

# 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.org](http://www.codexalimentarius.org)

Agenda Item 6

CX/NFSDU 12/34/9-Add.2

Original language only!

## 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 of the procedure)*

#### Comments from:

CANADA

CHILE

COSTA RICA

EUROPEAN UNION

NEW ZEALAND

NORWAY

THAILAND

UNITED STATES OF AMERICA

ICGMA

IDF

## CANADA

Appendix A. Draft Revised *General Principles for the Addition of Essential Nutrients to Foods*, Sept, 2012

Table 3: Proposed Revised Text from Table 2 – Clean Version	Comments from Canada
<p><b>INTRODUCTION</b> (Revised) The [<i>General Principles</i>] 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.</p>	Canada agrees with the revised introduction.
(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.	Canada agrees with this principle.
(new) The Principles are applicable, as appropriate, to both mandatory and voluntary addition of essential nutrients unless otherwise indicated.	Canada agrees with the addition of this statement but suggest that it might be better positioned under scope.
(new) National authorities may also consult FAO/WHO publications for further guidance on nutrient addition.	Canada agrees with this principle.
<p><b>1. SCOPE</b> These Principles apply to the addition of essential nutrients to foods, not including vitamin and mineral food supplements<sup>1</sup>.</p> <p><sup>1</sup>See the Codex <i>Guidelines for Vitamin and Mineral Food Supplements</i> (CAC/GL-55-2005)</p>	Canada agrees with this revised statement, however we suggest adding the principle about mandatory and voluntary addition currently in the introduction under scope.
<p><b>2. DEFINITIONS</b> For the purpose of these Principles:</p>	<p>If they are used in the document, Canada suggests adding definitions in this section or referencing to other existing Codex definitions for:</p> <ul style="list-style-type: none"> <li>- “foods for special dietary uses”</li> <li>- “INL 98”</li> <li>- “NRV”</li> </ul>
<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>	Canada agrees with this revised definition and agrees with the deletion of the definition of the term nutrient since it is not used in the document. However, we note that the Codex Nutritional Risk Analysis Principles and Guidelines cite this document for both definitions of nutrient and essential nutrient.
<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>	Canada suggests removing “flavour and odour” as they cannot always be equivalent in substitute foods – e.g. meat substitutes. Canada agrees with deleting the example of plant-based beverage as examples are not provided for other terms like restoration.
<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>	Canada agrees with this definition. We suggest adding (s) to the word nutrient.
<p><b>If retained, Proposed revised definition for option 3):</b> <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>	Canada suggests removing the definition for fortification if it is no longer used in the document.
<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</p>	Canada agrees with this definition. We are unsure if the end of the sentence “or in order to compensate for natural variations in essential nutrients” is necessary.

<p>compensate for natural variations in essential nutrients.]</p>	
<p><b>2.6 (new) <i>Mandatory nutrient additions</i></b> is when National Authorities require food manufacturers to add specified essential nutrients to particular foods or food categories.</p>	<p><b>Canada agrees with this definition.</b></p>
<p><b>2.7 (new) <i>Voluntary nutrient addition</i></b> is when National Authorities permit food manufacturers to add specified essential nutrients to particular foods or food categories</p>	<p><b>Canada agrees with this definition.</b></p>
<p><b>2.9 <i>Special purpose foods</i></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><b>Canada agrees with the revised definition. We note that the definition for FSDU in Codex labeling standard says “Foods for Special Dietary Uses are those foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders and which are presented as such[13].”</b>  <b>[13] This includes foods for young infants and children</b>   <b>If foods for young infants and children are considered FSDU, the committee should consider deleting the text in brackets.</b></p>
<p><b>2.11 (new) <i>Population</i></b> refers to a national population or specific population group(s) as appropriate.</p>	<p><b>Canada agrees with this definition.</b></p>
<p><b>3.0 PRINCIPLES</b></p>	
<p><b>3.1 (New) Fundamental Principles</b></p>	<p><b>Canada notes that for completeness, a principle related to safety should probably be added to the Fundamental Principles, Section 3.1.</b></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 more essential nutrients in the population;</li> <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><b>Canada agrees with this principle and suggests removing all the brackets.</b></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><b>Canada agrees with this principle and suggests removing all the brackets. We suggest adding “essential” before nutrient addition in the first sentence while retaining the rest of the text:</b></p> <p>National authorities should determine whether essential 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>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</p>	<p><b>Canada agrees with this principle. We note that the language used here “national food standards, regulations or guidelines” differs from what is used in the introduction “developing guidelines and legal texts”. The committee may consider using “national food standards, regulations or guidelines” both here and in the introduction as this text is more descriptive.</b></p>

<p>they should be present.</p>	
<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</p>	<p>Canada agrees with this principle.</p>
<p><b>3.2 (New) Selection of Nutrients and Determination of amounts</b></p>	
<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>Canada agrees with this principle with edits. We prefer to use “amount of an added” instead of “addition of an” essential nutrient since it is the amount of nutrient added that should be scientifically and nutritionally justified. We also believe that it may be sufficient to say “scientifically and nutritionally justified and not refer to principle 3.1.1. For increased clarity and to avoid duplication (the UL information is covered in other principles) we suggest the following edits:</p> <p><del>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] be carefully considered to {reduce}{limit} the risk of adverse effects from excessive intakes considering [total intakes] from all [relevant] sources [including from food supplements and not result in an insignificant intake. of [the added] essential nutrient[s], [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.]</del></p> <p>Clean version:                  The amount of an added essential nutrient should be scientifically and nutritionally justified and should be carefully considered to {limit} the risk of adverse effects from excessive intakes considering total intakes including from food supplements and to not result in an insignificant intake.</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>Canada agrees with this principle. We suggest not retaining the text in brackets in the first sentence as it is redundant since consideration of populations at risk of excessive intake would be expected to be included in an assessment of potential exposure to excessive intakes. We also suggest not retaining the second sentence as we believe this information is already addressed in 3.3.1.</p> <p>Clean version with minor edit for clarification :                  3.2.2 (new) The Upper Level of Intake should be used as a reference to assess potential exposure to excessive intakes of essential nutrients and to estimate safe limits of addition.</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</p>	<p>Canada prefers the first option as we believe it is clearer and less prescriptive. We also suggest the following edits for clarification:</p> <p>Potential change to population intakes resulting from essential nutrient addition should be estimated as part of the decision making <del>about nutrient addition to</del></p>

<p>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 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><b>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 dietary intake reference values for adequacy and for safety.”</b></p> <p><b>We are concerned that the text in the 2<sup>nd</sup> option suggests it is ok to have individual foods with added essential nutrients up to the UL.</b></p>
<p><b>3.2.4 (new)</b> 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>.</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><b>Canada agrees with this principle with edits. We also believe it is not necessary to make reference to what National authorities may do in this principle.</b></p> <p>Where an Upper Level of Intake is not available, [<del>National authorities may consider</del>] the scientific evidence to support the safe addition of an essential nutrient [should be considered], including [demonstration of <del>an upper</del> a level or a range of-intake that is unlikely to result in adverse health effects] for example [<del>for the potential relevance of</del> Highest Observed Intake<sup>1</sup>.</p>
<p><b>[3.2.5 (new)</b> 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>Canada believes it is important to take into consideration the severity of the adverse health effect on which the UL is based to inform restrictions on essential nutrients permitted to be added to foods on a voluntary basis as it may allow for more or less flexibility depending on the nutrient.</b></p>
<p><b>3.2.6 Former 3.3</b> 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><b>Canada agrees with this principle and prefers “the amount of an essential nutrient”. Canada suggests that the committee consider incorporating this principle with the principle under 3.2.1.</b></p>
<p><b>3.2.(new)</b> 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><b>Canada agrees with this principle and prefers the first option for the bracketed text but believes this principle is primarily relevant to voluntary addition. We also believe the information presented in the second option may already be covered in 3.1.3 but could partly be incorporated into this.</b></p> <p><b>Revised text:</b>  <b>When national authorities may establish minimum limits for the addition of essential nutrient to foods, they should take into account the intended purpose of addition and, <del>Minimum amounts for the addition of essential nutrients to foods should take into account the</del> conditions of use for a “source of” claim in the Guidelines for use of nutrition and health claims (CAC/GL 23-1997).</b></p>

<p><b>3.3 (New) Selection of Foods</b></p> <p><b>3.3.1 (new)</b> [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, 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><b>Canada prefers option 2 with edits including a concept from option 1 as we believe that voluntary addition should usually not be permitted in staple foods unless it is part of an agreed upon public health program. We also suggest combining 3.3.1 and 3.3.2 by adding “nutritional value of the foods” in the first sentence.</b></p> <p>The selection of appropriate foods to which essential nutrients may be added is best determined by National Authorities <del>national/regional/local level</del> taking into account the nutritional value of the foods, dietary habits and socioeconomic situations. <del>The need to avoid any risks to health.</del> When not part of a public health program, <b>voluntary nutrient addition to staple foods should be carefully considered to reduce the risk of adverse effects from excessive intakes.</b></p> <p><b>Clean version:</b></p> <p>The selection of appropriate foods to which essential nutrients may be added is best determined by National Authorities taking into account the nutritional value of the foods, dietary habits and socioeconomic situations.-When not part of a public health program, <b>voluntary nutrient addition to staple foods should be carefully considered to reduce the risk of adverse effects from excessive intakes.</b></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><b>Canada suggest combining this principle with 3.3.1 for simplicity.</b></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><b>Canada suggests deleting this principle.</b></p>
<p><b>[3.3.5 (new)</b> Essential nutrients should not be added to alcoholic beverages.]</p>	<p><b>Canada agrees with this principle and would prefer to keep it separate as it also conveys an important concept.</b></p>
<p><b>3.4 (new) Technological aspects</b></p>	<p><b>Canada believes that this section should be retained as it conveys important principles.</b></p>
<p><b>3.4.1 (new)</b> 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><b>Canada agrees with this principle.</b></p>
<p><b>3.4.2 Former 3.4 with modifications</b> The added essential nutrient should be sufficiently stable in the food under customary conditions of processing, packaging, storage, distribution and use.</p>	<p><b>Canada agrees with this principle.</b></p>
<p><b>3.4.3 Former 3.6</b> The added essential nutrient should [have minimal impact on the original food characteristics] / [not impart undesirable characteristics to the food] (e.g.</p>	<p><b>Canada agrees with this principle. We prefer the first option for the bracketed text as we believe that it is more feasible to say minimal impact rather than no</b></p>

<p>colour, taste, flavour, texture, cooking properties) and should not unduly shorten shelf-life.</p>	<p><b>impact.</b></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>Canada agrees with this principle. We would suggest retaining the word “standardized” as we believe it is an important concept and would also use the term “bioavailability” rather than availability as it is a term well understood in nutrition.</b></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><b>Canada agrees with this revised principle and prefers the second option for the bracketed text at the beginning of the sentence. For the bracketed text later in the sentence we prefer a shortened version of the first option – see below.</b></p> <p>3.5.1 (new) <del>[It is important that National authorities] / [National authorities should] monitor population intakes of essential nutrients</del> 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] <del>or [the purposes identified in 3.1.1]</del> 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>Canada questions why this principle is needed. The main purpose of monitoring is to measure changes after an intervention and this could be done using other measures such as blood or urinary data.</b></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 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><b>Canada agrees with this principle but suggests edits to simplify the text.</b></p> <p>There should be a demonstrated public health need for increasing the intake of an essential nutrient in <del>one or more</del> a 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 or sub-clinical evidence of deficiency, <del>subclinical evidence of deficiency</del>, [suboptimal nutritional status], <del>[evidence from valid biochemical indicators]</del>, and estimates indicating inadequate or potentially inadequate intake of nutrients, <del>estimates indicating potentially inadequate intakes of nutrients, and/or by estimates of possible deficiencies because of changes in food habits.</del></p> <p>Clean version:          There should be a demonstrated public health need for increasing the intake of an essential nutrient in a population 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 or sub-clinical evidence of deficiency, suboptimal nutritional status, and estimates indicating inadequate or potentially inadequate intake of nutrients</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</p>	<p><b>Canada agrees with this principle and believes that the bracketed text is not necessary. We suggest that the</b></p>

<p>population at risk [of inadequate intake].</p>	<p><b>committee consider using the term “target population” instead of “population at risk”.</b>  <b>Clean version: The food(s) selected as a vehicle for the added essential nutrient(s) should be consumed by the target population.</b></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><b>Canada believes this principle may be deleted as the information is covered in 3.1.3.</b></p>
<p>[Switch order with 4.1.3]:          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><b>Canada agrees with this principle.</b></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>Canada believes that cost-effectiveness is not only related to the intended consumer so we suggest removing that part of the sentence.</b></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><b>Canada generally agrees with having a principle related to restoration. We believe that the term “significant contributor to intake” should be used rather than “significant source” as restoration efforts should focus on “staple” foods (“significant source of energy and/or essential nutrients in the food supply” was the original text).</b></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 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.]</p>	<p><b>However, Canada notes, on further reflection, that, if it is accepted that the intention of 4.2.1 is to capture foods that are significant contributors to intake in the population, the method described in 4.2.2 does not actually determine this. Rather it determines if the food is a significant source of the nutrient in a way similar to that used to set “source of” claim criterion for labelling, which is independent of how much is consumed by the population. The aspect of significant contributor to intake or source in the food supply is not accounted for.</b></p> <p><b>As previously recommended, Canada considers that, as work progresses, it might be worthwhile for the committee to re-look at how the benchmarks for significant contributor to intake and significant source for restoration and nutritional equivalence were derived and determine if they should be revised or if this level of detail is necessary in the General Principles.</b></p> <p><b>If a reference value is used in the updated benchmarks, Canada suggests referring to a single reference value that is well understood globally and defined by Codex. While not developed for this purpose, the NRV is one such value and may serve the purpose. Alternatively, countries may wish to develop a single value pertinent to their populations such as a weighted average dietary intake reference value weighted according to their population age/sex distribution. We also suggest retaining the term “in a reasonable daily intake” as using “in a reasonable daily consumption” is awkward. Canada suggests that the committee consider deleting the bracketed part at the end of the sentence since if a nutrient does not have an established NRV, it is most</b></p>



	<p>likely not a nutrient of public health significance.</p> <p>The sentence “[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.]” should be presented as a separate principle (principle 4.2.3) as per the principles for nutritional equivalence.</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>Canada agrees with this principle. We believe that “source” should be the term used for nutritional equivalence as the focus is on foods being represented as a substitute for another food therefore the concept of “contributor to intake” is not important in this case. If the committee agrees with the above, “in the population” should be deleted.</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].  <del>Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this need not be equivalent.</del></p>	<p>-We believe that the term “significant source” should be the term used as per the comments provided in 4.3.1.                  -As noted for the principles on restoration, Canada suggests using the term NRV as it is a single value and a term well understood globally and defined by Codex or alternatively, countries may wish to develop a single value pertinent to their populations such as a weighted average dietary intake reference value weighted according to their population age/sex distribution.                  -Delete the last sentence so that it appears as a separate principle under 4.3.3                  -As noted in 4.2.1, Canada considers that it might be worthwhile for the committee to re-look at how the benchmarks for significant contributor to intake and significant source for restoration and nutritional equivalence were derived and determine if they should be revised.</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>Canada agrees with this principle.</p>
<p><b>4.4 Nutrient addition to Special Purpose Foods</b></p>	
<p>4.4.1 <i>Former 7.1</i> [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.]  <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>Canada prefers 2<sup>nd</sup> option as it is clear and concise. We suggest ending the sentence after population as we believe the rest of the information is unnecessary.</p>

## CHILE

(English)

- *"Introduction"*.

**Re:** We are in agreement with leaving this point as it currently stands in the document.

- *"(new) The [General Principles] [Guidelines] for the Addition of Essential Nutrients to Foods [take into consideration provisions in] [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), where applicable"*.

**Re:** There is agreement with the proposal of the "Recommendation" text

- *"(new) The General Principles for the Addition of Essential Nutrients to Food are applicable, as appropriate, to both mandatory and voluntary addition of essential nutrients unless otherwise indicated"*.

**Re:** The committee members are in agreement with the proposed modifications.

- *"(new) National authorities should also consult the FAO/WHO Guidelines on food fortification with micronutrients (WHO, 2006) for further information"*.

**Re:** The committee members are in agreement with the proposed modifications.

- *"[DEFINITIONS] [DESCRIPTION]"*

**Re:** We believe it is adequate to keep this as "Definition" and not as "Description".

- *"2.1 Nutrient means any substance normally consumed as a constituent of food: which provides energy; or (b) which is needed for growth and development and maintenance of healthy life; or (c) a deficit of which will cause characteristic biochemical or physiological changes to occur"*.

**Re:** The committee members are in agreement with the proposed modifications.

- *"2.2 Essential nutrient means any substance normally consumed as a constituent of food which cannot be synthesized in adequate amounts by the body and (a) which is needed for growth and development and the maintenance of healthy life and cannot be synthesized in adequate amounts by the body; or (b) a deficit of which will cause characteristic biochemical or physiological changes to occur."*

**Re:** The committee members are in agreement with the proposed modifications.

- *"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"*.

**Re:** We agree to withdrawing [Flavour and Odour] from the text.

- *"2.4 (former 2.3) Nutritional equivalence means being of the addition of one or more essential nutrient to a substitute food to achieve a similar nutritive value to its normal counterpart in terms..."*.

**Re:** The committee members are in agreement with the proposed modifications.

- *"2.5 Fortification or, which may be called enrichment, means the addition of one or more essential nutrients to a food, whether or not it is normally..."*

**Re:** The committee members are in agreement with the proposed modifications.

- *"3.1 (New) Fundamental [Overarching] [General] Principles"*

**Re:** Abstention

- *"3.1.3 (New) National authorities should determine whether [nutrient addition] fortification should be mandatory or voluntary..."*

**Re:** The committee members are in agreement with the proposed modifications.

- *"3.1.4 (Former 3.11 with modifications) The mandatory and voluntary addition of essential nutrients to foods..."*

**Re:** The committee members are in agreement with the proposed modifications.

- *"3.1.5 (Former 3.8 with additions) Addition of essential nutrients to foods should not be used to mislead or deceive the consumer, including...."*

**Re:** The members agree to the text, but without square brackets.

- *"3.1.1 Essential nutrients may be appropriately..."*

**Re:** The committee members are in agreement with the proposed modifications for question 1.

**Re:** Abstention for question No. 2

- *"3.1.2 The above purposes may be achieved by restoration, nutritional equivalence of substitute foods, fortification nutrient addition mandated to correct inadequate intakes, and ensuring the appropriate nutrient composition of a special purpose food or other addition in accordance with these principles."*

**Re:** The committee members are in agreement with the proposed modifications.

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

**Re:** Abstention

- *"3.2.1 Former 3.2 with modifications (also considered to cover 6.2.5): The 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 be present...."*

**Re:** The committee members agree and, due to exclusion of the first definition, it should be the second proposal.

- *"3.2.3 (new) Potential change to population intakes should be estimated as part of the decision making about nutrient addition...."*

**Re<sub>1</sub>:** The limitation must respond to the risk analysis and not to the criterion of sufficiency or insufficiency and, in relation to the aforementioned, we think that this this type of observation must be included.

