturing practice, or during normal storage and handling procedures, [or in order to compensate for natural variations in essential nutrients.]</p>	<p>We support inclusion of this definition with retention of the bracketed text for clarification and harmonization.</p>
<p><b>2.6 (new) Mandatory nutrient addition</b> is when National Authorities require food manufacturers to add specified essential nutrients to particular foods or food categories.</p>	<p>The Philippines supports the addition of these new definitions (mandatory and voluntary nutrient addition)</p>
<p><b>2.7 (new ) Voluntary nutrient addition</b> is when National Authorities permit food manufacturers to add specified essential nutrients to particular foods or food categories</p>	
<p><b>2.9 Special purpose foods</b> 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 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].</p>	<p>The definition is not clear and quite confusing. There is an existing and recognized standard for Food for Special Dietary Use which is clearly defined and with specific target.</p>
<p><b>2.11 (new) Population</b> refers to a national population or specific population group(s) as appropriate.</p>	
<p><b>3.0 PRINCIPLES</b></p>	
<p><b>3.1 (New) Fundamental Principles</b></p>	<p>The Philippines supports addition of this new section as this is consistent with the decision made at the 32<sup>nd</sup> CCNFSDU session that Section 3 include a separate section on fundamental principles (REP 11/NFSDU, para 67).</p>
<p>3.1.1 Essential nutrients may be appropriately added to foods for the purpose of:</p> <ul style="list-style-type: none"> <li>• contributing to correcting a demonstrated deficiency or [inadequate intakes] of one or</li> </ul>	<p>The Philippines support the retention of the bracketed text [inadequate intakes] since the principle behind the national voluntary food</p>

<p>more essential nutrients in the population;</p> <ul style="list-style-type: none"> <li>• contributing to meeting [requirements] of one or more essential nutrients and reducing the risk of [inadequate intakes and/or] deficiency;</li> <li>• contributing to the maintenance or improvement of health and/or nutritional status of the population and/or</li> <li>• maintaining or improving the nutritional quality of foods;</li> </ul>	<p>fortification program is to address inadequate intakes of the Filipino population based on national nutrition surveys.</p>
<p>3.1.3 (New) National authorities should determine whether [nutrient addition] should be mandatory or voluntary [This decision may be based on severity and extent of public health need as demonstrated by scientific evidence. The kinds and amounts of essential nutrients to be added and the food vehicle chosen will depend upon the particular nutritional problems to be corrected or prevented, the characteristics of the target populations, and their food consumption patterns.</p>	<p>The Philippines supports the proposed new text since RA 8976 mandates the Philippines National Authorities (Department Of Health) in determining whether nutrient addition should be mandatory and voluntary Codex text supports this in the draft principle.</p> <p>Similarly, the scientific evidence in the codex draft is being supported by Section 2 of RA 8976, to wit: <i>as manifested in dietary, biochemical or clinical evidences of deficiency</i></p> <p>The proposed codex text is also acceptable as it gives national authorities flexibility to determine the kinds and amounts of essential nutrients to be added based on current national nutritional situation.</p>
<p>3.1.4 The addition of essential nutrients to foods should be in accordance with food law and other policies established by national authorities. When provision is made in national food standards, regulations or guidelines for the addition of essential nutrients to foods, specific provisions should be included identifying the foods, the essential nutrients required or permitted to be added and where appropriate the minimum and maximum levels at which they should be present.</p>	<p>This provision allows government authorities the primary discretion for addition of essential nutrients. The Philippines support this provision. The minimum amount of addition of an essential nutrient should take into account the intended purpose, and all other sources of the essential nutrient in the diet, and all relevant sources. It is also important to establish maximum limits for the addition of essential nutrients to food in order to reduce any potential risks for adverse effects on health. Maximum limits for the addition of essential nutrients to foods should be based on the set of generally agreed criteria. Consideration of scientific evidence to support the safe addition of an essential nutrient, including demonstration of an upper level or a range of intake that is unlikely to result in adverse health effects should be considered by national authorities.</p>

3.1.5 (Former 3.8 with additions) Addition of essential nutrients to foods should not be used to mislead or deceive the consumer	We support this section since the primary aim of our regulation is to protect the consumers.
<b>3.2 (New) Selection of Nutrients and Determination of amounts</b>	
<p><b>3.2.1</b> Former 3.2 with modifications (also considered to cover former 6.2.5): The [amount of an added] or [addition of an] essential nutrient should be [scientifically and nutritionally justified] [in line with one or more of the purposes stated in 3.1.1] and not result in either an excessive intake or, for the target population, an insignificant intake of [the added] essential nutrient[s], considering [total intakes] from all [relevant] sources [including food supplements], [Upper Levels of intake and identification of special subpopulations at risk] [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.]</p>	<p>The first option is wordy and the concerns being addressed by the text were already addressed in 3.1.1. Ergo, the Philippines supports the second option which is more straightforward and clear on principle, to wit:</p> <p>The addition of essential nutrients to food should be nutritionally and scientifically justified and not result in either inadequate or excessive intakes of essential nutrients, considering total intake of the added nutrients from foods and food supplements, upper levels of intake and identification of special sub populations at risk.</p>
<p><b>3.2.2</b> (new) The Upper Level of Intake should be used to assess potential exposure to excessive intakes of essential nutrients and to estimate safe limits of addition, [including considerations of populations at risk of excessive intake]. [This exposure assessment should also help to identify the need for any restrictions on the types of foods to which nutrients should be added.]</p>	<p>The Philippines supports the alternative texts to 3.2.2 and 3.2.3, to wit:</p> <p><i>Alternative for 3.2.2 and 3.2.3: [National authorities may establish maximum limits for the addition of essential nutrients to foods to reduce any potential risks for adverse effects on health. Maximum limits for the addition of essential nutrients to foods should be based on the following criteria:</i></p>
<p><b>3.2.3</b> (new) Potential change to population intakes should be estimated as part of the decision making about nutrient addition [to evaluate safety and adequacy]. Assessment of potential exposure could be made through a dietary modelling approach of scenarios using data on population intakes, proposed amounts of an essential nutrient in a target food and daily intake reference values for adequacy and for safety.”</p> <p><i>Alternative for 3.2.2 and 3.2.3: [National authorities may establish maximum limits for the addition of essential nutrients to foods to reduce any potential risks for adverse effects on health. Maximum limits for the addition of essential nutrients to foods should be based on the following criteria:</i></p> <p><i>(i) Upper Level of Intake (UL) of essential nutrients established by scientific risk assessment based on generally accepted scientific data, taking into consideration, as appropriate, the varying degrees of sensitivity of different consumer groups;</i></p> <p><i>(ii) the daily intake of essential nutrients from other dietary sources.</i></p> <p><i>When the maximum levels are set, due account may be taken of the reference intake values of essential nutrients for the population. When maximum amounts are close to the Upper Level of Intake (UL) restrictions of foods to which nutrients may be added</i></p>	<p><i>(i) Upper Level of Intake (UL) of essential nutrients established by scientific risk assessment based on generally accepted scientific data, taking into consideration, as appropriate, the varying degrees of sensitivity of different consumer groups;</i></p> <p><i>(ii) the daily intake of essential nutrients from other dietary sources.</i></p> <p><i>When the maximum levels are set, due account may be taken of the reference intake values of essential nutrients for the population. When maximum amounts are close to the Upper Level of Intake (UL) restrictions of foods to which nutrients may be added should take account of the contribution of individual foods to the overall diet of the population in general or of sub-groups of the population.]</i></p> <p>The above provisions clearly give the National Authorities the upper hand to select nutrients and determine the right amounts. The above texts in italics are in line with the Codex Guidelines on Mineral Food Supplements. Dietary modelling should be left to National Authorities</p>