**Re<sub>2</sub>:** The committee members are in agreement with the proposed modifications, related to the focus for controlling the addition of essential nutrients to foodstuffs.

- *"3.2.4 (new) Where an Upper Level of Intake is not available, the scientific evidence to support the safe addition of an essential nutrient should include..."*

**Re:** We think that the HOI would be the best criterion in the absence of UL

- *"3.2.5 (new) The severity of the adverse effect on which the Upper Intake Level (UL) is based should be reviewed by national authorities and should inform"*

**Re:** We believe it is necessary to consider the severity of adverse effects whenever there is a justified benefit for public health.

- *"3.3.2 (new) The selection of appropriate foods to which essential nutrients may be added should take into account the nutritional value of the foods and is best determined by National Authorities...."*

**Re:** As there is no clear definition of the nutritional value for the addition of nutrients, we have no means of issuing an opinion although, operationally, we believe that an alternative would be to say which foods have to be added.

We also think of the effectiveness that regulation of advertising may have on disposition to add essential nutrients and their net content.

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

**Re:** We think that these ought to be retained and maintained.

- *"4.1 Nutrient Addition Mandated For Purposes of fortification [Correcting]/[Reducing] Inadequate Intakes"*

**Re:** The committee members agree that this matter ought to be considered.

- *"(4.1.4) 6.2.5 The amount of the essential nutrient added should not result in excessive intakes by individuals with a high intake of a fortified food".*

**Re:** We agree on the need to consider what is proposed in this point.

- *"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".*

**Re:** We agree to the suggested change, but we do not believe that this section ought to go to Section 3 because it is something that concerns obligatory and not voluntary fortification.

- *"4.2.2 Former 4.2 A food should be considered...."*

**Re:** We think that INL 98 or a daily intake +2DS ought to be used

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

**Re:** We believe that this section ought to be kept because it contributes to protecting dietary quality.

- *"4.4 Nutrient addition to Special Purpose Foods".*

**Re:** This section must be considered for special purposes because the need exists.

- *"4.4.1 Former 7.1 [Essential] nutrients may be added to special purpose foods, including foods for special dietary uses, to ensure na..."*

**Re:** The committee considers keeping "Nutrient Density" because this term intends what is actually required in a product and not only what it contains, explaining it in a better way.

## **COSTA RICA**

Costa Rica agradece al Grupo de trabajo electrónico (GTE) coordinado por Canadá, con la asistencia de Nueva Zelanda, por la preparación del informe de la referencia. A continuación detallamos nuestra posición con respecto a los aspectos que deberían discutirse en el Comité:

### **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.

En la introducción, Costa Rica apoya las ediciones realizadas al texto. Estamos a favor del uso del término "Principios Generales" y además consideramos que son las autoridades nacionales las que elaboran las directrices y textos legales relacionados con la adición de nutrientes esenciales a los alimentos.

*(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.

Costa Rica apoya las frases "Los principios" y "tienen en cuenta disposiciones de" nos parecen más explicativas en cuanto al contenido del texto revisado.

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

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

Costa Rica apoya los nuevos párrafos que se refieren a que los principios aplican tanto a la fortificación obligatoria como a la voluntaria, así como el que se refiere a que los documentos de FAO/OMS pueden ser consultados con respecto al tema de adición de nutrientes.

## 1. SCOPE

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

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

En el ámbito de aplicación, Costa Rica apoya las ediciones propuestas, consideramos que el texto modificado queda muy claro.

**2.1 Nutrient** means any substance normally consumed as a constituent of food:

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

Con respecto a la defición de “nutriente”, Costa Rica considera que podría eliminarse, dado que el documento solo menciona “nutrientes esenciales”. Sin embargo, en caso que el Comité decidiera mantener la definición, estamos de acuerdo en que se elimine el término “saludable” en el inciso (b).

**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.

Costa Rica apoya las ediciones realizadas a la definición de nutriente esencial, consideramos que es completa y abarca el aspecto más importante de la esencialidad de un nutriente, es decir que no puede ser sintetizado por el cuerpo en cantidades adecuadas y por tanto debe ser aportado por la dieta.

**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.~~]

Costa Rica considera que no necesariamente los alimentos sucedáneos comparten su aroma y olor, pues su composición difiere. Sin embargo, Costa Rica propone agregar en su lugar la frase “entre otras características organolépticas”, con el objeto de dejarlo abierto a otras posibilidades. No consideramos necesario el ejemplo que aparece entre corchetes, por lo que sugerimos sea eliminado.

**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.

Costa Rica apoya las ediciones realizadas a la definición de Equivalencia nutricional, considera que la opción que propone el grupo de trabajo, es la más clara.

**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}.

Costa Rica considera que la opción tres para la definición de fortificación es la que cubre tanto la fortificación obligatoria, como la voluntaria. Sin embargo, sugerimos se mantenga el sinónimo de “enriquecimiento” puesto que los terminos se ha utilizado como equivalentes históricamente y por ello se utilizan indistintamente en el etiquetado de alimentos. Por otra parte, dado que los principios se refieren a “adición de nutrientes esenciales a los alimentos”, nos parece necesario definir fortificación, como una de las formas de agregar nutrientes a los alimentos.

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

Costa Rica apoya las ediciones realizadas a la definición de Equivalencia nutricional, sin embargo consideramos que debe corregirse el orden de la frase “de nutrientes esenciales” y el plural de pérdidas, tal como se resalta en el texto que se transcribe. Consideramos que la definición es necesaria, así como la frase entre corchetes. Es una práctica común agregar nutrientes esenciales por variación natural en el contenido del alimento, y por lo tanto debería considerarse este tipo de adición como una restitución.

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

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

Costa Rica apoya las ediciones realizadas a las definiciones de adición obligatoria y voluntaria de nutrientes.

~~**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].

“**Foods for Special Dietary Uses** are those foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders and which are presented as such.<sup>1</sup> The composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist.

<sup>1</sup> This includes foods for infants and young children.”

Costa Rica considera que debería reemplazarse la definición que se anota para alimentos para propósitos especiales por la que aparece en el la norma Codex Stan 146-1985 Norma General del Codex para el etiquetado y declaración de propiedades de alimentos preenvasados para regímenes especiales, tal como lo propusieron algunos miembros del GTE. No deberían existir definiciones diferentes si ya un término está incluido en otra norma del Codex.

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

Costa Rica apoya el mantener la definición de población, tal como lo propone el GTE.

## **3.0 PRINCIPLES**

### **3.1 (New) Fundamental Principles**

Costa Rica está de acuerdo con el título en 3.0 y el subtítulo en 3.1.

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;

Costa Rica apoya las ediciones y la ubicación de los principios fundamentales en la sección 3.1.1.

~~3.1.2 The above purposes may be achieved by restoration, nutritional equivalence of substitute foods, fortification nutrient addition mandated to correct inadequate intakes, and ensuring the appropriate nutrient composition of a special purpose food or other addition in accordance with these principles.”<sup>2</sup>~~

Costa Rica apoya eliminar el punto 3.1.2, ya que no considera que sea necesario.

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.

Costa Rica apoya las ediciones realizadas al punto 3.1.3 y por tanto sugiere se eliminen los corchetes.

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.

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

Costa Rica apoya las ediciones realizadas a los puntos 3.1.3, 3.1.4 y 3.1.5.

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

Costa Rica apoya las ediciones realizadas al punto 3.2.

**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 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.}~~

Costa Rica apoya las ediciones realizadas al punto 3.2.1 y por tanto la remoción de los corchetes. Al inicio del párrafo preferimos la opción que dice “La adición de un”.

**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.]~~

**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.”~~

*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.*

Costa Rica apoya el texto alternativo que aparece en letra itálica para los puntos 3.2.2 y 3.2.3 y por tanto la remoción de los corchetes.

**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}~~ ~~{for the potential relevance of Highest Observed Intake}~~.

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.)

Para el punto 3.2.4, Costa Rica apoya el texto “autoridades nacionales pueden considerar”, dado que deben ser ellos quienes determinen el riesgo de efectos adversos a la salud, en caso que no existan niveles de ingesta máxima.

~~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.~~

Dado lo señalado en el punto 3.2.4, Costa Rica no considera necesario el punto 3.2.5 y por tanto sugiere eliminarlo.

~~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.~~

Costa Rica apoya la frase “adición de un nutriente esencial” por considerar que aclara en mayor medida la idea que el punto 3.2.6 desea transmitir.

~~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.~~~~

Costa Rica apoya el texto propuesto para el punto 3.2.7 a excepción del párrafo final. Consideramos que el principio queda claro con las dos primeras ideas, es decir: el establecimiento de valores mínimos, y la posibilidad de tomar en cuenta las condiciones para el uso de declaraciones para “fuente de” establecidas en las Directrices del Codex para el uso de declaraciones nutricionales y saludables, para evitar el engaño al consumidor.

### 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.~~~~

Costa Rica apoya el título de la sección 3.3, asimismo considera que la tercera opción que se presenta para el texto del inciso 3.3.1 es más clara que las anteriores, ya que refiere a los principios fundamentales para la adición de nutrientes esenciales a los alimentos.