<p><i>should take account of the contribution of individual foods to the overall diet of the population in general or of sub-groups of the population.]</i></p>	<p>which have the better understanding of the nutritional needs of its populations.</p>
<p><b>3.2.4</b> (new) Where an Upper Level of Intake is not available, [National authorities may consider] the scientific evidence to support the safe addition of an essential nutrient [should be considered], including [demonstration of an upper level or a range of intake that is unlikely to result in adverse health effects] [or the potential relevance of Highest Observed Intake].</p> <p>footnote 1: <b>Highest observed intake</b> – 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. (appropriate source to be cited.)</p>	<p>The Philippines can support the deletion of the square bracket in <del>[national authorities may consider]</del>–In the absence of international guidance on upper level like that of WHO/FAO or of Codex, the national authorities may consider available scientific evidence to support the addition of essential nutrient including demonstration of an upper level or a range of intake that is unlikely to result in adverse health effects.</p> <p>The Philippines also supports the definition of “highest observed intake” as it appears in the Nutritional Risk Analysis Principles and Guidelines for the Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses. This is also in line with the new revised introduction of the document.</p>
<p><b>[3.2.5</b> (new) The severity of the adverse effect on which the Upper Level of Intake (UL) is based should be reviewed to inform restrictions on the addition of essential nutrients to foods.]</p>	
<p><b>3.2.6</b> <i>Former 3.3</i> The [amount of an essential nutrient added] / [addition of an essential nutrient] to a food should not result in an adverse effect on the metabolism of any other nutrient.</p>	<p>The Philippines supports retention of the bracketed text to wit: ‘The amount of essential nutrient added to a food should not result in an adverse effect on the metabolism of any other nutrient’. Safety is always an uppermost consideration in nutrient addition for whatever purpose.</p>
<p><b>3.2.7</b> (new) National authorities may establish minimum limits for the addition of essential nutrient to foods. [Minimum amounts for the addition of essential nutrients to foods should take into account the conditions of use for a source of claim in the Guidelines for use of nutrition and health claims (CAC/GL 23-1997)]. [The minimum amount of addition of an essential nutrient should take into account the intended purpose, and all other sources of the essential nutrient in the diet, including food supplements.]</p>	<p>The Philippines supports retention of the bracketed texts. The guidelines for the use of nutrition and health claims (CAC/GL 23-1997 may also be put in the introduction, so all relevant Codex documents that may be used in this Principle or Guidelines are clearly identified.</p>
<p><b>3.1</b> (new) [Certain foods may have to be excluded from voluntary nutrient addition 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 in non-target populations.]</p> <p>Or</p> <p>[The selection of appropriate foods to which essential nutrients may be added is best determined at national/regional/local level taking into account dietary habits,</p>	<p>The Philippines does not support inclusion of this new provision. The use of term ‘ubiquity’ is subjective. Staple foods are often considered ubiquitous but can be an appropriate food for both voluntary and mandatory fortification as observed in iodine in salt and vitamin D in milk. Moreover, any exclusion should be supported by scientific evidence.</p> <p>The Philippines supports the removal of square bracket from second</p>

<p>socioeconomic situations and the need to avoid any risks to health.]</p> <p>Or</p> <p>[The selection of food(s) to which to add an essential nutrient(s) should primarily be based on achieving appropriate purposes of nutrient addition as identified in 3.1.1.]</p>	<p>option:</p> <p>{The selection of appropriate foods to which essential nutrients may be added is best determined at national/regional/local level taking into account dietary habits, socioeconomic situations and the need to avoid any risks to health.}</p> <p>The Philippines supports Option 3 since this is in line with the national policy.</p>
<p><b>3.3.2 (new)</b> The selection of appropriate foods [or categories of foods] to which essential nutrients [may] / [may not] be added should take into account the nutritional value of the foods and is best determined by National Authorities.</p> <p>[In addition, essential nutrients should not be added to alcoholic beverages and unprocessed foods, including, but not limited to, fruit, vegetables, meat, poultry and fish.] (Note: With this option, new 3.3.4 and 3.3.5 would be deleted.)</p>	<p>The Philippines proposes to delete the square bracket on the following text and subsequently delete options 3.3.4 and 3.3.5:</p> <p><b>3.3.2 (new)</b> The selection of appropriate foods {or categories of foods}to which essential nutrients {may}/<del>{may not}</del> be added should take into account the nutritional value of the foods and is best determined by National Authorities.</p> <p>{In addition, essential nutrients should not be added to alcoholic beverages and unprocessed foods, including, but not limited to, fruit, vegetables, meat, poultry and fish.} (Note: With this option, new 3.3.4 and 3.3.5 would be deleted.)</p> <p>The phrase may not is no longer necessary as the word “may” actually implies the possibility or options of not doing the addition of essential nutrients.</p>
<p><b>[3.3.4 (new)</b> Essential nutrients should not be added to unprocessed foods, including, but not limited to, fruit, vegetables, meat, poultry and fish.]</p>	<p><del><b>[3.3.4 (new)</b> Essential nutrients should not be added to unprocessed foods, including, but not limited to, fruit, vegetables, meat, poultry and fish.]</del></p>
<p><b>[3.3.5 (new)</b> Essential nutrients should not be added to alcoholic beverages.]</p>	<p><del><b>[3.3.5 (new)</b> Essential nutrients should not be added to alcoholic beverages.]</del></p>
<p><b>3.4 (new) Technological aspects</b></p>	
<p>3.4.1 (new) The sources of the added 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 [in the following order]: FAO/WHO standards, international Pharmacopoeias or recognized international standards, or national legislation.</p>	<p>The Philippines proposes to delete the text: <del>[in the following order]</del>. Purity criteria should not be prioritised but listed.</p>