~~3.3.2 (new) The selection of appropriate foods ~~for 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.~~

~~~~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.~~~~



Costa Rica apoya la nueva redacción propuesta para la sección 3.3.2 que contempla el texto identificado en 3.3.4 y 3.3.5. Esta opción deja claro cuales serían los alimentos que no deberían ser sujetos de la adición de nutrientes esenciales, de una manera más resumida y práctica.

### 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.

Costa Rica apoya la redacción propuesta para la sección 3.4.1, sin embargo no considera necesaria la frase “en el siguiente orden” y por tanto sugiere eliminarla.

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.

Costa Rica apoya la redacción propuesta para la sección 3.4.2

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.

Costa Rica apoya la redacción propuesta para la sección 3.4.3 y considera que la opción de “tener el mínimo impacto en las características originales del alimento” es una idea más clara que el no impartir características no deseables. En el fondo lo que se quiere es no modificar en gran medida las características propias del producto que se fortifica.

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.

Costa Rica considera que no es necesario agregar la palabra “estandarizada” al punto 3.4.4, dado que para lograr biodisponibilidad, consistencia, distribución y estabilidad, se debe hacer una adición estandarizada.

### 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.

En el punto 3.5.1, Costa Rica considera que la frase “Las autoridades nacionales deberían” es más clara en cuanto a la intención e importancia del monitoreo. Asimismo, preferimos la frase “los propósitos identificados en 3.1.1”, puesto que si ya están descritos, no deberían repetirse con el riesgo de olvidar alguno de ellos.

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

Costa Rica no considera necesario el texto del punto 3.5.2.

### 4.0 ~~[Principles for]~~ Types of Nutrient Addition

Costa Rica considera que el título queda claro sin la frase “principios para”, por lo tanto sugiere que se elimine esa frase.

#### 4.1 (new) ~~Addition [to Address a Demonstrated Public Health Need]~~ ~~[and Mandatory Addition of Essential Nutrients]~~

Costa Rica considera que el título debería ser “Adición obligatoria de nutrientes esenciales” que es el término que aparece en la sección de definiciones.

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.

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].

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

[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.

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.

Costa Rica apoya el contemplar una sección referida a la adición obligatoria de nutrientes esenciales.

#### **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].

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 referente 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.]

Costa Rica apoya el contemplar una sección referida a la adición de nutrientes esenciales para fines de restitución.

#### **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].

4.3.2 *Former 5.2* A food being substituted or partially substituted should be considered a significant contributor to intake of an Essentials 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.

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.

Costa Rica apoya el contemplar una sección referida a la adición de nutrientes esenciales para fines de equivalencia nutricional.

#### **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}.

Costa Rica apoya el contemplar una sección referida a la adición de nutrientes esenciales en alimentos para regímenes especiales.

## EUROPEAN UNION

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

### GENERAL COMMENTS

#### Structure for the Document

The EU generally agrees with the proposed structure for the document and welcomes the inclusion of certain sub-headings under Section 3 to help clarify the scope of the section. However, the EU reiterates its doubts about the need to include certain definitions on Section 2, such as for nutritional equivalence and restoration.

Furthermore, the EU considers that as the purposes of addition of essential nutrients to foods and the principles applicable to all types of addition, are laid down in the Introduction section and/or Section 3 of the document, it is not necessary, for the sake of simplification, to include separate subsections that provide additional principles for the specific types of addition of essential nutrients, such as restoration or nutritional equivalence.

Furthermore, the EU has a number of proposals for modifications to be made within the separate Sections. An overview of these changes is presented in an Annex to the comments.

#### Introduction

The EU considers that it is appropriate to insert the reasons for the addition of essential nutrients to foods in the introductory section of the document. Therefore, the EU believes that the purposes of addition provided by paragraph 3.1.1 should be placed in the Introduction section of the document rather than in Section 3.

#### Mandatory versus Voluntary Addition of Essential Nutrients

The EU reiterates its comments regarding the inclusion of those principles that are specifically applicable to mandatory addition of nutrients in a separate section so as to clarify and simplify the document. This would contribute to the aim of simplifying and clarifying the document.

### DETAILED COMMENTS

In addition to the general comments the EU has the following comments on specific aspects of the draft revised document.

#### INTRODUCTION

The EU considers that the purposes for the addition of essential nutrients to foods provided by paragraph 3.1.1 should be included in the Introduction section of the document and has the following comments to make on the proposed text:

##### *Paragraph 3.1.1*

The EU supports use of the less specific term "*requirements*" rather than "*recommended nutrient intakes*". The EU agrees with deletion of the term "*or specific population groups*" and proposes to delete the reference to "*poor nutritional status*" from the 1<sup>st</sup> and 2<sup>nd</sup> bullet points because it is adequately covered by the 3<sup>rd</sup> bullet point. Therefore, the EU proposes to move this paragraph to the Introduction with the following changes.

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

- contributing to correcting a demonstrated deficiency or [inadequate intakes ~~or poor nutritional status~~] of one or more essential nutrients in the population ~~or specific population groups~~;*

- contributing to meeting ~~recommended nutrient intakes~~ [requirements] of one or more essential nutrients and reducing the risk of [inadequate intakes, ~~poor nutritional status~~ and/or] deficiency;
- contributing to the maintenance or improvement of health and/or nutritional status of the population ~~or specific population groups~~ and/or
- maintaining or improving the ~~overall~~ nutritional quality of foods;"

### **First and second paragraphs**

With regard to the first paragraph of the Introduction section, the EU agrees with the proposed additions and deletions to the text. However, the EU would propose to replace the phrase "national authorities" by "national and/or regional authorities" in order to take into account the different situations between the CMO and the CMCs. This change will be proposed throughout the document.

The EU is in favour of maintaining the original wording (i.e. "take into consideration") in the second paragraph.

### **Third and fourth paragraphs**

The EU considers that the third paragraph should be placed in an introductory paragraph to Section 3 "Principles" and proposes certain changes to the text as follows:

*"The [General Principles] for the Addition of Essential Nutrients to Food are applicable, as appropriate, to ~~both mandatory and voluntary~~ all types of addition of essential nutrients unless otherwise indicated."*

The EU agrees with the proposed wording for the fourth paragraph. However, in the light of the comment above, the EU proposes to replace "National authorities" by "National and/or regional authorities".

## **SECTION 1 - SCOPE**

The EU agrees with the proposed wording for this paragraph.

## **SECTION 2 - DEFINITION**

In accordance with the general comments, the EU considers that in order to simplify the text and to avoid duplication, it is not necessary to include certain definitions in the document. The EU believes that the text of the definition for mandatory nutrient addition should be moved to a separate section that identifies the principles for mandatory nutrient addition and that the definition for voluntary nutrient addition is not needed as the principles it intends to cover are included in the Introduction.

Furthermore, the EU reiterates its doubts on the need to include definitions for fortification, restoration, nutritional equivalence and for substitute foods. It is not clear how such definitions will be used in conjunction with the purposes and basic principles laid down in the Introduction and Section 3 as these are applicable to all types of nutrient addition. The EU would appreciate a discussion on the need for and the circumstances under which such definitions would be used.

### **Paragraphs 2.1 and 2.2**

The EU agrees with the deletion of paragraph 2.1 that provides the definition of "nutrient". However, the EU notes that in the definition for an "essential nutrient", the phrase "which cannot be synthesised in adequate amounts by the body" has been included whereas the bullet point "a deficit of which will cause characteristic bio-chemical or physiological changes to occur" has been deleted. The EU cannot agree with this deletion unless there is a good reason to remove this bullet point.

The EU agrees with deletion of the word "healthy".

### **Paragraphs 2.3, 2.4, 2.5 and 2.8**

As mentioned above, the EU does not consider it necessary to maintain the definitions for "substitute foods", "nutritional equivalence" and "restoration".

With regard to paragraph 2.5, the EU considers that the definition of "fortification" should not be retained in the document as the term has been replaced by "nutrient addition" throughout the document.

**Paragraphs 2.6 and 2.7**

The EU proposes to move paragraph 2.6 that defines "mandatory nutrient addition" to subsection 4.1. The EU agrees with the proposed changes to the paragraph however, the EU proposes to replace "*national authorities*" by "*national and/or regional authorities*" and to replace "*mandatory nutrient addition*" by "*mandatory addition of essential nutrients to foods*".

The EU does not consider it necessary to provide a definition for voluntary nutrient addition as the purposes and principles for voluntary nutrient addition are already given in the Introduction section and Section 3 of the document.

**Paragraph 2.9**

The EU believes that there is no need for a definition and additional principles for the addition of essential nutrients to special purpose foods as these are adequately covered by other Codex standards such as those that are relevant to foods for special dietary uses and to foods for infants and young children.

**Paragraphs 2.10 and 2.11**

The EU agrees with the deletion of paragraph 2.10 that defines "*nutrient density*" and of paragraph 2.11 that defines "*standardisation*".

The EU agrees with the proposed wording for paragraph 2.11 (new) that defines "*population*".

**SECTION 3 - PRINCIPLES**

The EU agrees with naming Section 3 "Principles" and considers that this section should include those principles that apply to all types of addition of essential nutrients to foods. The EU reiterates that the points included under sub-section 3.1 ("Fundamental Principles") and the other sub-sections of Section 3 should be limited in number and brief so as to simplify the document.

**Introductory paragraph**

As mentioned in the comments for the Introduction section of the document, the EU considers that the following paragraph should be placed in an introductory paragraph to Section 3 "Principles":

*"The [General Principles] for the Addition of Essential Nutrients to Food are applicable, as appropriate, to both mandatory and voluntary all types of addition of essential nutrients unless otherwise indicated."*

**Sub-section 3.1 - Fundamental Principles****Paragraph 3.1.1**

As mentioned in the Introduction section, the EU considers that paragraph 3.1.1 that provides the purposes of addition of essential nutrients to foods should be moved to the Introduction section of the document with the following changes.

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

- contributing to correcting a demonstrated deficiency or [inadequate intakes ~~or poor nutritional status~~] of one or more essential nutrients in the population ~~or specific population groups~~;*
- contributing to meeting [recommended nutrient intakes]/ [requirements] of one or more essential nutrients and reducing the risk of [inadequate intakes, ~~poor nutritional status~~ and/or] deficiency;*
- contributing to the maintenance or improvement of health and/or nutritional status of the population ~~or specific population groups~~ and/or*
- maintaining or improving the ~~overall~~ nutritional quality of foods;"*

**Paragraph 3.1.2**

The EU agrees with the deletion of this paragraph.

**Paragraph 3.1.3**

With regard to the first sentence, the EU believes that as it is up to the national/regional authorities to determine whether there is a need for the mandatory addition of essential nutrients to foods to address a

public health concern, the phrase "*or voluntary*" should be deleted. Furthermore, the EU proposes, for reasons of consistency and clarity, to replace the text in square brackets, "*nutrient addition*", by "*the addition of essential nutrients to foods*". Therefore, the EU proposes the following changes to the paragraph:

*"National and/or regional authorities should determine whether [~~nutrient addition~~] fortification the addition of essential nutrients to foods should be mandatory ~~or voluntary~~".*

With regard to the second and third sentences of paragraph 3.1.3, the EU considers that it is not necessary to specify the conditions to take into account when choosing the type of nutrient addition, such as the extent of public health need. The choice of mandatory addition of essential nutrients to foods in order to address a specific public health concern is the responsibility of national/regional authorities and the EU proposes to include those principles that are applicable to mandatory nutrient addition in a separate section (section 4.1). The EU considers that the principles provided by the last two sentences of paragraph 3.1.3 are covered by the paragraphs that are proposed for inclusion in section 4.1.

#### **Paragraph 3.1.4**

With regard to the second sentence of this paragraph, the EU proposes to maintain the wording in paragraph 3.11 of the existing General Principles (CAC/GL 09-1987) as it considers that the requirement to include specific provisions identifying the appropriate foods introduces a new element to the paragraph and goes beyond what should (i.e. an obligation) be included in national food standards, regulations or guidelines.

Furthermore, the EU considers that the specific provisions that "*may*" rather than "*should*" be included in national food standards, regulations or guidelines should identify the essential nutrients "*that may be added*", rather than "*the essential nutrients required or permitted to be added*".

Therefore, the EU proposes the following changes to the paragraph:

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

#### **Paragraph 3.15**

The EU does not agree with the proposed deletion in this paragraph of the reference to presentation and labelling practices and the health benefit of the food as this helps to clarify the intention of the principle, and proposes the following text for this paragraph:

*"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]/[and possible additional health benefit] of the food."*

### **Sub-section 3.2 – Selection of Nutrients and Determination of amounts**

#### **Paragraph 3.2.1**

The EU considers that the addition of an essential nutrient should be risk-based rather than "*scientifically and nutritionally justified in line with one or more of the purposes stated in 3.1.1*" as proposed. Furthermore, the EU proposes to delete the term "*including food supplements*" and to include the phrase "*considering total intake from all relevant sources*". Furthermore, the EU considers that this paragraph should state that the "*addition*" (rather than the "*amount*") of the added essential nutrient should be risk-based. The EU believes that the addition of essential nutrients to foods in amounts that are safe is covered by the proposed alternative paragraph for paragraphs 3.2.2 and 3.2.3. Therefore, the EU proposes the following changes to paragraph 3.2.1:

*"The ~~[amount of an added] or [addition of an]~~ essential nutrient should be risk-based and [scientifically and nutritionally justified] [in line with one or more of the purposes stated in 3.1.1] and be present at a level which will not result in either an excessive intake or, for the target population, an insignificant intake of [the added] essential nutrient[s], considering [total intakes] amounts from all [relevant] other sources [including food supplements], [Upper Levels of intake*

*and identification of special subpopulations at risk] 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.]"*

### **Paragraphs 3.2.2 and 3.2.3**

The EU does not consider it necessary to elaborate on dietary modelling and the use of the Upper Level of Intake so as to ensure that the addition of an essential nutrient will not result in excessive amounts. Therefore, The EU prefers the alternative paragraph in italics proposed for 3.2.2 and 3.2.3 to guide the setting of maximum amounts of added nutrients. The EU proposes to replace "national authorities" by "national and/or regional authorities" in the first sentence of the alternative text in italics for paragraphs 3.2.2 and 3.2.3.

### **Paragraph 3.2.4**

The EU supports the deletion of the phrase "National authorities may consider" as follows:

*"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]. ~~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 to provide evidence to ensure that aggregate exposure to the essential nutrient in question is within acceptable limits.]"~~*

### **Paragraph 3.2.5**

The EU considers that it is not necessary to take into account the severity of adverse effects in addition to the UL. It is sufficient to consider the UL of the essential nutrient, which is also in line with the risk-based principles provided by the Codex Guidelines for Vitamin and Mineral Food Supplements (CAC/GL 55-2005). Therefore, the EU proposes to delete paragraph 3.2.5.

### **Paragraph 3.2.6**

The EU considers that paragraph 3.2.6 should be deleted.

### **Paragraph 3.2.7**

The EU considers that minimum limits for the addition of essential nutrients to foods may be established to ensure that consumers are not misled and that the foods to which the nutrients are added meet the purpose of the addition of nutrients to foods as described in paragraph 3.1.1 of the document. Therefore, the EU proposes to maintain the deleted phrase in the first sentence of the paragraph and to delete the last sentence as follows:

*"National and/or regional authorities may establish minimum limits for the addition of essential nutrient to foods to ensure that consumers are not misled and that the foods to which the nutrients are added meet the purpose of the addition of nutrients to foods as described in the Introduction of the [General Principles][Guidelines]. [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.]"~~*

## **Sub-section 3.3 – Selection of Foods**

### **Paragraph 3.3.1**

The EU prefers the second option for paragraph 3.3.1 as the selection of foods to which essential nutrients may be added so as to avoid any risks to health should take into account the specific dietary habits and socioeconomic situations at local level.

### **Paragraph 3.3.2**

The EU proposes the following wording for paragraph 3.3.2 to reflect the possibility ("may") for national authorities to determine the appropriate foods or categories of foods to which essential nutrients may not be added:

*"Foods or categories of foods to which particular groups of essential nutrients may not be added may be determined by national authorities taking into account their nutritional value."*

Furthermore, the EU does not agree with inclusion of the paragraph referring to alcoholic beverages and unprocessed foods, as it considers that the actual selection of foods or categories of foods to which essential nutrients may not be added is not relevant within the context of international guidelines. This is further demonstrated by the difficulties in defining these categories of foods and beverages in an international guideline document.

### **Paragraphs 3.3.4 and 3.3.5**

As mentioned above, the EU considers that paragraphs 3.3.4 and 3.3.5 should be deleted.

### **Sub-section 3.4 – Technological Aspects**

The EU considers that the technological aspects set out in paragraphs 3.4.2, 3.4.3 and 3.4.4 cannot be considered to be principles.

The EU considers that the principles provided by paragraph 3.4.1 should be maintained and proposes to move this paragraph to section 3.2 as it concerns an important aspect of the selection of nutrients. This would also contribute to the simplification of the document.

### **Paragraph 3.4.1**

The EU does not agree with providing the order in which existing standards for purity criteria should be taken into account and therefore proposes to delete the text in square brackets ("*in the following order*").

### **Paragraphs 3.4.2, 3.4.3 and 3.4.4**

As mentioned above, the EU proposes the deletion of these paragraphs.

### **Sub-section 3.5 – Monitoring**

#### **Paragraph 3.10**

The EU agrees with deletion of paragraph 3.10.

#### **Paragraph 3.5.1**

The EU prefers the following options for paragraph 3.5.1:

*"[It is important that National and/or regional authorities] ~~/[National authorities should]~~ monitor population ~~total~~ intakes, from all sources, including ~~of the essential nutrients essential~~ added to foods ~~from all dietary and supplement sources and in order~~ to assess the extent to which ~~the selected public health need for other purpose for addition~~ ~~or~~ [the purposes identified in 3.1.1] is are addressed and to ensure that any risk of excessive intakes is minimised."*

#### **Paragraph 3.5.2**

The EU supports the inclusion of paragraph 3.5.2 and prefers to use the term "*approach*" rather than "*method*".

### **Section 4.0 – [Principles for] Types of Nutrient Addition**

The EU considers that as the purposes of addition of essential nutrients to foods and the principles applicable to all types of addition as laid down in the Introduction section and in section 3 of the document, it is not necessary, for the sake of simplification, to include separate subsections that provide additional principles for the specific types of addition of essential nutrients, such as restoration and nutritional equivalence.

Nevertheless, the EU would welcome a discussion about the relevance of including principles for the different types of nutrient addition in international guidelines.

### **Sub-section 4.1 - Addition of Essential Nutrients [to Address a Demonstrated Public Health Need] [and Mandatory Addition]**

The EU agrees with the justification that there are some principles that are applicable only to mandatory addition of nutrients and these should be included in a separate section.



However, the EU does not agree with inclusion in the title of this section of the phrase "*to address a demonstrated public health need*" as this refers to the purpose of addition which is already provided by paragraph 3.1.1. The purposes for nutrient addition provided by paragraph 3.1.1 apply to all types of nutrient addition.

#### **Paragraph 2.6 (new)**

As mentioned in the comments for the Definition section, the EU proposes to move the definition for mandatory nutrient addition to this separate section with the following changes:

*"Mandatory ~~nutrient~~ addition of essential nutrients to foods is ~~occurs~~ when national authorities ~~governments~~ require food manufacturers to add specified essential nutrients to particular foods or food categories, ~~of foods.~~ ~~for a specific purpose.~~"*

#### **Paragraph 4.1.1**

The EU proposes to delete the second sentence that states that "*a demonstrated public health need, however, may also be addressed through voluntary addition*". The purposes for the addition of essential nutrients to foods are provided by paragraph 3.1.1 and these apply to all types of addition. Therefore, it would be superfluous to include in a section that provides those principles that are specific to the mandatory addition of nutrients, that a demonstrated public health need may also be addressed through voluntary addition. Therefore, the EU suggests deleting this sentence.

The EU agrees with the other proposed changes to the paragraph.

#### **Paragraph 4.1.2**

The EU agrees with the proposed text.

#### **Paragraph 4.1.3**

The EU considers that both the terms "*reduce inadequate intakes*" and "*correct or prevent the deficiency*" should be maintained and proposes the following changes to the paragraph:

*"The amount of the essential nutrient added to the food should aim to be sufficient to reduce inadequate intakes and/or correct or prevent the deficiency that results in ~~meet~~ the public health need ~~when the food is consumed in habitual amounts by the population at risk.~~"*

#### **Paragraph 4.1.4**

The EU agrees with the proposed text.

#### **Paragraph 4.1.5**

The EU considers that this paragraph is of relevance to the mandatory addition of essential nutrients and therefore should be retained in Section 4.

#### **Sub-section 4.2 Nutrient Addition for Purposes of Restoration**

As mentioned above, the EU considers that this section should be deleted.

#### **Sub-section 4.3 Nutrient Addition for Purposes of Nutritional Equivalence**

As mentioned above, the EU considers that this section should be deleted.

#### **Sub-section 4.4 Nutrient addition to Special Purpose Foods**

The EU considers that there is no need for a section that covers "special purpose foods" as these foods are covered by other relevant Codex standards and guidelines, such as those for foods intended for infants and young children, and for use in Very Low Energy Diets. The EU notes that these Codex standards have been adopted or amended after the last revision of the General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987) in 1991.

Therefore, the EU considers that the revision of the General Principles document provides an opportunity to bring it in line with these more recently updated Codex standards for foods that are designed to perform a specific function. In addition, deletion of this section would remove any confusion resulting from the inclusion of principles related to "special purpose foods" in the General Principles for the addition of essential nutrients to foods.

Therefore, the EU would prefer deletion of this section and of the definition of "special purpose foods" in section 2, and would consider including a reference in the document to the relevant standards that could be applicable.

## ANNEX

### ***EU comments – proposed changes to the General Principles for the Addition of Essential Nutrients to Foods***

#### **INTRODUCTION**

The *General Principles for the Addition of Essential Nutrients to Foods (the Principles)* are intended to provide guidance to national and/or regional 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.

**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;"

**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.

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

#### **1. SCOPE**

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

<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:

**2.2** Essential nutrient means any substance normally consumed as a constituent of food which cannot be synthesised in adequate amounts by the body and which is needed for growth and development and the maintenance of life or a deficit of which will cause characteristic bio-chemical or physiological changes to occur.

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

#### **3. PRINCIPLES**

**(new)** The General Principles are applicable, as appropriate, to all types of addition of essential nutrients unless otherwise indicated.

##### **3.1 Fundamental Principles**

**3.1.3** National and/or regional authorities should determine whether the addition of essential nutrients to foods should be mandatory.

**3.1.4 (Former 3.11 with modifications)** 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 may be included identifying the essential nutrients that may be added and where appropriate the minimum and maximum levels at which they should be present.

**3.1.5** (Former 3.8 with additions) 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.

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

**3.2.1** (new) The addition of an essential nutrient to food should be risk-based and not result in either an excessive intake or an insignificant intake of the essential nutrient, considering total intakes from all relevant sources, Upper Levels of intake and identification of special sub populations at risk.

#### ***Alternative for Paragraphs 3.2.2 and 3.2.3***

National and/or regional 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."

**3.2.4** (new) Where an Upper Level of Intake is not available, 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.

**3.2.7** (new) "National and/or regional authorities may establish minimum limits for the addition of essential nutrient to foods to ensure that consumers are not misled and that the foods to which the nutrients are added meet the purpose of the addition of nutrients to foods as described in the Introduction of the General Principles. 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) ".

**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 FAO/WHO standards, international Pharmacopoeias or recognized international standards or national legislation.

### **3.3. Selection of Foods**

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.

**3.3.2** Foods or categories of foods to which particular groups of essential nutrients may not be added may be determined by national authorities taking into account their nutritional value.

### **3.5 Monitoring**

**3.5.1** (new) It is important that national and/or regional authorities 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 the purposes identified in 3.1.1 is addressed and to ensure that any risk of excessive intakes is minimised.

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

#### 4.1 Mandatory Addition of Essential Nutrients

2.6 (new) Mandatory nutrient addition is when national and/or regional authorities require food manufacturers to add specified essential nutrients to particular foods or food categories.

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 groups through the mandatory addition of essential nutrients. This need may be demonstrated by actual clinical or subclinical evidence of deficiency, estimates indicating inadequate or potentially inadequate levels of intake of nutrients or by estimates of possible deficiencies likely to develop because of changes taking place in food habits.

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

4.1.3 Former 6.2.4 The amount of the essential nutrient added to the food should be sufficient to reduce inadequate intakes, correct or prevent the deficiency when the food is consumed in habitual amounts by the population at risk.

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.

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.

#### NEW ZEALAND

New Zealand appreciates the opportunity to contribute to the work on the review of the General Principles on the Addition of Essential Nutrients to Foods. We commend the electronic working group in progressing what has been a very challenging area of work.

We support the proposed outline of the General Principles that the eWG has put forward. We would however support a rewording of the sections and the title. We do agree that all of the content of the report are “principles” and that the title could reflect that and be “**Principles for the Addition of Essential Nutrients to Foods**”. This would then enable section 3 to be called “**General Principles**”.

In general we support most of the sections although we think that the level of detail in defining “significant contributor” under restoration and nutritional equivalence, is unnecessary and we recommend deleting these sections.

#### *Specific Comments on text:*

New Zealand is supportive to the majority of the recommendations of the eWG. Some specific comments are:

Regarding discussion on the strength of evidence on the severity and extent of public health need to support a decision of mandatory addition of essential nutrients to foods, New Zealand supports that this should be taken at a national level and on a case by case basis.

Regarding the definition of **essential nutrient**, New Zealand agrees that reference to maintenance of a “healthy life” should be replaced with maintenance of “life”. Many consumers may not be considered to be healthy for reasons other than nutritional.

New Zealand does not think that there is a need to have the term **nutrient** defined as well as essential nutrient. This is particularly the case as the term nutrient is not used in the current document.

The term “**fortification**” is not used in the document and therefore should not be specifically defined in the document. There are other documents that can be referred to if such a definition is required.

The eWG has proposed a few simplifications and deletions of paragraphs and New Zealand supports all of these simplifications.

With regard to Upper Levels, there is currently a duplication of discussions on this and the Committee should discuss how best to succinctly cover this. New Zealand supports its coverage in 3.2.2 only and not both in 3.2.1 and 3.2.2.

New Zealand supports the new section 3.2.5 which covers the severity of adverse health effects for both mandatory and voluntary addition of essential nutrients.

New Zealand knows that agreement on a title for section 4.1 is problematic. Our preference is the title “**Addition of Essential Nutrients to Address a Demonstrated Public Health Need**”. This recognises that public health need may be addressed through both voluntary and mandatory addition of essential nutrients.

New Zealand recommends the deletion of sections 4.2.2 and 4.3.2 – both of which define a significant contributor. The level of detail is unnecessary and does not differentiate between a significant contributor of a nutrient to the total diet as compared to a significant contributor of a nutrient to an individual food.

### 3.3 Selection of Foods

3.3.1 New Zealand does not support excluding foods that are ubiquitous in the food supply. We would support option 2 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.

## NORWAY

Norway would like to thank Canada and New Zealand for preparing the Report of the Electronic Working Group. We are pleased to provide some comments on the Proposed Draft Revision, as presented in Appendix A, Table 3.

The comments are given in the attached table.

| <b>Table 3: Proposed Revised Text from Table 2 – Clean Version</b>                                                                                                                                                                                                                                                                                                                                                 | <b>Norwegian comments</b>                                                                                                                                                                                                                                                                                                                                   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>INTRODUCTION</b></p> <p><i>(Revised) The <del>{General Principles}</del> 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.</i></p> | <p>We agree with the title “The General Principles”.</p>                                                                                                                                                                                                                                                                                                    |
| <p><i>(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.</i></p>                                                                                                                                     | <p>We agree with this statement.</p>                                                                                                                                                                                                                                                                                                                        |
| <p><i>(new) National authorities may also consult FAO/WHO publications for further guidance on nutrient addition.</i></p>                                                                                                                                                                                                                                                                                          | <p>We agree with the revised text.</p>                                                                                                                                                                                                                                                                                                                      |
| <p><b>1. SCOPE</b><br/>           These Principles apply to the addition of essential nutrients to foods, not including vitamin and mineral food supplements<sup>1</sup>.</p> <p><sup>1</sup>See the Codex <i>Guidelines for Vitamin and Mineral Food Supplements</i> (CAC/GL-55-2005)</p>                                                                                                                         | <p>We support this revised text.</p>                                                                                                                                                                                                                                                                                                                        |
| <p><b>2. DEFINITIONS</b><br/>           For the purpose of these Principles:</p>                                                                                                                                                                                                                                                                                                                                   | <p>We agree in that the definition of “nutrient” has been deleted, since the term is not used in the document.</p> <p>If technically possible, the reference in the Codex document <i>Nutritional Risk Analysis Principles</i> to these General Principles as the source of the definition of nutrient and essential nutrient could be changed, so that</p> |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | the reference of the definitions is changed to the <i>Guidelines on nutrition labelling (CAC/GL 2-1985)</i> .                                                                                                                                              |
| <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.                                                                                                                                                                                                                                                                                                                                                                                        | We regard this definition of essential nutrient as acceptable.                                                                                                                                                                                             |
| <b>If retained, Proposed revised definition for option 3):</b><br><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].                                                                                                                                                                                                                                                                                                                                                                                                           | In our opinion this definition is unnecessary since fortification is not referred to in the document.                                                                                                                                                      |
| <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.                                                                                                                                                                                                                                                                                                                                                                                                                                           | We agree with this text.                                                                                                                                                                                                                                   |
| <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                                                                                                                                                                                                                                                                                                                                                                                                                                             | We agree with this text.                                                                                                                                                                                                                                   |
| <b>3.0 PRINCIPLES</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                            |
| <b>3.1 (New) Fundamental Principles</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                            |
| 3.1.1 Essential nutrients may be appropriately added to foods for the purpose of: <ul style="list-style-type: none"> <li>• contributing to correcting a demonstrated deficiency or [inadequate intakes] of one or more essential nutrients in the population;</li> <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> | In our opinion, using the words “inadequate intakes” and “requirements” seems adequate.                                                                                                                                                                    |
| 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.                                                                                                                                 | We support to move both the sentences in square brackets to section 4, since these sentences describe principles for specific types of addition.                                                                                                           |
| 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 agree in the revised text.                                                                                                                                                                                                                              |
| <b>3.2 (New) Selection of Nutrients and Determination of amounts</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                            |
| <b>3.2.3 (new)</b> 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                                                                                                                                                                                                                                                            | We support this principle. We believe that dietary modelling and UL constitutes important aspects of risk assessment of nutrient addition, in order to avoid excessive intakes of nutrients from the diet, including fortified foods and food supplements. |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>food and daily intake reference values for adequacy and for safety.”</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] [for the potential relevance of Highest Observed Intake]<sup>1</sup>.</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>We support to use other values based on scientific documentation on adverse effects, when an UL is not available, and are in favour of using the concept of Highest Observed Intake.</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>We support this principle.</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)]. [<del>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.</del>]</p>                                                                                                                                                                                                               | <p>Norway considers that the minimum amounts for the addition of essential nutrients to foods should be determined on the basis of the conditions of use for a source of claim in the Guidelines for use of nutrition and health claims (CAC/GL 23-1997).</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <p><b>3.3 (New) Selection of Foods</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <p><b>3.3.1</b> (new) [<del>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>Ør</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>Ør</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> | <p>In order to protect the public understanding of what constitutes healthy foods, we are in favour of a principle which states that staple foods principally should be excluded from voluntary nutrient addition.</p> <p>We note that foods commonly consumed by the general public (such as milk, butter/margarine, salt, cereals, etc.), are often used as vehicles when the purpose is to correct or prevent deficiencies in the general population. Therefore, we support that the principle in section 3.3.1 should not be applicable to nutrient addition for purposes of correcting or preventing inadequate intakes. However, sometimes <u>voluntary nutrient addition</u> can be used as a tool by governments to achieve similar purposes as mandatory fortification, and in such cases we would not regard this principle as valid. However, we understand that the current wording “may have to be excluded” allow for such cases of nutrient addition as explained above.</p> |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>3.3.2 (new)</b> The selection of <del>appropriate</del> foods [or categories of foods] to which essential nutrients <del>[may]</del>/ [may not] be added should take into account the nutritional value of the foods and is best determined by National Authorities.</p> <p>Nutrient addition to energy-dense and nutrient-poor foods should be avoided.</p> <p>Or</p> <p>Consideration should be given to the content of risk-increasing nutrients in potential target foods to assess whether an increased consumption resulting from nutrient addition would pose [risks for non-communicable diseases and] other relevant health risks</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>We support the first paragraph in section 3.3.2, with some modifications. In addition we propose to add a sentence to which clearly reflect which foods that essential nutrients should not be added, being the energy-dense and nutrient-poor foods. Alternatively, we support the text suggested by Australia with a modification. Suggested amendments to section 3.3.2 are shown in strike-outs and red colored text.</p> <p>Norway believes it is important to include principles that restrict voluntary fortification of energy-dense and nutrient-poor foods. Adding essential nutrients to foods associated with an unhealthy diet – energy-dense foods that are considered to have a negligible nutritional value – can convey the impression that they are healthier. Thus, nutrient addition may stimulate increased consumption of food groups that the health authorities encourage a reduced intake of. We believe it is important that general principles restricting voluntary nutrient addition of energy-dense and nutrient-poor foods are set on an international level. However, we agree that development of detailed provisions must be done at regional/national level taking into account dietary habits and other relevant aspects. This principle should however not apply to nutrient addition for purposes of correcting or preventing inadequate intakes, if the positive effects of adding outweigh negative effects of intake (ex. iodine to salt).</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>We support this principle.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <p><b>{3.3.5 (new)</b> Essential nutrients should not be added to alcoholic beverages.}</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <p>We support this principle.</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 <del>[in the following order]</del>: FAO/WHO standards, international Pharmacopoeias or recognized international standards, or national legislation.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <p>We support this provision, but propose to remove the text in the square brackets.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <p><b>3.5 Monitoring</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <p>3.5.1 (new) [It is important that National authorities]–/ <del>[National authorities should]</del> monitor population intakes from all sources including the essential nutrients added to foods to assess the extent to which [the selected public</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <p>We consider monitoring to be important, but that it should not be expressed as an obligation in the global principles. We therefore support the text “It is important that</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |



|                                                                                                                                                                                                                                                |                                                                                                                                                          |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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.                                                                            | National authorities”.                                                                                                                                   |
| <del>3.5.2 (new) Monitoring of total nutrient intakes should use the same approach as used in deciding the nutrient addition.</del>                                                                                                            | We do not support this text, since we consider that the approaches used in deciding the nutrient addition is not necessarily the same as for monitoring. |
| <b>4.0 [Principles for] Types of Nutrient Addition</b>                                                                                                                                                                                         |                                                                                                                                                          |
| <b>4.1 (new) Addition of Essential Nutrients {to Address a Demonstrated Public Health Need} and Mandatory Addition}</b>                                                                                                                        | In our opinion it seems as a good idea to include the text in both square brackets.                                                                      |
| 4.1.2 <i>Former</i> 6.2.2 The food(s) selected as a vehicle for the added essential nutrient(s) should be consumed by the population at risk <del>{of inadequate intake}</del> .                                                               | We agree to include the new text.                                                                                                                        |
| [Switch order with 4.1.3]:<br>4.1.4. <i>Former</i> 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. | We agree to switch order with 4.1.3.                                                                                                                     |

## THAILAND

would like to express our appreciation for the effort of Canada and New Zealand for preparing the Draft Revision of the Codex General Principles for the Addition of Essential Nutrient to Foods (CAC/GL 9-1987).

We would like to propose our comments on specific sections as the followings.

### - Section 2: DEFINITIONS

#### - 2.4 Substitute food

The words “flavour and odour” should be deleted, as they are inconsistent with the example mentioned in the end of the section. So, this section should be read as follows:

*“2.4 Substitute food is a food which is designed to resemble a common food in appearance, 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}~~.”*

#### - 2.5 Fortification

This document mainly emphasizes on principles for food fortification; however the term “fortification”, which has been widely used, is not mentioned in the document. So, it is agreed to add the definition for “fortification” in the document. However, the phrase in a square bracket at the end of the descriptions should be deleted.

So, the definition of fortification should be read as follows:

*“2.5 Fortification means the addition of one or more essential nutrients to a food, hence this general principle could be refer to as general principle for food fortification. ~~{whether or not it is normally contained in the food}~~”*

#### - 2.9 Special purpose foods

Since a scope of the document applies to all food, hence the phrase “and also include foods intended for infants and young children” at the end of this section should be deleted.

### - Section 3. PRINCIPLES

#### - 3.1 Fundamental Principles

##### - Sub section 3.1.1

We are of the opinion that Fundamental Principles for the Addition of Essential Nutrients to Foods would be emphasized to improve nutritional quality of foods for fulfillment of nutrient requirement. With

regard to improvement of health, there are so many factors involved such as physical activity and lifestyle, then the word “or improvement” in 3<sup>rd</sup> bullet should be deleted and a square bracket in 1<sup>st</sup> and 2<sup>nd</sup> bullet should be removed.

So, this sub section should be read as follows:

*“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;”*

### - Sub section 3.1.3

It is proposed that a square bracket should be removed from the term “nutrient addition” and the rest of this paragraph should be deleted, as the method for addition of essential nutrients is already mentioned in the next section.

So, this sub section should be read as follows:

*“3.1.3 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.~~”*

## - 3.2 Selection of Nutrients and Determination of amounts

### -Sub section 3.2.1

- The term “addition of an essential nutrient” should be used rather than “The amount of an added essential nutrient”.

- The phrase “in line with one or more of the purposes stated in 3.1.1” should be deleted, since all the principles are already consistent with the fundamental in 3.1.1.

- A square bracket should be removed from “scientifically and nutritionally justified”.

- The phrase “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” should be deleted, as “Upper levels for intake” is already mentioned in “exposure of essential nutrient[s]” in section 3.2.3.

- The phrase “Upper Levels of intake and identification of special subpopulations at risk” should be deleted, as the previous texts clearly mention the words “for the target population”.

It is proposed that this section should be read as follows:

*“3.2.1 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 ~~that~~ ~~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.~~”*

### - Sub section 3.2.2

- A square bracket should be removed from “including considerations of populations at risk of excessive intake”.

- The phrase “This exposure assessment should also help to identify the need for any restrictions on the types of foods to which nutrients should be added” should be deleted, as Upper levels of intake is already mentioned in the method for exposure of essential nutrient[s] in 3.2.3 .

So, this section should be read:

*“3.2.2 The Upper Level of Intake should be used to assess potential exposure to excessive intakes of essential nutrient[s] and to estimate safe limit[s] 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.]”~~”*

### - Sub section 3.2.3

A square bracket should be removed from “to evaluate safety and adequacy”.

So, this section should be read:

*“3.2.3 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.”*

### - Sub section 3.2.4

- The phrase “National authorities may consider” should be deleted, because it is already recognized that all concerned aspects and consideration are conducted by national authorities.

- The phrase “or the potential relevance of Highest Observed Intake<sup>1</sup>” should be deleted, since it seems unnecessary.

- Then, footnote 1 should be deleted accordingly.

So, this section should be read:

*“3.2.4 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]~~ ~~for 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~~

### - Sub section 3.2.5

We are of the opinion that the whole sentence of sub section 3.2.5 are difficult to understand and need more interpretation and clarification.

### - Sub section 3.2.6

It is proposed to use the term “addition of an essential nutrient” through the entire document for consistency”, in the meantime the term “amount of an essential nutrient added” should be deleted.

So, this section should be read:

*“3.2.6 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.”*

### - Sub section 3.2.7

To be clear and concise, this sub section should be amended as follows:

*“3.2.7 National authorities may establish minimum limits for the addition of essential nutrient to foods considering ~~[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.†~~”

### - 3.3 Selection of Foods

- For the structure of the section, it should start with the positive principle and then follow with the intermediate and prohibited principle.

- The term “or categories of foods” should be deleted, as the meaning of “food” is already sufficient and comprehensive.

- Furthermore, the section should be amended to be clear and concise.

So, this section should be reordered and amended as the followings:

~~“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.]~~

~~○#~~

~~[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.]~~

~~○#~~

~~†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.†”~~

3.3.2 The selection of appropriate foods [for categories of foods] to which **whether** essential nutrient[s] [may] / [may not] be added should take into account the nutritional value of the foods and is best determined by National Authorities.

3.3.3 ~~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.†~~

~~3.3.2 (new) The selection of appropriate foods [for 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.~~

3.3.4 ~~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.†~~

~~†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.†~~

### - 3.4 Technological aspects

#### - Sub section 3.4.1

A square bracket should be removed from this section. So, it should be read:

“3.4.1 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.”

#### - Sub section 3.4.3

All square brackets should be removed from this section. So, it should be read:

“3.4.3 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”.

#### - Sub section 3.4.4

- It is unnecessary to add the term “standardized”.
- The word “bio” should not be added, as the word “bioavailability” is already mentioned in sub section 3.4.1.
- To be clear, it is proposed to add the word “satisfactory” before the word “manner”

So, this sub section should be read:

*“3.4.4 Technology and processing facilities should be available to permit the ~~standardized~~ addition of the essential nutrient to a food in a satisfactory manner to ensure nutrient ~~bio~~availability, consistency, distribution and stability.”*

### - 3.5 Monitoring

#### - Sub section 3.5.1

-The term “National authorities should” should be retained, meanwhile the phrase “It is important that National authorities” should be deleted.

- A square bracket should be removed from “the selected public health need or other purpose for addition”. And, to be clear and more concise, the texts should be revised to “the selected public health need or other purpose for addition identified in 3.1.1”.

So, this subsection should be read as follows:

*“3.5.1 ~~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.”*

### - 4.0 [Principles for] Types of Nutrient Addition

It is proposed that the title of this section should be amended as follows:

***“4. Specific ~~Principles for~~ Types of Nutrient Addition”***

#### - Sub section 4.1

The title of this sub section should also be amended as follows:

***“4.1 ~~Addition of Essential~~ Mandatory Nutrients Addition ~~to Address a Demonstrated Public Health Need~~ ~~and Mandatory Addition~~”***

#### - Sub section 4.1.1

##### -The first sentence

- The term “populations” should be replaced with “population groups”.
- To be clear and specific, the word “in specific situation” should be added after “which”.

##### - The second sentence

This sentence should be deleted, because it mentions voluntary addition which is inconsistency with the title of the section which addresses mandatory nutrient addition.

So, this sub section should be read as follows:

*4.1.1 There should be a demonstrated public health need for increasing the intake of an essential nutrient in one or more populations groups ~~which, in specific situation 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.*

#### - Subsection 4.1.2

The words “of inadequate intake” should be deleted.

This section should then read:

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

#### **- Subsection 4.1.4**

The phrase “amount of the food consumed by the lower and upper percentiles of the population” should be deleted.

This section should then read:

*“4.1.4. 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”.*

## **4.2 Nutrient Addition for Purposes of Restoration**

### **- Sub section 4.2.1**

The term “source” should be used; meanwhile the term “contributor to intake” should be deleted. And, to avoid confliction with 4.1, which concerns mandatory nutrient addition, this section should be read:

*“4.2.1 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~~.”*

### **- Sub section 4.2.2**

- To be consistent with current situations and works of CCNFSDU in establishing NRVs for vitamin and mineral and NRVs-NCD, it is agreed to use the term “NRVs” in this section.

- The last sentence should be deleted, as it is duplicated with section 4.3.3.

This sub section should then read:

*“4.2.2 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**

To be in line with sub section 4.2, this section should be amended to read as follows:

*“4.3.1 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~~.”*

*4.3.2 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.”*~~

## **4.4 Nutrient addition to Special Purpose Foods**

The alternative proposed texts should be chosen, as it is concise and more understanding.

So this section should be read:

~~4.4.1 *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.~~

## UNITED STATES OF AMERICA

The United States of America is pleased to offer the following comments on the Proposed Draft Revision of the Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987) in CX/NFSDU 12/34/9.