<p>3.4.2 <i>Former 3.4 with modifications</i> The added essential nutrient should be sufficiently stable in the food under customary conditions of processing, packaging, storage, distribution and use.</p>	<p>The provision is acceptable, given that the purpose of addition of nutrients is replenishing what was lost during processing and storage and therefore should not affect the overall quality of the food.</p>
<p>3.4.3 <i>Former 3.6</i> The added essential nutrient should [have minimal impact on the original food characteristics] / [not impart undesirable characteristics to the food] (e.g. colour, taste, flavour, texture, cooking properties) and should not unduly shorten shelf-life.</p>	<p>The provision is acceptable, given that the purpose of addition of nutrients is replenishing what was lost during processing and storage and therefore should not affect the overall sensory acceptance of the food.</p> <p>The Philippines supports deletion of the square brackets: {have minimal impact on the original food characteristics} (e.g. colour, taste, flavour, texture, cooking properties) and should not unduly shorten shelf-life.</p> <p>We support deletion of the bracketed text [not impart undesirable characteristics to the food] since “undesirable characteristic” are difficult to qualify.</p>
<p>3.4.4 <i>Former 3.7</i> Technology and processing facilities should be available to permit the [standardized] addition of the essential nutrient to a food in a manner to ensure nutrient [bio]availability, consistency, distribution and stability.</p>	
<p><b>3.5 Monitoring</b></p>	
<p>3.5.1 (new) [It is important that National authorities] / [National authorities should] monitor population intakes from all sources including the essential nutrients added to foods to assess the extent to which [the selected public health need or other purpose for addition] <i>or</i> [the purposes identified in 3.1.1] is addressed and to ensure that any risk of excessive intakes is minimized.</p>	<p>The Philippines supports the following texts as this is consistent with our local legislation without the square brackets:</p> <p>National authorities should monitor population intakes from all sources including the essential nutrients added to foods to assess the extent to which the selected public health need or other purpose for addition is addressed and to ensure that any risk of excessive intakes is minimized.</p>
<p>3.5.2 (new) Monitoring of total nutrient intakes should use the same approach as used in deciding the nutrient addition.</p>	
<p><b>4.0 [Principles for] Types of Nutrient Addition</b></p>	
<p><b>4.1 (new) Addition of Essential Nutrients [to Address a Demonstrated Public Health Need] [and Mandatory Addition]</b></p>	
<p>4.1.1 <i>Former 6.2.1</i> There should be a demonstrated public health need for increasing the intake of an essential nutrient in one or more populations [which may be accomplished by mandatory addition of essential nutrients. A demonstrated public health need, however, may also be addressed through voluntary</p>	<p>The Philippines proposes to delete the wording below. The important thing on the principle is that when there is a demonstrated public health need, this should be based on all available scientific evidence without the need for enumerating the specific evidences of nutrient deficiencies</p>