### I. GENERAL COMMENTS

#### Structure of Document and Nature of Provisions

The eWG respondents considered that most if not all provisions in CAC/GL 9-1987 are principles (CX/NFSDU 12/34/9). In addition, the majority supported continuing with a structure that includes the broad areas of scope, definitions, (overarching) principles, and principles for specific types of nutrient addition. Accordingly, we propose the following edits to Table 3 to reflect this support and the nature of provisions in Table 3 (and in CAC/GL 9-1987):

#### ~~GENERAL~~ PRINCIPLES FOR THE ADDITION OF

#### ESSENTIAL NUTRIENTS TO FOODS

#### INTRODUCTION

#### 1. SCOPE

#### 2. DEFINITIONS

#### 3. [GENERAL] [OVERARCHING] PRINCIPLES

#### 4. ~~[PRINCIPLES FOR]~~ SPECIFIC TYPES OF NUTRIENT ADDITION

Specifically, we propose that the document title be changed to “Principles...” and that the Section 3 and 4 headings distinguish between the general or overarching principles in Section 3 and principles for specific types (or purposes) of nutrient addition in Section 4. We agree with most eWG respondents that the Introduction should focus on the document’s purpose, and appropriate purposes of nutrient addition should be addressed as a general/overarching principle in Section 3.

#### Purpose of this Document

We agree with retaining this document’s stated purpose to provide guidance to National Authorities through a set of principles that serve as a basis for the rational and safe addition of essential nutrients to foods. In this regard, the Introduction in CAC/GL 09-1987 states that this document is intended “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.” We consider that “rational” nutrient addition that is scientifically and nutritionally justified and in accordance with good manufacturing practice provides a means for countries to achieve “safe” nutrient addition to all foods including foods for infants and young children, and will continue to be a cornerstone of reducing risk of excessive intakes.

#### Principles for Specific Types of Nutrient Addition

We agree with retaining principles for specific types and purposes of nutrient addition as reflected in CAC/GL 9-1987, including to address a demonstrated public health need (4.1), restore nutrients lost during processing or storage (4.2), and to achieve nutritional equivalence of substitute foods (4.3). We consider that these principles can assist governments in achieving rational and safe nutrient addition, and in maintaining or improving the nutritional quality of foods and the health and nutritional status of their populations. In

discussing these principles in the plenary, the U.S. considers that it would be most meaningful to discuss each of the principles in Section 4 of the document.

### Potential Role of Both Mandatory and Voluntary Nutrient Addition in Addressing a Demonstrated Public Health Need

In new section 4.1, the U.S. agrees with the introductory text that acknowledges that voluntary addition of essential nutrients to foods may also play a role in meeting a demonstrated need for increasing the intake of an essential nutrient in an at risk population(s). This has been the case in the United States. For example, in the early 1920's iodine was first added to table salt in the U.S. based on the prevalence of goiter at that time. Current U.S. regulations permit iodine to be added to salt for human food use in the form of cuprous iodide or potassium iodide. Salt packages must indicate on the label whether or not the salt supplies iodide (a necessary nutrient), but the addition of iodine to salt is *voluntary*. As another example, amendments were made in U.S. standards of identity for several enriched cereal grain products (e.g., enriched flour, enriched corn meals) in 1996 to require folic acid fortification based on a demonstrated need for women of childbearing age. However, it is *voluntary* on the part of food manufacturers whether they use these enriched cereal grains, or alternatively, use unenriched cereal grains which have separate standards of identity. This example further illustrates that there is not always a clear distinction between voluntary and mandatory nutrient addition (i.e., a manufacturer is required to add folic acid to enriched cereal grain products at specified levels according to the standard of identity, but is not required to use enriched cereal grain products).

## II. SPECIFIC COMMENTS

Please refer to the attached table for specific U.S. comments on proposed draft amendments to the General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987) as identified in CX/NFSDU 12/34/9, Appendix A Table 3 (clean version of proposed text).

| U.S. Suggested Edits to CX/NFSDU 12/34/9, Appendix A Table 3, p. 52-57 (Clean Version of document)<br>(U.S. proposed new text is underlined; proposed deletions are identified with strikeout.)                                                                                                                                                                                                                                                                                             | U.S. Comments                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>TITLE</b></p> <p><del>General</del> Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987)</p>                                                                                                                                                                                                                                                                                                                                                                  | <p>The entire document encompasses both general/overarching principles) applicable to all types of nutrient addition and other principles for specific application, including for specific types and purposes of nutrient addition. Accordingly, we propose changing the document title to "Principles". This would also be consistent with the use of the term "Principles" in this draft to refer to the entire document.</p>                                                                                                                                                                                                                                                             |
| <p><b>INTRODUCTION</b></p> <p><i>(Revised) The <del>General Principles</del> 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, <u>and that prevent the indiscriminate addition of nutrients to foods.</u></i></p> | <p>- We propose changing "General Principles" to "Principles" based on our above comments. We agree that the introduction should focus on the purpose of this document, and not elaborate on appropriate purposes of adding nutrients which the Committee agreed at its 32<sup>nd</sup> (2010) session to transfer to Section 3 on principles (REP11/NFSDU, paras 57-58 and 67, and Appendix VII). We further agree with identifying rational and safe nutrient addition as a basis for the principles in this guidance. In addition, we consider it is important to retain the underlined text in the Introduction because it further clarifies an important purpose of this document.</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>We agree with this new provision.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <p>(new) The Principles are applicable, as appropriate, to both mandatory and voluntary addition of essential nutrients unless otherwise indicated.</p>                                                                                                                                                                                                                                                                                                                                     | <p>We agree with this new provision.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |



|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (new) National authorities may also consult FAO/WHO publications for further guidance on nutrient addition.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | We agree with this new provision.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <p><b>1. SCOPE</b><br/>         These Principles apply to the addition of essential nutrients to foods, not including vitamin and mineral food supplements<sup>1</sup> and infant formula.<sup>2</sup> <u>With regard to other foods for special dietary uses, national authorities may consider these principles, as appropriate, in conjunction with the provisions in Codex standards and guidelines for these foods.</u></p> <p><sup>1</sup>See the Codex <i>Guidelines for Vitamin and Mineral Food Supplements</i> (CAC/GL-55-2005).<br/> <sup>2</sup>See the Codex <i>Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants</i> (CODEX STAN 72-1981).</p> | <p>We agree with the exclusion of vitamin and mineral food supplements from the Scope and also consider that these principles do not apply to infant formula. In addition, we propose to add a second sentence to clarify the applicability of these principles to other foods for special dietary uses.</p> <p>If the Committee supports this clarification, we are uncertain that there is a need to retain a separate section on “Nutrient Addition to Special Purpose Foods” (4.4) and a definition of “Special Purpose Foods”, and suggest placing these in brackets for discussion.</p>                 |
| <p><b>2. DEFINITIONS</b><br/>         For the purpose of these Principles:</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <p>The U.S. proposes to retain the definitions below and to reorder them more logically, which takes into consideration the current structure of the document.</p> <p>2.1 Nutrient<br/>         2.2 Essential Nutrient<br/>         2.3 Mandatory Nutrient Addition<br/>         2.4 Voluntary Nutrient Addition<br/>         2.5 Restoration<br/>         2.6 Substitute food<br/>         2.7 Nutritional equivalence<br/>         [2.8 Special purpose foods]<br/>         Note: As explained below, we propose restoring the definition of “nutrient” and deleting the definition of “fortification”.</p> |
| <p><b>2.1 Nutrient</b> means any substance normally consumed as a constituent of food:<br/>         (a) which provides energy; or<br/>         (b) which is needed for growth and development and maintenance of [healthy] life; or<br/>         (c) a deficit of which will cause characteristic biochemical or physiological changes to occur.</p>                                                                                                                                                                                                                                                                                                                                                  | <p>We propose retaining the definition of “nutrient” in CAC/GL 09-1987. We propose placing “healthy” in brackets for further discussion, noting that the reference to “healthy” life is included in the Codex nutritional risk analysis principles but not in the Guidelines on Nutrition Labelling.</p>                                                                                                                                                                                                                                                                                                      |
| <p><b>2.2 Essential nutrient</b> means any [nutrient] [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>With the proposal to retain the definition of “nutrient”, we consider that it would be clearer to refer to “nutrient” instead of “substance” in the definition of “essential nutrient”, but recognize that the current definition is used in other Codex texts.</p>                                                                                                                                                                                                                                                                                                                                        |
| <p><del>2.3</del> <b>2.6 (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>At this time, we do not have a strong preference for whether “flavour and odour” is retained or deleted. We support retaining plant protein-based beverages as an example of a substitute food for milk.</p>                                                                                                                                                                                                                                                                                                                                                                                               |
| <p><b>2.4 2.7 (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>We agree with this definition as amended.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <p><b>If retained, Proposed revised definition for option 3):</b><br/> <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>We consider it unnecessary to retain a definition for “fortification” given the term is not used in these revised provisions. Instead, we support referring to “nutrient addition” throughout the Principles (with appropriate qualifying text for specific sections as needed). We</p>                                                                                                                                                                                                                                                                                                                    |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <p>support this decision to avoid confusion because countries define “fortification” in different ways, with certain countries defining “fortification” to mean simply nutrient addition, and others defining “fortification” to mean appropriate nutrient addition to achieve one or more specified purposes. If a definition for “fortification” is retained, we could accept this revised definition, and consider it helpful to retain the text in brackets.</p>                                                                                                                                                                                                                                                                                                                 |
| <p><del>2.8</del> <b>2.5</b> <i>Restoration</i> 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, <del>for in order to compensate for natural variations in essential nutrients.</del></p>                                                                                                                | <p>We support retaining the simplified revised definition of “restoration” as it pertains to related principles later in this document which we support retaining. However, we are uncertain about the need for and appropriateness of including the new proposed text in brackets. It would be helpful if examples could be provided. In addition, we question whether nutrient addition to compensate for natural variations in essential nutrients is in fact “restoration” .</p>                                                                                                                                                                                                                                                                                                 |
| <p><del>2.6</del> <b>2.3</b>(new) <i>Mandatory nutrient addition</i> is when National Authorities require food manufacturers to add specified essential nutrients to particular foods or food categories.</p>                                                                                                                                                                                                                                      | <p>We agree with this definition.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <p><del>2.7</del> <b>2.4</b>(new ) <i>Voluntary nutrient addition</i> is when National Authorities permit food manufacturers to add specified essential nutrients to particular foods or food categories</p>                                                                                                                                                                                                                                       | <p>We agree with the definition.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <p><del>2.9</del> <b>2.8</b> <i>Special purpose foods</i> 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, <del>and also include foods intended for infants and young children.</del></p> | <p>We suggest placing this definition in brackets. (Please refer to our comments on Section 1- Scope.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <p><b>2.11 (new) Population</b> refers to a national population or specific population group(s) as appropriate.</p>                                                                                                                                                                                                                                                                                                                                | <p>We support this new definition with the understanding that it is included to simplify wording that occurs later in the Principles.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <p><b>3.0 [GENERAL ] [OVERARCHING] PRINCIPLES</b></p> <p><u>The following provisions are [general] [overarching] principles for the addition of nutrients. They address the purpose of nutrient addition, the determination of mandatory or voluntary nutrient addition, the selection of foods and nutrients and determination of amounts, technological aspects, and monitoring.</u></p>                                                         | <p>We propose that Section 3 be titled either “General” or “Overarching” Principles. We consider that further clarification is needed in the Section 3 heading to distinguish between the principles in Section 3 and Section 4. Moreover, we proposed renaming the entire document as “Principles for the Addition of Essential Nutrients to Foods” consistent with this draft’s use of the term “Principles” to refer to the entire document, and thus consider it would be confusing to name Section 3 “Principles” without further description. In addition, to aid the reader, we propose brief introductory text to section 3 to identify the nature of the general/overarching principles in Section 3.<br/>- Additional comment: Should Section “3.0” be changed to “3”?</p> |
| <p><b>3.1 (New) Fundamental Principles</b></p>                                                                                                                                                                                                                                                                                                                                                                                                     | <p>We support this separate subsection in Section 3 for fundamental, high-level principles that identify appropriate purposes of nutrient addition as agreed to at the 2010 CCNFSDU session (REP11/NFSDU, paras 57-58, 67 and Appendix VII).</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 <u>preventing or</u> correcting a demonstrated deficiency or <del>inadequate intakes</del> of one or more essential nutrients in the population;</li> <li>contributing to meeting [requirements] <u>[recommended intakes]</u> of one or more essential</li> </ul>                                  | <p>We propose edits to 3.1.1 to reduce redundancy and simplify text without changing the meaning.</p> <p>We propose further consideration of “recommended intakes” as an alternative to “requirements” as a broader term that includes but is not be limited to INL<sub>98</sub> values (e.g., to include recommended intakes of folic acid intake</p>                                                                                                                                                                                                                                                                                                                                                                                                                               |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>nutrients and reducing the risk of [inadequate intakes and/or] deficiency;</p> <ul style="list-style-type: none"> <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>for women of childbearing potential to reduce risk of neural tube defects and recommended intakes for potassium to lower blood pressure.)</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. <del>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.</del></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <p>We support including only the first two sentences in new 3.1.3 to succinctly address who determines if nutrient addition should be mandatory or voluntary and how. As reflected in Section 4, we consider that the third sentence (with its reference to correcting particular problems for a target population) which was formerly in a section on nutrient addition to meet a demonstrated need in a population (i.e., Section 6.1 of the Principles) should be moved back to new Section 4 (which addresses this topic).</p>                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <p>3.1.4 <del>The addition of essential nutrients to foods should be in accordance with food law and other policies established by national authorities.</del> 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>With regard to the proposed new sentence, we agree that the addition of essential nutrients should be in accordance with food law and other policies established by national authorities. However, we do not see the need to add this new proposed text (which is not in CAC/GL 09-1987), because it is implicit and understood that nutrient addition should be in accordance a government’s regulations and policies.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <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</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <p>We support retaining this principle as amended.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <p><b>3.2 (New) Selection of Nutrients and Determination of Amounts</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <p>We support the proposed new subheading.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <p><b>3.2.1</b> Former 3.2 with modifications (also considered to cover former 6.2.5): The {amount of an added} <del>or {addition of an}</del> 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 <del>the</del> <u>any</u> target population, an insignificant intake of {the added} essential nutrient[s], considering {total intakes} from all <del>{relevant}</del> dietary sources {including food supplements}. Former 3.3. <u>In addition, The amount of an essential nutrient added</u> <del>/ {addition of an essential nutrient}</del> to a food should not result in an adverse effect on the metabolism of any other nutrient. <del>{Upper Levels of intake and identification of special subpopulations at risk}</del> <del>{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.}</del></p> | <p>-We support retaining the text in brackets in the first sentence to clarify that <i>amounts</i> of nutrients added to food should be “scientifically and nutritionally justified in line with one or more purposes stated in 3.1.1.” The clarification that nutrient addition should be scientifically justified supports a main aspect of this work which is to include nutrient addition for the purpose of meeting recommended intakes and reducing risk of inadequate intake as demonstrated by relevant scientific data.<br/>         - We propose replacing “relevant sources” with “dietary sources” and retaining “including food supplements” for clarification.<br/>         - We consider that former 3.3 is more appropriately placed in 3.2.1 than in new 3.2.7, and support the text option that refers to “the amount of an essential nutrient added.”<br/>         - With new 3.2.2 below, we do not see the need for the last sentence in 3.2.1.</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>We agree with the wording of the first sentence, and retention of the second sentence in brackets for further consideration.</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</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <p>We agree with the Committee’s consideration of new 3.2.3 which provides additional guidance on the use of the UL.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                               |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>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 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>We reviewed this alternative proposal, but do not see how it adds essential information compared to the text in 3.2.1, 3.2.2 and 3.2.3.</p>                                                                                                                |
| <p><b>3.2.4</b> (new) Where an Upper Level of Intake is not available, <del>[National authorities may consider]</del> the scientific evidence to support the safe addition of an essential nutrient <del>{should be considered}</del>, including <del>{demonstration of evidence for an upper level or a range of intake that is unlikely to result in adverse health effects}</del> <u>including consideration of the potential relevance</u> of Highest Observed Intakes<sup>1</sup>.</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>- Given that the Introduction states that these Principles are intended to provide guidance to national authorities, we do not consider it necessary to refer to national authorities in 3.2.4.</p> <p>-We propose additional edits for consideration.</p> |
| <p><del>{3.2.5</del> (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<del>}</del></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <p>We agree with the wording of this new principle.</p>                                                                                                                                                                                                       |
| <p><del>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.</del></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <p>We consider that this provision may be more appropriately placed in 3.2.1.</p>                                                                                                                                                                             |
| <p><b>3.2.7</b> (new) <del>When</del> National authorities <del>may</del> establish minimum [limits] [levels] for the addition of essential nutrient to foods, <del>[Minimum amounts for the addition of essential nutrients to foods-</del> <u>they should take into account the intended purpose as identified in 3.1.1, and may also consider</u> conditions of use for “a source” of claim in the Guidelines for use of nutrition and health claims (CAC/GL 23-1997)]. <del>[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.]</del></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <p>-We consider that the main focus of this new principle should be on what national authorities should consider when establishing minimum levels, and propose edits to combine concepts in the three sentences into one.</p>                                 |
| <p><b>3.3 (New) Selection of Foods</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <p>We agree with this new subheading.</p>                                                                                                                                                                                                                     |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>3.3.1 (new)</b> <del>{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 and should taking into account the intended purpose as identified in 3.1.1, dietary practices habits, socioeconomic situations and the need to avoid any risks to health.}</del></p> <p><del>Or</del></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> | <p>- We propose deleting this first new proposed principle. For example, we consider that voluntary addition of essential nutrients to staple foods can sometimes help address a public health need (e.g., the voluntary use by manufacturers of enriched flour in foods in the U.S with added folic acid).</p> <p>- We propose edits to combine the concepts in the second and third text options.</p> <p>-We do not consider it necessary to include the phrase “and is best determined at (the) national/regional/local level” given that this document is identified as guidance for national authorities.</p> |
| <p><b>3.3.2 (new)</b> <del>The selection of appropriate Foods {for categories of foods} to which essential nutrients {may} or {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>                                                                                                                                                                                                                                                                                                                 | <p>We suggest edits to clarify and simplify. We do not consider it necessary to refer to national authorities in 3.3.2 given that this document is identified as guidance for national authorities.</p> <p>We suggest retaining the separate provisions in 3.3.4 and 3.3.5.</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>We agree with the new principle.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <p><b>3.3.5 (new)</b> Essential nutrients should not be added to alcoholic beverages.]</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <p>We agree with this new principle.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <p><b>3.4 (new) Technological aspects</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <p><b>3.4.1 (new)</b> 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>We support this new principle that with the bracketed text reflects a simplified version of Section 3.1.2 in the Guidelines for Vitamin and Mineral Food Supplements (CAC/GL 55—2005).</p>                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <p><b>3.4.2 Former 3.4 with modifications</b> The added essential nutrient should be sufficiently stable in the food under customary conditions of processing, packaging, storage, distribution and use.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <p>We support retaining this principle with the modification to add “processing”.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <p><b>3.4.3 Former 3.6</b> 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>We support retaining this principle and can accept either option for text in brackets.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <p><b>3.4.4 Former 3.7</b> Technology and processing facilities should be available to permit the <del>{standardized}</del> addition of the essential nutrient to a food in a manner to ensure nutrient [bio]availability, consistency, distribution and stability.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <p>We support retaining former 3.7 as amended.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <p><b>3.5 Monitoring</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <p><b>3.5.1 (new)</b> <del>{It is important that National authorities} /</del></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <p>- We are uncertain if the reference to national authorities is</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><del>[National authorities should] [to ]</del>monitor intakes of <u>specific essential nutrients</u> from all sources including the essential nutrients added to foods to assess the extent to which <del>[the selected public health need or other purpose for addition] or [the purposes identified in 3.1.1]</del> <u>is are</u> addressed and to ensure that any risk of excessive intakes is minimized.</p>                                                                                                                                                                                                                                                                                                                                                   | <p>needed here given this guidance is for national authorities.<br/>                 - We propose adding “of specific nutrients”.<br/>                 - We consider that the other two bracketed text options are similar but prefer the second option which is more specific.</p>                                                                                                                                                                                                                                              |