<p>addition.] This need may be demonstrated by clinical evidence of deficiency, subclinical evidence of deficiency, [suboptimal nutritional status], [evidence from valid biochemical indicators], estimates indicating inadequate intake of nutrients, estimates indicating potentially inadequate intakes of nutrients, and/or by estimates of possible deficiencies because of changes in food habits.</p>	<p>because this might be limiting.</p> <p>4.1.1 <i>Former 6.2.1</i> There should be a demonstrated public health need for increasing the intake of an essential nutrient in one or more populations <del>[which may be accomplished by mandatory addition of essential nutrients. A demonstrated public health need, however, may also be addressed through voluntary addition.]</del> This need may be demonstrated by all available scientific evidences. <del>clinical evidence of deficiency, subclinical evidence of deficiency, [suboptimal nutritional status], [evidence from valid biochemical indicators], estimates indicating inadequate intake of nutrients, estimates indicating potentially inadequate intakes of nutrients, and/or by estimates of possible deficiencies because of changes in food habits.</del></p>
<p>4.1.2 <i>Former 6.2.2</i> The food(s) selected as a vehicle for the added essential nutrient(s) should be consumed by the population at risk [of inadequate intake].</p>	
<p>4.1.3. The amount of the essential nutrient added to the food should aim to be sufficient to meet the public health need.</p>	
<p>[Switch order with 4.1.3]:</p> <p>4.1.4. <i>Former 6.2.3</i> The intake of the food selected as a vehicle should be stable and uniform and the [amount of the food consumed by the lower and upper percentiles of the population] should be known.</p>	
<p>4.1.5 <i>Former 3.9 revised</i> The cost effectiveness of the addition of essential nutrients to foods for the intended consumer should be considered.</p>	
<p><b>4.2 Nutrient Addition for Purposes of Restoration</b></p>	
<p>4.2.1 <i>Former 4.1</i> Where the food has been identified as a significant [source] / [contributor to intake] of essential nutrients in the population, and particularly where there is [a] demonstrated public health need, restoration of the essential nutrients of concern lost during processing, storage or handling, should be [recommended].</p>	
<p>4.2.2 <i>Former 4.2</i> 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 [daily intake reference value]/ [recommended nutrient intake]/ [NRV]/ [ INL 98] in a reasonable daily [intake] / [consumption] of the food (or in the case of an essential</p>	<p>For the matter of consistency in all codex texts, the Philippines recommends to retain all texts in square brackets that are consistent with the Principles in Nutrient Reference Values (NRVs)</p>

<p>nutrient for which there is no [daily intake reference value]/ [recommended nutrient intake]/ [NRV]/ [ INL 98] 10% of the average daily intake of the nutrient).</p> <p>[Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this nutrient need not be restored.]</p>	
<p><b>4.3 Nutrient Addition for Purposes of Nutritional Equivalence</b></p>	
<p>4.3.1 <i>Former 5.1</i> Where a substitute food is intended to replace a food which has been identified as a significant [source] / [contributor to intake] of essential nutrients in the [population ], and particularly where there is [a] demonstrated public health need, nutritional equivalence in terms of the essential nutrients of concern should be [recommended].</p>	
<p>4.3.2 <i>Former 5.2</i> A food being substituted or partially substituted should be considered a significant contributor to intake 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% of the [recommended nutrient intake]/[NRV]/ [INL 98].</p> <p>Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this need not be equivalent.</p>	<p>For the matter of consistency in all codex texts, the Philippines recommends to retain all texts in square brackets that are consistent with the Principles in Nutrient Reference Values (NRVs)</p>
<p>4.3.3 <i>Former 5.3</i> 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.</p>	
<p><b>4.4 Nutrient addition to Special Purpose Foods</b></p>	
<p><b>4.4.1 <i>Former 7.1</i></b> [Essential] nutrients may be added to special purpose foods, including foods for special dietary uses, to ensure an appropriate and adequate nutrient content [for their intended use] [based on the principles in this guidance wherever applicable]. Where appropriate, such addition should be made with due regard to the nutrient [composition] of such foods. [Consideration should be given to the target population and their nutrient requirements based on general reference intakes such as RNIs.]</p> <p><i>Alternative:</i> [Essential] nutrients may be added to special purpose foods to ensure an appropriate and adequate nutrient content [for their intended use] Consideration should be given to the nutrient requirements [of the target population] based on [relevant] [daily intake reference values].</p>	<p>The Philippines supports the principle and changes as proposed in the EWG except for the addition of “such as RNIs”. The revised statements should be:</p> <p>Essential nutrients may be added to special purpose foods, including foods for special dietary uses, to ensure an appropriate and adequate nutrient content for their intended use-based on the principles in this guidance wherever applicable- Where appropriate, such addition should be made with due regard to the nutrient composition of such foods. Consideration should be given to the target population and their nutrient requirements based on general reference intakes.</p>

## **IADSA -International Alliance of Dietary/Food Supplement Associations**

IADSA welcomes the opportunity to comment on the Report of the Electronic Working Group on the Proposed Draft Revision of the Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/CL 9-1987). IADSA comments are as follows:

### **GENERAL COMMENTS**

1. Page 2 (Background) IADSA believes that there should be a greater focus on addressing requirements of key micronutrient compounds for long-term health and well-being, and not only on preventing or correcting demonstrated micronutrient deficiencies. The maximisation of a healthy lifespan and greater recognition of the health benefits of micronutrients should be key issues as well as prevention of deficiency diseases.
2. IADSA strongly supports not just the desirability of using scientific risk assessment to guide decision-making, but also a clear principle stating that any determinations of levels to which permitted nutrients could be added are established by scientific risk assessment based on generally accepted scientific data. The use of scientific risk assessment, e.g. use of Upper Safe Level (UL) and Highest Observed Intake (HOI) should be the key criterion for setting maximum amounts in foods with added nutrients and in food supplements.
3. IADSA supports a pragmatic approach to the General Principles, recognising that significant compromises are required to embrace the diversity of views on the structure of the document and status of Principles versus Guidance.
4. In the interests of clarity and understanding, it may be acceptable to retain/repeat elements of text as long as the meaning is accurate and not misleading. Similarly, IADSA supports the pragmatic solution to minimise change from the original document when there is no agreement.

### **SPECIFIC COMMENTS**

#### **INTRODUCTION**

IADSA supports that the revised text states that the principles are applicable to mandatory and voluntary addition and that FAO/WHO publications are included as reference.

#### **1. SCOPE**

IADSA supports that the statement includes “not including vitamin and mineral food supplements” and the footnote.

#### **2. DEFINITIONS**

IADSA supports the definitions as presented. In addition:

- IADSA supports the definition for “essential nutrient”, removing the word ‘healthy’ in consistency with the Guidelines on Nutrition Labelling.
- IADSA considers that since **Section 2.7** refers to voluntary nutrient addition, the text should say when a food manufacturer **chooses** to add specific nutrients. If the addition has to gain permission from national authorities, it is no longer voluntary.

#### **3. PRINCIPLES**

IADSA supports the use of the word “fundamental” in **Section 3.1**.

IADSA considers that the words in **Section 3.1.4** “other policies established by national authorities” are too vague and possibly restrictive.

IADSA supports the statement in **Section 3.1.5** on that “additions of essential nutrients to foods should not be used to mislead or deceive consumers”.

#### **3.2 (NEW) SELECTION ON NUTRIENTS AND DETERMINATION OF AMOUNTS**

IADSA agrees with alternative text for **Sections 3.2.2, 3.2.3 and 3.2.4**.

However, for clarity IADSA proposes to consider the following wordings for **Sections 3.2.1 to 3.2.4**:

- 3.2.1** The addition of an essential nutrient should be scientifically and nutritionally justified in line with one or more of the purposes states in 3.1.1 and be present at a level that will not result in either an excessive or an insignificant intake of the added essential nutrient.

**3.2.2** The amounts added to foods should take into account (a) the upper safe levels of the nutrient established by scientific risk assessment based on generally accepted scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different population groups; (b) the intake of nutrients (e.g. vitamins and minerals) from all dietary sources (conventional foods, foods with added nutrients and food supplements) including exposures considered to be inadequate or excessive.

**3.2.3** The upper safe level (or tolerable upper intake level) UL is the maximum level of total chronic intake of a nutrient from all sources that is judged to be unlikely to pose a risk of adverse health effects to humans. Where a UL cannot be established, another risk assessment value, the Highest Observed Intake (HOI) approach developed by FAO/WHO in 2006 can be used. In the absence of a UL, the HOI is the highest intake based on the available data to show the absence of adverse effects up to that intake. **Note: reference to both UL and HOI as risk assessment values is accepted by Codex in its Nutritional Risk Analysis Principles and Guidelines for application to the work of the Codex Committee on Nutrition and Foods for Special Dietary Uses (Codex Alimentarius Commission Procedural Manual, 19<sup>th</sup> Edition, 2010 – pages 120-126).**

**3.2.4 (now under alternative text for 3.2.2 and 3.2.3)**

If the reference intakes (RDA or pNRV) for the population are close to the UL/HOI, the following criteria should be taken into account:

- a) Contribution of individual foods/products to the overall diet of the population in general or of subgroups of the population
- b) The nutritional composition of the foods/products

**SECTION 3.2.5 (new):** IADSA considers that the Upper Level of Intake (UL) already includes allowance for adverse effects by definition and that the text in this section could be used to restrict voluntary additions unnecessarily.

**SECTION 3.3.1 (new):** The text in this section refers to certain foods being excluded from voluntary addition because of their ubiquity in the food supply and potential high exposure. This may be restrictive and subjective. Therefore, IADSA suggests combining the two alternative texts.

**SECTION 3.5.1 (new):** IADSA recommends that the words “public health need” should be deleted from the text and that it should refer only to **the purpose of the addition**.

**SECTION 3.5.2 (new):** IADSA considers that the meaning is unclear in this section.

#### **4.0 PRINCIPLES FOR TYPES OF NUTRIENT ADDITION**

**SECTION 4.1:** IADSA considers that this section needs to clearly state mandatory addition.

**SECTION 4.1.4:** IADSA considers that this section mixes technical selection of appropriate food vehicle and exposure (intake) data. Most countries will not have P2.5, P5, P95 or P97.5 intake data.

#### **ICBA - International Council of Beverages Associations**

The International Council of Beverages Associations (ICBA) is an international nongovernmental organization that represents the interests of the worldwide nonalcoholic beverage industry. The members of ICBA operate in more than 200 countries and produce, distribute, and sell a variety of nonalcoholic beverages, including sparkling and still beverages such as soft drinks, juice-containing beverages, bottled waters, and ready-to-drink coffees and teas.

With respect to Agenda Items 6:

- ICBA supports the revision of the General Principles. We agree that there is a need to update the current document based on new scientific understanding and prevailing practices. In particular, the current document does not recognize the potential of vitamins and minerals to contribute to optimum health, when consumed beyond levels that prevent deficiency.

- ICBA believes that the addition of nutrients to foods should be based on benefits to public health and that any limits should be based exclusively on matters related to safety. As such, we do not support the exclusion of any food or beverage based on nutrient composition or ubiquity in the food supply.
  - Use of nutrient composition categorizes foods and beverages as “good” or “bad” without taking into account portion size or frequency of consumption within the context of the total diet.
  - Allowances for the addition of nutrients should not disparage or demonize any food or beverage, or the role that the food or beverage can have in a sensible, balanced diet.
  - In setting dietary guidance, focus should be placed on “how much” of a food or beverage is consumed (portion control) and “how often” it is consumed, within context of the overall diet.
- ICBA emphasizes the need for governments and other stakeholders to implement consumer education programs, with the goal of building consumers’ awareness, understanding and use of nutrition information as a tool for making dietary choices that meet individual calorie and nutrient needs.
- Issues related to consumer communication and understanding should be addressed through the *Codex Guidelines for the Use of Nutrition and Health Claims*.

Based on the above, ICBA supports the following changes to the text as presented in Appendix A, Table 3.

<b>3.3 (New) Selection of Foods</b>	.
<p><del>3.3.1 (new) [Certain foods may have to be excluded from voluntary nutrient addition 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 in non-target populations.]</del></p> <p>Or</p> <p><del>[The selection of appropriate foods to which essential nutrients may be added is best determined at national/regional/local level taking into account dietary habits, socioeconomic situations and the need to avoid any risks to health.]</del></p> <p>Or</p> <p><del>[The selection of food(s) to which to add an essential nutrient(s) should primarily be based on achieving appropriate purposes of nutrient addition as identified in 3.1.1.]</del></p>	ICBA does not agree that is necessary to restrict the addition of essential nutrients to certain foods, or conversely exclude certain foods from the addition of essential nutrients. The addition of essential nutrients should be safe and rational. Setting limitations can lead to the elimination of food vehicles that are effective carriers of essential nutrients, such as the use of salt as a vehicle for the addition of iodine.
<p><del>3.2 (new) The selection of appropriate foods [or categories of foods] to which essential nutrients [may] / [may not] be added should take into account the nutritional value of the foods and is best determined by National Authorities.</del></p> <p><del>[In addition, essential nutrients should not be added to alcoholic beverages and unprocessed foods, including, but not limited to, fruit, vegetables, meat, poultry and fish.] (Note: With this option, new 3.3.4 and 3.3.5 would be deleted.)</del></p>	
<del>{3.3.4 (new) Essential nutrients should not be added to unprocessed foods, including, but not limited to, fruit, vegetables, meat, poultry and fish.}</del>	ICBA supports retention of this provision
<del>4.2.2 Former 4.2 A food should be considered a significant contributor to intake of an essential</del>	ICBA supports deletion of 4.2.2. It is extremely detailed and would be complicated to apply.



<p><del>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 [daily intake reference value]/ [recommended nutrient intake]/ [NRV]/ [INL 98] in a reasonable daily [intake] / [consumption] of the food (or in the case of an essential nutrient for which there is no [daily intake reference value]/ [recommended nutrient intake]/ [NRV]/ [INL 98] 10% of the average daily intake of the nutrient).</del></p> <p><del>[Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this nutrient need not be restored.]</del></p>	
--	--