| <p><del>3.5.2 (new) Monitoring of total nutrient intakes should use the same approach as used in deciding the nutrient addition.</del></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <p>We recommend deleting this proposed new principle because we regard it as overly simplistic and potentially misleading. Monitoring the impact of nutrient addition to address a public health need may involve multiple measures (e.g., intake data, biochemical indicators, health outcomes) and different approaches to intake assessment than approaches used to decide on levels of and foods for nutrient addition to address a public health need (e.g., dietary modeling with various nutrient addition scenarios)</p> |
| <p><b>4.0 [Principles for] <u>Specific Types of Nutrient Addition</u></b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <p>We propose naming this heading “Principles for Specific Types of Nutrient Addition” to clarify that the provisions in Section 4 are in fact principles, and to distinguish them from the general/overarching principles in section 3.<br/>                 - Additional comment: Should Section “4.0” be changed to “4”?</p>                                                                                                                                                                                                  |
| <p><b>4.1 (new) Addition of Essential Nutrients <del>{to Address a Demonstrated Public Health Need}</del> <del>[and Mandatory Addition]</del></b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <p>We consider that the provisions in this section address addition of nutrients to address a demonstrated public health need which is often but not always accomplished through mandatory nutrient addition.</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 clinical evidence of deficiency, subclinical evidence of deficiency, [suboptimal nutritional status], <del>{evidence from valid biochemical indicators}</del>, <del>estimates indicating inadequate intake of nutrients, estimates indicating potentially inadequate intakes of nutrients,</del> and/or by estimates of possible deficiencies because of changes in food habits.</p> | <p>-We support the removal of brackets from all text except “suboptimal nutritional status”. We would like to further consider whether there are examples of “suboptimal nutritional status” that are different from the other evidence identified in 4.1.1.<br/>                 -We propose to delete the reference to “<i>potentially inadequate intakes</i>” because we do not consider this sufficient to demonstrate a public health need.</p>                                                                             |
| <p><i>Former 6.1.</i> The kinds and amounts of essential nutrients to be added and <u>eligible foods to be fortified for nutrient addition to address a public health need</u> will depend upon the particular nutritional problems to be corrected, the characteristics of the target population, and the food consumption patterns of the area.</p>                                                                                                                                                                                                                                                                                                                                                                                                                 | <p>We consider that former 6.1 with its reference to correcting particular problems for a target population (with the proposed underlined amendments) should be placed in Section 4 which concerns principles for addressing a demonstrated public health need, rather than in Section 3.</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>We do not have a strong preference for whether the bracketed text should be retained as it should not affect the meaning.</p>                                                                                                                                                                                                                                                                                                                                                                                                 |
| <p>4.1.3. <i>Former 6.2.4</i> The amount of the essential nutrient added to the food should aim to be sufficient to meet the public health need <u>when consumed in [normal] [habitual] amounts by the population at risk.</u></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <p>We consider it necessary to retain the underlined text which was in former 6. 2.4 to convey the main point of this principle.</p>                                                                                                                                                                                                                                                                                                                                                                                             |
| <p>[Switch order with 4.1.3]:<br/>                 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 <del>{amount of the food consumed by the lower and upper percentiles of the population}</del> should be known.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <p>We support this text with removal of the brackets.</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>We agree with this text.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <p><b>4.2 Nutrient Addition for Purposes of Restoration</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <p>-We suggest edits to refer to the food being “a significant</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <p>4.2.1 <i>Former 4.1</i> Where the food has been identified as</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <p>-We suggest edits to refer to the food being “a significant</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                               |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>a significant <del>{source}</del>/<del>{contributor to intake}</del> of essential nutrients <u>of concern</u> in the population (<u>based on its nutrient content and/or frequency of consumption</u>), and particularly where there is [a] demonstrated public health need, restoration of the essential nutrients <del>of concern</del> lost during processing, storage or handling, should be <del>{recommended}</del>.</p>                                                                                                                                                                                                                                                                                                                                                              | <p>contributor to intake of essential nutrients based on nutrient content and/or frequency of consumption.<br/>-We suggest referring to “nutrients of concern” earlier.</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 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><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> | <p>We are uncertain if this level of detail is needed and consider that it may be possible to simplify the language in 4.2.2. Below is alternative text for consideration:</p> <p style="padding-left: 40px;">4.2.2 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 <u>[that would meet conditions for a “source” claim, or if the total daily intake of the essential nutrient from the food is greater than or equal to [10%] [15%] of the NRV. ]</u></p> <p>- We propose deleting the last new bracketed sentence in the absence of a clear rationale for why it was proposed to be added here.</p> |
| <p><b>4.3 Nutrient Addition for Purposes of Nutritional Equivalence</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <p>We support retaining this heading.</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 <del>{source}</del>/<del>{contributor to intake}</del> of essential nutrients <u>of concern</u> in the <del>{population}</del>- <u>based on its nutrient content and/or frequency of consumption</u>, and particularly where there is [a] demonstrated public health need, nutritional equivalence in terms of the essential nutrients <del>of concern</del> should be <del>{recommended}</del>.</p>                                                                                                                                                                                                                                                               | <p>For rationale for proposed edits, see 4.2.1</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 <u>nutrient</u> need not be equivalent.</p>                                                                                                                                                                                                                                                                                  | <p>We are uncertain if this level of detail is needed in 4.3.2, and suggest that “5%” also be placed in brackets.</p> <p>We support retaining the last principle with the addition of “nutrient”.</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>We support retaining this principle. For example, for nutrients such as saturated fat and sodium, the level of these nutrients in a substitute food need not be raised to be equivalent with the food it replaces.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <p><b>[4.4 Nutrient addition to Special Purpose Foods]</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <p>With our suggested edits to the Scope in Section 1, we are uncertain that there is a need to retain a separate section on “Nutrient Addition to Special Purpose Foods” (4.4) and suggest placing 4.4 and 4.4.1 in brackets for discussion.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <p><b>[4.4.1 Former 7.1</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 <del>{composition}</del> of such foods. [Consideration should be given to the target population</p>                                                                                                                                                                                                                                                                                                                         | <p>See above comments.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

|                                                                                                                                                                                                                                                                                                                                                                                                                        |  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| <p>and their nutrient requirements based on general reference intakes such as RNIs.]]</p> <p><i>Alternative:</i> <del>[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].</del></p> |  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|

| <b>U.S. Suggested Edits to CX/NFSDU 12/34/9, Appendix A Table 3, p. 52-57 (Clean Version of document)</b><br><b>(U.S. proposed new text is underlined; proposed deletions are identified with strikeout.)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>U.S. Comments</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>TITLE</b></p> <p><del>General</del> Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <p>The entire document encompasses both general/overarching principles) applicable to all types of nutrient addition and other principles for specific application, including for specific types and purposes of nutrient addition. Accordingly, we propose changing the document title to “Principles”. This would also be consistent with the use of the term “Principles” in this draft to refer to the entire document.</p>                                                                                                                                                                                                                                                             |
| <p><b>INTRODUCTION</b></p> <p><i>(Revised)</i> The <del>General Principles</del> 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, <u>and that prevent the indiscriminate addition of nutrients to foods.</u></p>                                                                                                                                                                                                            | <p>- We propose changing “General Principles” to “Principles” based on our above comments. We agree that the introduction should focus on the purpose of this document, and not elaborate on appropriate purposes of adding nutrients which the Committee agreed at its 32<sup>nd</sup> (2010) session to transfer to Section 3 on principles (REP11/NFSDU, paras 57-58 and 67, and Appendix VII). We further agree with identifying rational and safe nutrient addition as a basis for the principles in this guidance. In addition, we consider it is important to retain the underlined text in the Introduction because it further clarifies an important purpose of this document.</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>We agree with this new provision.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <p>(new) The Principles are applicable, as appropriate, to both mandatory and voluntary addition of essential nutrients unless otherwise indicated.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <p>We agree with this new provision.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <p>(new) National authorities may also consult FAO/WHO publications for further guidance on nutrient addition.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <p>We agree with this new provision.</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> <u>and infant formula.</u><sup>2</sup> <u>With regard to other foods for special dietary uses, national authorities may consider these principles, as appropriate, in conjunction with the provisions in Codex standards and guidelines for these foods.</u></p> <p><sup>1</sup>See the Codex <i>Guidelines for Vitamin and Mineral Food Supplements</i> (CAC/GL-55-2005).<br/> <sup>2</sup>See the Codex <i>Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants</i> (CODEX STAN 72-1981).</p> | <p>We agree with the exclusion of vitamin and mineral food supplements from the Scope and also consider that these principles do not apply to infant formula. In addition, we propose to add a second sentence to clarify the applicability of these principles to other foods for special dietary uses.</p> <p>If the Committee supports this clarification, we are uncertain that there is a need to retain a separate section on “Nutrient Addition to Special Purpose Foods” (4.4) and a definition of “Special Purpose Foods”, and suggest placing these in brackets for discussion.</p>                                                                                               |



|                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>2. DEFINITIONS</b><br/>For the purpose of these Principles:</p>                                                                                                                                                                                                                                                           | <p>The U.S. proposes to retain the definitions below and to reorder them more logically, which takes into consideration the current structure of the document.</p> <p>2.1 Nutrient<br/>2.2 Essential Nutrient<br/>2.3 Mandatory Nutrient Addition<br/>2.4 Voluntary Nutrient Addition<br/>2.5 Restoration<br/>2.6 Substitute food<br/>2.7 Nutritional equivalence<br/>[2.8 Special purpose foods]<br/>Note: As explained below, we propose restoring the definition of “nutrient” and deleting the definition of “fortification”.</p>                                                                                                                                                                                                                    |
| <p><u>2.1 Nutrient means any substance normally consumed as a constituent of food:</u><br/>(a) which provides energy; or<br/>(b) which is needed for growth and development and maintenance of [healthy] life; or<br/>(c) a deficit of which will cause characteristic biochemical or physiological changes to occur.</p>       | <p>We propose retaining the definition of “nutrient” in CAC/GL 09-1987. We propose placing ‘healthy’ in brackets for further discussion, noting that the reference to “healthy” life is included in the Codex nutritional risk analysis principles but not in the Guidelines on Nutrition Labelling.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <p><b>2.2 Essential nutrient</b> means any [nutrient] [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>With the proposal to retain the definition of “nutrient”, we consider that it would be clearer to refer to “nutrient” instead of “substance” in the definition of “essential nutrient”, but recognize that the current definition is used in other Codex texts.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <p><del>2.3</del> <b>2.6 (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>At this time, we do not have a strong preference for whether “flavour and odour” is retained or deleted. We support retaining plant protein-based beverages as an example of a substitute food for milk.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <p><del>2.4</del> <b>2.7 (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>We agree with this definition as amended.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <p><b>If retained, Proposed revised definition for option 3):</b><br/><del>2.5</del> <b>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>We consider it unnecessary to retain a definition for “fortification” given the term is not used in these revised provisions. Instead, we support referring to “nutrient addition” throughout the Principles (with appropriate qualifying text for specific sections as needed). We support this decision to avoid confusion because countries define “fortification” in different ways, with certain countries defining “fortification” to mean simply nutrient addition, and others defining “fortification” to mean appropriate nutrient addition to achieve one or more specified purposes. If a definition for “fortification” is retained, we could accept this revised definition, and consider it helpful to retain the text in brackets.</p> |
| <p><del>2.8</del> <b>2.5 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, <del>for in order to compensate for natural variations in essential nutrients.</del></p>    | <p>We support retaining the simplified revised definition of “restoration” as it pertains to related principles later in this document which we support retaining. However, we are uncertain about the need for and appropriateness of including the new proposed text in brackets. It would be helpful if examples could be provided. In addition, we question whether nutrient addition to compensate for natural variations in essential nutrients is in fact “restoration” .</p>                                                                                                                                                                                                                                                                     |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><del>2.6</del> <del>2.3</del>(new) <b>Mandatory nutrient addition</b> is when National Authorities require food manufacturers to add specified essential nutrients to particular foods or food categories.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <p>We agree with this definition.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <p><del>2.7</del> <del>2.4</del>(new ) <b>Voluntary nutrient addition</b> is when National Authorities permit food manufacturers to add specified essential nutrients to particular foods or food categories</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <p>We agree with the definition.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <p><del>[2.9</del> <del>2.8</del> <b>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, <del>and also include foods intended for infants and young children</del>.]</p>                                                                                                                                                                                                                                                 | <p>We suggest placing this definition in brackets. (Please refer to our comments on Section 1- Scope.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <p><b>2.11 (new) Population</b> refers to a national population or specific population group(s) as appropriate.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <p>We support this new definition with the understanding that it is included to simplify wording that occurs later in the Principles.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <p><del>3.0</del> <b>[GENERAL ] [OVERARCHING] PRINCIPLES</b></p> <p>The following provisions are <del>[general] [overarching] principles for the addition of nutrients. They address the purpose of nutrient addition, the determination of mandatory or voluntary nutrient addition, the selection of foods and nutrients and determination of amounts, technological aspects, and monitoring.</del></p>                                                                                                                                                                                                                                                                                                | <p>We propose that Section 3 be titled either “General” or “Overarching” Principles. We consider that further clarification is needed in the Section 3 heading to distinguish between the principles in Section 3 and Section 4. Moreover, we proposed renaming the entire document as “Principles for the Addition of Essential Nutrients to Foods” consistent with this draft’s use of the term “Principles” to refer to the entire document, and thus consider it would be confusing to name Section 3 “Principles” without further description. In addition, to aid the reader, we propose brief introductory text to section 3 to identify the nature of the general/overarching principles in Section 3. - Additional comment: Should Section “3.0” be changed to “3”?</p> |
| <p><b>3.1 (New) Fundamental Principles</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <p>We support this separate subsection in Section 3 for fundamental, high-level principles that identify appropriate purposes of nutrient addition as agreed to at the 2010 CCNFSDU session (REP11/NFSDU, paras 57-58, 67 and Appendix VII).</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 <del>preventing or</del> correcting a demonstrated deficiency or <del>inadequate intakes</del> of one or more essential nutrients in the population;</li> <li>contributing to meeting <del>[requirements] [recommended intakes]</del> of one or more essential nutrients <del>and reducing the risk of [inadequate intakes and/or] deficiency;</del></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>We propose edits to 3.1.1 to reduce redundancy and simplify text without changing the meaning.</p> <p>We propose further consideration of “recommended intakes” as an alternative to “requirements” as a broader term that includes but is not be limited to INL<sub>98</sub> values (e.g., to include recommended intakes of folic acid intake for women of childbearing potential to reduce risk of neural tube defects and recommended intakes for potassium to lower blood pressure.)</p>                                                                                                                                                                                                                                                                                 |
| <p>3.1.3 (New) National authorities should determine whether <del>[nutrient addition]</del> should be mandatory or voluntary <del>{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.</del></p>                                                                                                                                                                                 | <p>We support including only the first two sentences in new 3.1.3 to succinctly address who determines if nutrient addition should be mandatory or voluntary and how. As reflected in Section 4, we consider that the third sentence (with its reference to correcting particular problems for a target population) which was formerly in a section on nutrient addition to meet a demonstrated need in a population (i.e., Section 6.1 of the Principles) should be moved back to new Section 4 (which addresses this topic).</p>                                                                                                                                                                                                                                               |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>3.1.4 <del>The addition of essential nutrients to foods should be in accordance with food law and other policies established by national authorities.</del> 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>With regard to the proposed new sentence, we agree that the addition of essential nutrients should be in accordance with food law and other policies established by national authorities. However, we do not see the need to add this new proposed text (which is not in CAC/GL 09-1987), because it is implicit and understood that nutrient addition should be in accordance a government’s regulations and policies.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <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</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <p>We support retaining this principle as amended.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <p><b>3.2 (New) Selection of Nutrients and Determination of Amounts</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <p>We support the proposed new subheading.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <p><b>3.2.1</b> Former 3.2 with modifications (also considered to cover former 6.2.5): <del>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 any target population, an insignificant intake of {the added} essential nutrient[s], considering {total intakes} from all {relevant} dietary sources {including food supplements}.</del> Former 3.3. <u>In addition, The {amount of an essential nutrient added} or {addition of an essential nutrient} to a food should not result in an adverse effect on the metabolism of any other nutrient.</u> <del>{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.]</del></p>                                                                                                                                                                                                      | <p>-We support retaining the text in brackets in the first sentence to clarify that <i>amounts</i> of nutrients added to food should be “scientifically and nutritionally justified in line with one or more purposes stated in 3.1.1.” The clarification that nutrient addition should be scientifically justified supports a main aspect of this work which is to include nutrient addition for the purpose of meeting recommended intakes and reducing risk of inadequate intake as demonstrated by relevant scientific data.<br/>         - We propose replacing “relevant sources” with “dietary sources” and retaining “including food supplements” for clarification.<br/>         - We consider that former 3.3 is more appropriately placed in 3.2.1 than in new 3.2.7, and support the text option that refers to “the amount of an essential nutrient added.”.<br/>         - With new 3.2.2 below, we do not see the need for the last sentence in 3.2.1.</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, <del>{including considerations of populations at risk of excessive intake}.</del> [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>We agree with the wording of the first sentence, and retention of the second sentence in brackets for further consideration.</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</i></p> | <p>We agree with the Committee’s consideration of new 3.2.3 which provides additional guidance on the use of the UL.</p> <p>We reviewed this alternative proposal, but do not see how it adds essential information compared to the text in 3.2.1, 3.2.2 and 3.2.3.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><i>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><b>3.2.4</b> (new) Where an Upper Level of Intake is not available, <del>[National authorities may consider]</del> the scientific evidence to support the safe addition of an essential nutrient <del>[should be considered]</del>, including <del>[demonstration of evidence for an upper level or a range of intake that is unlikely to result in adverse health effects]</del> <u>including consideration of the potential relevance</u> of Highest Observed Intakes<sup>1</sup>.</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>- Given that the Introduction states that these Principles are intended to provide guidance to national authorities, we do not consider it necessary to refer to national authorities in 3.2.4.<br/>-We propose additional edits for consideration.</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>We agree with the wording of this new principle.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <p><del><b>3.2.6 Former 3.3</b> 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.</del></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <p>We consider that this provision may be more appropriately placed in 3.2.1.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <p><b>3.2.7</b> (new) <u>When</u> National authorities <del>may</del> establish minimum [limits] [levels] for the addition of essential nutrient to foods, <del>– [Minimum amounts for the addition of essential nutrients to foods– they</del> should take into account the <u>intended purpose as identified in 3.1.1, and may also consider</u> conditions of use for “a source” of claim in the Guidelines for use of nutrition and health claims (CAC/GL 23-1997). <del>[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.]</del></p>                                                                             | <p>-We consider that the main focus of this new principle should be on what national authorities should consider when establishing minimum levels, and propose edits to combine concepts in the three sentences into one.</p>                                                                                                                                                                                                                                                                                                                                                                                   |
| <p><b>3.3 (New) Selection of Foods</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <p>We agree with this new subheading.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <p><b>3.3.1</b> (new) <del>[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 and should take into account the intended purpose as identified in 3.1.1, dietary practices habits, socioeconomic situations and the need to avoid any risks to health.]</del></p> <p>Or</p>                                                                                                                          | <p>- We propose deleting this first new proposed principle. For example, we consider that voluntary addition of essential nutrients to staple foods can sometimes help address a public health need (e.g., the voluntary use by manufacturers of enriched flour in foods in the U.S with added folic acid).</p> <p>- We propose edits to combine the concepts in the second and third text options.<br/>-We do not consider it necessary to include the phrase “and is best determined at (the) national/regional/local level” given that this document is identified as guidance for national authorities.</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>                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <p><b>3.3.2 (new)</b> <del>The selection of appropriate Foods {for categories of foods} to which essential nutrients {may} or {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> | <p>We suggest edits to clarify and simplify. We do not consider it necessary to refer to national authorities in 3.3.2 given that this document is identified as guidance for national authorities.</p> <p>We suggest retaining the separate provisions in 3.3.4 and 3.3.5.</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>We agree with the new principle.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <p><b>[3.3.5 (new)</b> Essential nutrients should not be added to alcoholic beverages.]</p>                                                                                                                                                                                                                                                                                                                                                                                                                                             | <p>We agree with this new principle.</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>We support this new principle that with the bracketed text reflects a simplified version of Section 3.1.2 in the Guidelines for Vitamin and Mineral Food Supplements (CAC/GL 55—2005).</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>We support retaining this principle with the modification to add “processing”.</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>We support retaining this principle and can accept either option for text in brackets.</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>We support retaining former 3.7 as amended.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <p><b>3.5 Monitoring</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <p>3.5.1 (new) <del>{It is important that National authorities} or {National authorities should} [to] monitor intakes of specific essential nutrients 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 are addressed and to ensure that any risk of excessive intakes is minimized.</del></p>                                                                                   | <ul style="list-style-type: none"> <li>- We are uncertain if the reference to national authorities is needed here given this guidance is for national authorities.</li> <li>- We propose adding “of specific nutrients”.</li> <li>- We consider that the other two bracketed text options are similar but prefer the second option which is more specific.</li> </ul>                                                                                                                                                            |
| <p><del>3.5.2 (new) Monitoring of total nutrient intakes should use the same approach as used in deciding the nutrient addition.</del></p>                                                                                                                                                                                                                                                                                                                                                                                              | <p>We recommend deleting this proposed new principle because we regard it as overly simplistic and potentially misleading. Monitoring the impact of nutrient addition to address a public health need may involve multiple measures (e.g., intake data, biochemical indicators, health outcomes) and different approaches to intake assessment than approaches used to decide on levels of and foods for nutrient addition to address a public health need (e.g., dietary modeling with various nutrient addition scenarios)</p> |
| <p><b>4.0 {Principles for} Specific Types of Nutrient</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <p>We propose naming this heading “Principles for Specific</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Addition</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Types of Nutrient Addition” to clarify that the provisions in Section 4 are in fact principles, and to distinguish them from the general/overarching principles in section 3.<br>- Additional comment: Should Section “4.0” be changed to “4”?                                                                                                                                                                                                                                                   |
| <b>4.1 (new) Addition of Essential Nutrients [to Address a Demonstrated Public Health Need]-[and Mandatory Addition]</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | We consider that the provisions in this section address addition of nutrients to address a demonstrated public health need which is often but not always accomplished through mandatory nutrient addition.                                                                                                                                                                                                                                                                                       |
| 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 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, <del>estimates indicating potentially inadequate intakes of nutrients</del> , and/or by estimates of possible deficiencies because of changes in food habits. | -We support the removal of brackets from all text except “suboptimal nutritional status”. We would like to further consider whether there are examples of “suboptimal nutritional status” that are different from the other evidence identified in 4.1.1.<br>-We propose to delete the reference to “ <i>potentially inadequate intakes</i> ” because we do not consider this sufficient to demonstrate a public health need.                                                                    |
| <i>Former 6.1.</i> The kinds and amounts of essential nutrients to be added and <u>eligible foods</u> <del>to be fortified for nutrient addition to address a public health need</del> will depend upon the particular nutritional problems to be corrected, the characteristics of the target population, and the food consumption patterns of the area.                                                                                                                                                                                                                                                                                                                                                                                 | We consider that former 6.1 with its reference to correcting particular problems for a target population (with the proposed underlined amendments) should be placed in Section 4 which concerns principles for addressing a demonstrated public health need, rather than in Section 3.                                                                                                                                                                                                           |
| 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].                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | We do not have a strong preference for whether the bracketed text should be retained as it should not affect the meaning.                                                                                                                                                                                                                                                                                                                                                                        |
| 4.1.3. <i>Former 6.2.4</i> The amount of the essential nutrient added to the food should aim to be sufficient to meet the public health need <u>when consumed in [normal] [habitual] amounts by the population at risk.</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | We consider it necessary to retain the underlined text which was in former 6. 2.4 to convey the main point of this principle.                                                                                                                                                                                                                                                                                                                                                                    |
| [Switch order with 4.1.3]:<br>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.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | We support this text with removal of the brackets.                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 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.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | We agree with this text.                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>4.2 Nutrient Addition for Purposes of Restoration</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 4.2.1 <i>Former 4.1</i> Where the food has been identified as a significant <del>[source]</del> [contributor to-intake] of essential nutrients <u>of concern</u> in the population ( <u>based on its nutrient content and/or frequency of consumption</u> ), and particularly where there is [a] demonstrated public health need, restoration of the essential nutrients <del>of concern</del> lost during processing, storage or handling, should be <del>recommended</del> .                                                                                                                                                                                                                                                            | -We suggest edits to refer to the food being “a significant contributor to intake of essential nutrients based on nutrient content and/or frequency of consumption.”<br>-We suggest referring to “nutrients of concern” earlier.                                                                                                                                                                                                                                                                 |
| 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 nutrient for which there is no [daily intake reference value]/ [recommended nutrient intake]/ [NRV]/ [ INL                                                                                                                                                                          | We are uncertain if this level of detail is needed and consider that it may be possible to simplify the language in 4.2.2. Below is alternative text for consideration:<br><br>4.2.2 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 <u>[that would meet conditions for a “source” claim, or if the total daily intake of the</u> |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>98] 10% of the average daily intake of the nutrient).]</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>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <p><u>essential nutrient from the food is greater than or equal to [10%] [15%] of the NRV. ]</u></p> <p>- We propose deleting the last new bracketed sentence in the absence of a clear rationale for why it was proposed to be added here.</p>   |
| <p><b>4.3 Nutrient Addition for Purposes of Nutritional Equivalence</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <p>We support retaining this heading.</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 <del>source</del>/[contributor to intake] of essential nutrients <u>of concern in the [population]- based on its nutrient content and/or frequency of consumption</u>, and particularly where there is [a] demonstrated public health need, nutritional equivalence in terms of the essential nutrients <del>of concern</del> should be <del>recommended</del>.</p>                                                                                                                                                                                                                                                                                                                                                                                | <p>For rationale for proposed edits, see 4.2.1</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 <u>nutrient</u> need not be equivalent.</p>                                                                                                                                                                                                                                                                                                                                                                  | <p>We are uncertain if this level of detail is needed in 4.3.2, and suggest that “5%” also be placed in brackets.</p> <p>We support retaining the last principle with the addition of “nutrient”.</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>We support retaining this principle. For example, for nutrients such as saturated fat and sodium, the level of these nutrients in a substitute food need not be raised to be equivalent with the food it replaces.</p>                         |
| <p><b>[4.4 Nutrient addition to Special Purpose Foods]</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <p>With our suggested edits to the Scope in Section 1, we are uncertain that there is a need to retain a separate section on “Nutrient Addition to Special Purpose Foods” (4.4) and suggest placing 4.4 and 4.4.1 in brackets for discussion.</p> |
| <p><b>[4.4.1 Former 7.1</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 <del>composition</del> 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><del>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].</del></p> | <p>See above comments.</p>                                                                                                                                                                                                                        |

| U.S. Suggested Edits to CX/NFSDU 12/34/9, Appendix A Table 3, p. 52-57 (Clean Version of document)<br>(U.S. proposed new text is underlined; proposed deletions are identified with strikeout.)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | U.S. Comments                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>TITLE</b></p> <p><del>General</del> Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <p>The entire document encompasses both general/overarching principles) applicable to all types of nutrient addition and other principles for specific application, including for specific types and purposes of nutrient addition. Accordingly, we propose changing the document title to “Principles”. This would also be consistent with the use of the term “Principles” in this draft to refer to the entire document.</p>                                                                                                                                                                                                                                                                    |
| <p><b>INTRODUCTION</b></p> <p><i>(Revised) The <del>{General Principles}</del> 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, <u>and that prevent the indiscriminate addition of nutrients to foods.</u></i></p>                                                                                                                                                                                                   | <p>- We propose changing “General Principles” to “Principles” based on our above comments. We agree that the introduction should focus on the purpose of this <i>document</i>, and not elaborate on appropriate purposes of adding nutrients which the Committee agreed at its 32<sup>nd</sup> (2010) session to transfer to Section 3 on principles (REP11/NFSDU, paras 57-58 and 67, and Appendix VII). We further agree with identifying rational and safe nutrient addition as a basis for the principles in this guidance. In addition, we consider it is important to retain the underlined text in the Introduction because it further clarifies an important purpose of this document.</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>We agree with this new provision.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <p>(new) The Principles are applicable, as appropriate, to both mandatory and voluntary addition of essential nutrients unless otherwise indicated.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <p>We agree with this new provision.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <p>(new) National authorities may also consult FAO/WHO publications for further guidance on nutrient addition.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <p>We agree with this new provision.</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> and infant formula.<sup>2</sup> <u>With regard to other foods for special dietary uses, national authorities may consider these principles, as appropriate, in conjunction with the provisions in Codex standards and guidelines for these foods.</u></p> <p><sup>1</sup>See the Codex <i>Guidelines for Vitamin and Mineral Food Supplements</i> (CAC/GL-55-2005).<br/> <sup>2</sup>See the Codex <i>Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants</i> (CODEX STAN 72-1981).</p> | <p>We agree with the exclusion of vitamin and mineral food supplements from the Scope and also consider that these principles do not apply to infant formula. In addition, we propose to add a second sentence to clarify the applicability of these principles to other foods for special dietary uses.</p> <p>If the Committee supports this clarification, we are uncertain that there is a need to retain a separate section on “Nutrient Addition to Special Purpose Foods” (4.4) and a definition of “Special Purpose Foods”, and suggest placing these in brackets for discussion.</p>                                                                                                      |
| <p><b>2. DEFINITIONS</b></p> <p>For the purpose of these Principles:</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <p>The U.S. proposes to retain the definitions below and to reorder them more logically, which takes into consideration the current structure of the document.</p> <ul style="list-style-type: none"> <li>2.1 Nutrient</li> <li>2.2 Essential Nutrient</li> <li>2.3 Mandatory Nutrient Addition</li> <li>2.4 Voluntary Nutrient Addition</li> <li>2.5 Restoration</li> <li>2.6 Substitute food</li> <li>2.7 Nutritional equivalence</li> </ul>                                                                                                                                                                                                                                                     |



|                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                                                                                                                                                                                                      | [2.8 Special purpose foods]<br>Note: As explained below, we propose restoring the definition of “nutrient” and deleting the definition of “fortification”.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>2.1 Nutrient</b> means any substance normally consumed as a constituent of food:<br>(a) which provides energy; or<br>(b) which is needed for growth and development and maintenance of [healthy] life; or<br>(c) a deficit of which will cause characteristic bio-chemical or physiological changes to occur.                     | We propose retaining the definition of “nutrient” in CAC/GL 09-1987. We propose placing ‘healthy’ in brackets for further discussion, noting that the reference to “healthy” life is included in the Codex nutritional risk analysis principles but not in the Guidelines on Nutrition Labelling.                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>2.2 Essential nutrient</b> means any [nutrient] [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.                                                                                    | With the proposal to retain the definition of “nutrient”, we consider that it would be clearer to refer to “nutrient” instead of “substance” in the definition of “essential nutrient”, but recognize that the current definition is used in other Codex texts.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <del>2.3</del> <b>2.6 (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.}              | At this time, we do not have a strong preference for whether “flavour and odour” is retained or deleted. We support retaining plant protein-based beverages as an example of a substitute food for milk.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <del>2.4</del> <b>2.7 (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.             | We agree with this definition as amended.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>If retained, Proposed revised definition for option 3):</b><br><del>2.5</del> <b>Fortification</b> means the addition of one or more essential nutrients to a food {whether or not it is normally contained in the food.}                                                                                                         | We consider it unnecessary to retain a definition for “fortification” given the term is not used in these revised provisions. Instead, we support referring to “nutrient addition” throughout the Principles (with appropriate qualifying text for specific sections as needed). We support this decision to avoid confusion because countries define “fortification” in different ways, with certain countries defining “fortification” to mean simply nutrient addition, and others defining “fortification” to mean appropriate nutrient addition to achieve one or more specified purposes. If a definition for “fortification” is retained, we could accept this revised definition, and consider it helpful to retain the text in brackets. |
| <del>2.8</del> <b>2.5 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.}                          | We support retaining the simplified revised definition of “restoration” as it pertains to related principles later in this document which we support retaining. However, we are uncertain about the need for and appropriateness of including the new proposed text in brackets. It would be helpful if examples could be provided. In addition, we question whether nutrient addition to compensate for natural variations in essential nutrients is in fact “restoration” .                                                                                                                                                                                                                                                                     |
| <del>2.6</del> <b>2.3(new) Mandatory nutrient addition</b> is when National Authorities require food manufacturers to add specified essential nutrients to particular foods or food categories.                                                                                                                                      | We agree with this definition.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <del>2.7</del> <b>2.4(new) Voluntary nutrient addition</b> is when National Authorities permit food manufacturers to add specified essential nutrients to particular foods or food categories                                                                                                                                        | We agree with the definition.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <del>2.9</del> <b>2.8 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 | We suggest placing this definition in brackets.<br>(Please refer to our comments on Section 1- Scope.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| special dietary use, <del>and also include foods intended for infants and young children</del> }]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>2.11 (new) Population</b> refers to a national population or specific population group(s) as appropriate.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | We support this new definition with the understanding that it is included to simplify wording that occurs later in the Principles.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>3.0 [GENERAL ] [OVERARCHING] PRINCIPLES</b><br><br>The following provisions are <del>[general] [overarching]</del> principles for the addition of nutrients. They address the purpose of nutrient addition, the determination of mandatory or voluntary nutrient addition, the selection of foods and nutrients and determination of amounts, technological aspects, and monitoring.                                                                                                                                                                                                                                                                                                                | We propose that Section 3 be titled either “General” or “Overarching” Principles. We consider that further clarification is needed in the Section 3 heading to distinguish between the principles in Section 3 and Section 4. Moreover, we proposed renaming the entire document as “Principles for the Addition of Essential Nutrients to Foods” consistent with this draft’s use of the term “Principles” to refer to the entire document, and thus consider it would be confusing to name Section 3 “Principles” without further description. In addition, to aid the reader, we propose brief introductory text to section 3 to identify the nature of the general/overarching principles in Section 3.<br>- Additional comment: Should Section “3.0” be changed to “3”? |
| <b>3.1 (New) Fundamental Principles</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | We support this separate subsection in Section 3 for fundamental, high-level principles that identify appropriate purposes of nutrient addition as agreed to at the 2010 CCNFSDU session (REP11/NFSDU, paras 57-58, 67 and Appendix VII).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 3.1.1 Essential nutrients may be appropriately added to foods for the purpose of: <ul style="list-style-type: none"> <li>contributing to <del>preventing or</del> correcting a demonstrated deficiency or <del>inadequate intakes</del> of one or more essential nutrients in the population;</li> <li>contributing to meeting <del>[requirements]</del> <u>recommended intakes</u> of one or more essential nutrients <del>and reducing the risk of [inadequate intakes and/or] deficiency;</del></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> | We propose edits to 3.1.1 to reduce redundancy and simplify text without changing the meaning.<br><br>We propose further consideration of “recommended intakes” as an alternative to “requirements” as a broader term that includes but is not be limited to INL <sub>08</sub> values (e.g., to include recommended intakes of folic acid intake for women of childbearing potential to reduce risk of neural tube defects and recommended intakes for potassium to lower blood pressure.)                                                                                                                                                                                                                                                                                   |
| 3.1.3 (New) National authorities should determine whether <del>[nutrient addition]</del> should be mandatory or voluntary <del>[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.</del>                                                                                                                                                                                      | We support including only the first two sentences in new 3.1.3 to succinctly address who determines if nutrient addition should be mandatory or voluntary and how. As reflected in Section 4, we consider that the third sentence (with its reference to correcting particular problems for a target population) which was formerly in a section on nutrient addition to meet a demonstrated need in a population (i.e., Section 6.1 of the Principles) should be moved back to new Section 4 (which addresses this topic).                                                                                                                                                                                                                                                  |
| 3.1.4 <del>The addition of essential nutrients to foods should be in accordance with food law and other policies established by national authorities.</del> 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.                                                                                                                                                                                               | With regard to the proposed new sentence, we agree that the addition of essential nutrients should be in accordance with food law and other policies established by national authorities. However, we do not see the need to add this new proposed text (which is not in CAC/GL 09-1987), because it is implicit and understood that nutrient addition should be in accordance a government’s regulations and policies.                                                                                                                                                                                                                                                                                                                                                      |
| 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 retaining this principle as amended.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>3.2 (New) Selection of Nutrients and Determination of Amounts</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | We support the proposed new subheading.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>3.2.1 Former 3.2 with modifications (also considered to cover former 6.2.5):</b> The <del>[amount of an added] or [addition of an]</del> essential nutrient should be <del>[scientifically and nutritionally</del>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | -We support retaining the text in brackets in the first sentence to clarify that <i>amounts</i> of nutrients added to food should be “scientifically and nutritionally justified                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>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 <del>the</del> <u>any</u> target population, an insignificant intake of [the added] essential nutrient[s], considering [total intakes]—from all <del>[relevant]</del> <u>dietary</u> sources [including food supplements]; <i>Former 3.3. In addition, 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. [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.]</i></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <p>in line with one or more purposes stated in 3.1.1.” The clarification that nutrient addition should be scientifically justified supports a main aspect of this work which is to include nutrient addition for the purpose of meeting recommended intakes and reducing risk of inadequate intake as demonstrated by relevant scientific data.</p> <ul style="list-style-type: none"> <li>- We propose replacing “relevant sources” with “dietary sources” and retaining “including food supplements” for clarification.</li> <li>- We consider that former 3.3 is more appropriately placed in 3.2.1 than in new 3.2.7, and support the text option that refers to “the amount of an essential nutrient added.”.</li> <li>- With new 3.2.2 below, we do not see the need for the last sentence in 3.2.1.</li> </ul> |
| <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>We agree with the wording of the first sentence, and retention of the second sentence in brackets for further consideration.</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) 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.]</i></p> | <p>We agree with the Committee’s consideration of new 3.2.3 which provides additional guidance on the use of the UL.</p> <p>We reviewed this alternative proposal, but do not see how it adds essential information compared to the text in 3.2.1, 3.2.2 and 3.2.3.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <p><b>3.2.4</b> (new) Where an Upper Level of Intake is not available, <del>[National authorities may consider]</del> the scientific evidence to support the safe addition of an essential nutrient [should be considered]; including <del>[demonstration of evidence for an upper level or a range of intake that is unlikely to result in adverse health effects]</del> <u>including consideration of the potential relevance</u> of Highest Observed Intakes<sup>1</sup>.</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</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <ul style="list-style-type: none"> <li>- Given that the Introduction states that these Principles are intended to provide guidance to national authorities, we do not consider it necessary to refer to national authorities in 3.2.4.</li> <li>-We propose additional edits for consideration.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>health effects have been identified. (appropriate source to be cited.)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <p><del>3.2.5</del> (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>We agree with the wording of this new principle.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <p><del>3.2.6 Former 3.3</del> 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>We consider that this provision may be more appropriately placed in 3.2.1.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <p><del>3.2.7</del> (new) <u>When</u> National authorities <del>may</del> establish minimum [limits] [<u>levels</u>] for the addition of essential nutrient to foods, <del>– [Minimum amounts for the addition of essential nutrients to foods– they should take into account the intended purpose as identified in 3.1.1, and may also consider 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.]</del></p>                                                                                                                                                     | <p>-We consider that the main focus of this new principle should be on what national authorities should consider when establishing minimum levels, and propose edits to combine concepts in the three sentences into one.</p>                                                                                                                                                                                                                                                                                                                                                                                      |
| <p><b>3.3 (New) Selection of Foods</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <p>We agree with this new subheading.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <p><del>3.3.1</del> (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 <del>best determined at national/regional/local level and</del> <u>should take</u> into account <u>the intended purpose as identified in 3.1.1, dietary practices habits, socioeconomic situations</u> 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>- We propose deleting this first new proposed principle. For example, we consider that voluntary addition of essential nutrients to staple foods can sometimes help address a public health need (e.g., the voluntary use by manufacturers of enriched flour in foods in the U.S with added folic acid).</p> <p>- We propose edits to combine the concepts in the second and third text options.</p> <p>-We do not consider it necessary to include the phrase “and is best determined at (the) national/regional/local level” given that this document is identified as guidance for national authorities.</p> |
| <p><del>3.3.2</del> (new) The selection of appropriate Foods {or categories of foods} to which essential nutrients {may} / or {may not} be added should take into account the nutritional value of the foods <u>and is best determined by National Authorities.</u></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>                                                                                                                                                                                                                                                                                               | <p>We suggest edits to clarify and simplify. We do not consider it necessary to refer to national authorities in 3.3.2 given that this document is identified as guidance for national authorities.</p> <p>We suggest retaining the separate provisions in 3.3.4 and 3.3.5.</p>                                                                                                                                                                                                                                                                                                                                    |
| <p><del>3.3.4</del> (new) Essential nutrients should not be added to unprocessed foods, including, but not limited to, fruit, vegetables, meat, poultry and fish.}</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <p>We agree with the new principle.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <p><del>3.3.5</del> (new) Essential nutrients should not be added to alcoholic beverages.]</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <p>We agree with this new principle.</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</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <p>We support this new principle that with the bracketed text reflects a simplified version of Section 3.1.2 in the Guidelines for Vitamin and Mineral Food Supplements</p>                                                                                                                                                                                                                                                                                                                                                                                                                                        |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| addition, purity criteria should take into account [in the following order]: FAO/WHO standards, international Pharmacopoeias or recognized international standards, or national legislation.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | (CAC/GL 55—2005).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 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.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | We support retaining this principle with the modification to add “processing”.                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 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.                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | We support retaining this principle and can accept either option for text in brackets.                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 3.4.4 <i>Former 3.7</i> Technology and processing facilities should be available to permit the <del>{standardized}</del> addition of the essential nutrient to a food in a manner to ensure nutrient [bio]availability, consistency, distribution and stability.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | We support retaining former 3.7 as amended.                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>3.5 Monitoring</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 3.5.1 (new) <del>{It is important that National authorities}</del> / <del>{National authorities should}</del> [to ] monitor intakes of <u>specific essential nutrients</u> from all sources including the essential nutrients added to foods to assess the extent to which <del>{the selected public health need or other purpose for addition}</del> or <del>{the purposes identified in 3.1.1}</del> <del>is</del> <u>are</u> addressed and to ensure that any risk of excessive intakes is minimized.                                                                                                                                                                                                                                                        | <ul style="list-style-type: none"> <li>- We are uncertain if the reference to national authorities is needed here given this guidance is for national authorities.</li> <li>- We propose adding “of specific nutrients”.</li> <li>- We consider that the other two bracketed text options are similar but prefer the second option which is more specific.</li> </ul>                                                                                                                                                     |
| 3.5.2 (new) <del>Monitoring of total nutrient intakes should use the same approach as used in deciding the nutrient addition.</del>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | We recommend deleting this proposed new principle because we regard it as overly simplistic and potentially misleading. Monitoring the impact of nutrient addition to address a public health need may involve multiple measures (e.g., intake data, biochemical indicators, health outcomes) and different approaches to intake assessment than approaches used to decide on levels of and foods for nutrient addition to address a public health need (e.g., dietary modeling with various nutrient addition scenarios) |
| <b>4.0 <del>{Principles for}</del> <u>Specific Types of Nutrient Addition</u></b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <p>We propose naming this heading “Principles for Specific Types of Nutrient Addition” to clarify that the provisions in Section 4 are in fact principles, and to distinguish them from the general/overarching principles in section 3.</p> <p>- Additional comment: Should Section “4.0” be changed to “4”?</p>                                                                                                                                                                                                         |
| <b>4.1 (new) Addition of Essential Nutrients <del>{to Address a Demonstrated Public Health Need}</del> <del>[and Mandatory Addition]</del></b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | We consider that the provisions in this section address addition of nutrients to address a demonstrated public health need which is often but not always accomplished through mandatory nutrient addition.                                                                                                                                                                                                                                                                                                                |
| 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 clinical evidence of deficiency, subclinical evidence of deficiency, [suboptimal nutritional status], <del>{evidence from valid biochemical indicators}</del> , <del>estimates indicating inadequate intake of nutrients, estimates indicating potentially inadequate intakes of nutrients,</del> and/or by estimates of possible deficiencies because of changes in food habits. | <ul style="list-style-type: none"> <li>-We support the removal of brackets from all text except “suboptimal nutritional status”. We would like to further consider whether there are examples of “suboptimal nutritional status” that are different from the other evidence identified in 4.1.1.</li> <li>-We propose to delete the reference to “<i>potentially inadequate intakes</i>” because we do not consider this sufficient to demonstrate a public health need.</li> </ul>                                       |
| <i>Former 6.1.</i> The kinds and amounts of essential nutrients to be added and <u>eligible</u> foods <del>to be fortified for nutrient addition to address a public health need</del> will depend upon the particular nutritional problems to be corrected, the                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | We consider that former 6.1 with its reference to correcting particular problems for a target population (with the proposed underlined amendments) should be placed in Section 4 which concerns principles for                                                                                                                                                                                                                                                                                                            |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>characteristics of the target population, and the food consumption patterns of the area.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <p>addressing a demonstrated public health need, rather than in Section 3.</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>We do not have a strong preference for whether the bracketed text should be retained as it should not affect the meaning.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <p>4.1.3. <i>Former 6.2.4</i> The amount of the essential nutrient added to the food should aim to be sufficient to meet the public health need <u>when consumed in [normal] [habitual] amounts by the population at risk.</u></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <p>We consider it necessary to retain the underlined text which was in former 6. 2.4 to convey the main point of this principle.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <p>[Switch order with 4.1.3]:<br/>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>We support this text with removal of the brackets.</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>We agree with this text.</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 <del>{source}</del> / [contributor to-intake] of essential nutrients <u>of concern</u> in the population (<u>based on its nutrient content and/or frequency of consumption</u>), and particularly where there is [a] demonstrated public health need, restoration of the essential nutrients <del>of concern</del> lost during processing, storage or handling, should be <del>{recommended}</del>.</p>                                                                                                                                                                                                                                                                                               | <p>-We suggest edits to refer to the food being “a significant contributor to intake of essential nutrients based on nutrient content and/or frequency of consumption.<br/>-We suggest referring to “nutrients of concern” earlier.</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 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).<br/><br/>[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>We are uncertain if this level of detail is needed and consider that it may be possible to simplify the language in 4.2.2. Below is alternative text for consideration:<br/><br/>4.2.2 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 <u>[that would meet conditions for a “source” claim, or if the total daily intake of the essential nutrient from the food is greater than or equal to [10%] [15%] of the NRV. ]</u><br/><br/>- We propose deleting the last new bracketed sentence in the absence of a clear rationale for why it was proposed to be added here.</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 <del>{source}</del> / [contributor to intake] of essential nutrients <u>of concern</u> in the <del>{population}</del> <u>based on its nutrient content and/or frequency of consumption</u>, and particularly where there is [a] demonstrated public health need, nutritional equivalence in terms of the essential nutrients <del>of concern</del> should be <del>{recommended}</del>.</p>                                                                                                                                                                                                                                                               | <p>We support retaining this heading.<br/><br/>For rationale for proposed edits, see 4.2.1</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].<br/><br/>Where there is a clear public health reason to moderate the</p>                                                                                                                                                                                                                                                                                                                                                               | <p>We are uncertain if this level of detail is needed in 4.3.2, and suggest that “5%” also be placed in brackets.<br/><br/>We support retaining the last principle with the addition of “nutrient”.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>intake of a specific nutrient, the level of this <u>nutrient</u> need not be equivalent.</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>We support retaining this principle. For example, for nutrients such as saturated fat and sodium, the level of these nutrients in a substitute food need not be raised to be equivalent with the food it replaces.</p>                         |
| <p><b>[4.4 Nutrient addition to Special Purpose Foods]</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <p>With our suggested edits to the Scope in Section 1, we are uncertain that there is a need to retain a separate section on “Nutrient Addition to Special Purpose Foods” (4.4) and suggest placing 4.4 and 4.4.1 in brackets for discussion.</p> |
| <p><b>[4.4.1 Former 7.1</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 <del>{composition}</del>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> <del>[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].</del></p> | <p>See above comments.</p>                                                                                                                                                                                                                        |

**ICGMA**

| <p><b>Section of the General Principles</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <p><b>Proposed ICGMA comments</b></p> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|
| <p><b>INTRODUCTION</b></p> <p>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 vbasis for the rational and safe addition of essential nutrients to foods.</p> <p>Same wording as before</p> <p><b>To be discussed in plenary:</b><br/>Should the purposes for addition be spelled out in Section 3 – currently the Basic Principles Section</p> | <p>ICGMA SUPPORTS</p>                 |
| <p>The [Principles] [take into consideration provision 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>Minor edits to wording</p>                                                                                                                                                                                                                                                                            | <p>ICGMA SUPPORTS</p>                 |
| <p>The [Principles] are applicable as appropriate to both mandatory and voluntary addition of essential nutrients unless otherwise indicated.</p> <p><b>C/B discussed in plenary</b><br/>Where to place this principle</p>                                                                                                                                                                                                                                                                                                                                                  | <p>ICGMA SUPPORTS</p>                 |
| <p>National authorities may also consult FAO/WHO publications for further guidance on nutrient addition.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <p>ICGMA SUPPORTS</p>                 |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                             |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                             |
| <p><b>1.0 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><sup>1</sup>See the Codex Guidelines for Vitamin and Mineral Food Supplements (CAC/GL 55 – 2005)</p> <p>Minor word changing</p> <p><b>C/B discussed in plenary</b><br/>Where to place in the document, the principle on applicability of principles to both mandatory and voluntary fortification</p>                                                                                                                                                                                    | ICGMA SUPPORTS                                                                                                                                                                                                                                                              |
| <p><b>2.0 DEFINITIONS</b><br/>For purposes of these [Principles]</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                             |
| <p><del><b>2.1 Nutrient</b> means any substance normally consumed as a constituent of food:</del></p> <p><del>a) which provides energy; or</del><br/><del>b) which is needed for growth and development and maintenance of healthy life; or</del><br/><del>e) a deficit of which will cause characteristic biochemical or physiological changes to occur.</del></p> <p>Proposed to remove definition<br/>Caveat: General Principles referenced as source of definition in the <i>Nutritional Risk Analysis Principles</i><br/>If retained would exclude “healthy” – which makes the definition the same as the one in <i>Guidelines on Nutrition Labelling</i></p> | ICGMA would like the definition for Nutrient removed. Nutrient is already defined in <i>Guidelines on Nutrition Labelling</i> A footnote with the definition of Essential Nutrient could link the reader to this definition in the <i>Guidelines on Nutrition Labelling</i> |
| <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 <del>healthy</del> life and which cannot be synthesized in adequate amount by the body</p> <p><b><u>To be discussed in plenary:</u></b><br/>Including in the definition</p> <p>or, a deficit of which will cause characteristic biochemical or physiological changes to occur</p>                                                                                                                                                                                                                | ICGMA SUPPORTS the definition as proposed<br><br>ICGMA DOES NOT SUPPORT the inclusion of or, a deficit of which...                                                                                                                                                          |
| <p><b>2.3 Substitute food</b> is a food which is designed to resemble a common food in appearance and texture, [flavor 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>To be discussed in plenary</b><br/>should [flavor and odour] be retained and the example [e.g. plant....] be removed?</p>                                                                                                                                                                                                                                   | ICGMA SUPPORTS definition with removal of [flavor and odour] and retention of example                                                                                                                                                                                       |
| <p><b>2.4 Nutritional equivalence</b> means the addition of one or more essential nutrients 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. <del>It is achieved when one or more essential nutrients are added to a product that is designed to resemble a common food in appearance, texture, in amounts such that the substitute product has a similar nutritive value, [in terms of the amount and bioavailability of</del></p>                                                                            | ICGMA SUPPORTS the definition as stated in the first sentence and the removal of the last sentence.                                                                                                                                                                         |



|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <del>the added essential nutrient.]</del>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <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><b><u>To be discussed in plenary:</u></b><br/>Whether there is a need for the definition at all.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | ICGMA does not have consensus whether this definition is required or not.                                                                                                                                                                                                                                                                                                                                                                           |
| <p><b>2.8 Restoration</b> means the addition to a food of essential nutrients in amounts to replace those lost during the course of good manufacturing practices, or during normal storage and handling procedures, [or in order to compensate for natural variations in essential nutrients]</p> <p><b><u>To be discussed in plenary:</u></b><br/>need for [ or in order to compensate for natural variations in essential nutrients] section at end.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | ICGMA would like to understand what is meant by [to compensate for natural variations in essential nutrients]. What would trigger such action?                                                                                                                                                                                                                                                                                                      |
| <b>2.6 Mandatory nutrient addition</b> is when National Authorities require food manufacturers to add specified essential nutrients to particular foods or food categories                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | ICGMA does not have consensus on whether this definition is required or not                                                                                                                                                                                                                                                                                                                                                                         |
| <b>2.7 Voluntary nutrient addition</b> is when National Authorities permit food manufacturers to add specified essential nutrients to particular foods or food categories                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | ICGMA does not have consensus on whether this definition is required or not.                                                                                                                                                                                                                                                                                                                                                                        |
| <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><b><u>To be discussed in plenary:</u></b><br/>deletion of component in [and also includes foods intended for infants and young children ]</p> <p>Up for discussion, is suggestion to replace above definition with the definition of Foods for Special Dietary Uses which is:<br/>Foods for Special Dietary Uses are those foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders and which are presented as such.<sup>1</sup> The composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist.<br/><sup>1</sup> this includes foods for infants and young children</p> | <p>ICGMA SUPPORTS THE DEFINITION for Special Purpose Foods including [and also includes foods intended for infants and young children]</p> <p>ICGMA does not support reverting to the definition for Foods for Special Dietary Uses as it implies use of the food is to meet a need associated with a condition. With Special Purpose Foods definition the food are not limited in such a manner but can be targeted at the general population.</p> |
| <b>2.10 Nutrient density</b> definition to be deleted                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | ICGMA SUPPORTS REMOVAL                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>2.11 Standardization</b> definition to be deleted                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | ICGMA SUPPORTS REMOVAL                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>2.12 Population</b> refers to a national population or specific population group(s) as appropriate                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | ICGMA SUPPORTS DEFINITION                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>3. Principles</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>3.1 Fundamental Principles</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <p><b>3.1.1 Essential nutrients</b> 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 more essential nutrients in the population</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <p>ICGMA SUPPORTS DEFINITION AS STATED, including the words in [ ] One exception:</p> <p>Under Bullet 2:<br/>Instead of [requirements] it should read:</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>[requirements or recommended nutrient intakes]. The [ ] should then be removed. Including both terms recognizes that countries used these terms for the same intent.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <p><b>3.1.2 The above purposes... recommendation is delete</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <p>ICGMA SUPPORTS DELETION</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <p><b>3.1.3 National Authorities</b> should determine whether [nutrient addition] should be mandatory or voluntary. [This decision <b>may</b> 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 <b>and the food vehicle chosen</b> will depend upon the particular nutritional problems to be <b>corrected or prevented</b>, the characteristics of the target populations, <b>and their food consumption patterns</b>.</p> <p><b>For Plenary to consider</b><br/>Moving the 3<sup>rd</sup> sentence: The kinds and amounts... to Section 4: Principles for [<del>Specific</del>] Types of Nutrient Addition</p> | <p>ICGMA SUPPORTS THE FOLLOWING WORDING:</p> <p>National Authorities should determine whether [nutrient addition] should be mandatory or voluntary. [This decision <b>should</b> be based on severity and extent of public health need as demonstrated by scientific evidence</p> <p>And<br/>Add onto to Sentence 1 of 3.1.1 the following component out of 3.1.4</p> <p>and where appropriate the minimum and maximum levels at which they should be present.</p> <p>And<br/>REMOVE sentence 3 of 3.1.3 – to be considered as an addition to Section 4: Principles for [<del>Specific</del>]Types of Nutrient Addition</p> |
| <p><b>3.1.4 The addition of essential nutrients</b> 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 essential nutrients required or permitted to be added and where appropriate the minimum and maximum levels at which they should be present.</p>                                                                                                                                                                                                                      | <p>ICGMA SUPPORTS REMOVAL OF 3.1.4 (this instruction to national authorities is not required) and the transfer of the following component into 3.1.3 as noted above</p> <p>“and where appropriate the minimum and maximum levels at which they should be present.”</p>                                                                                                                                                                                                                                                                                                                                                      |
| <p><b>3.1.5 Addition of essential nutrients</b> to foods should not be used to mislead or deceive the consumer.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <p>ICGMA SUPPORTS THIS AS WORDED</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |

**GENERAL COMMENT ON SECTION 3.2** Remains too ambiguous in how it has been presented for review to make comments at this time. ICGMA will monitor this section of discussion at plenary and provided input as it seems appropriate. ICGMA believes there will be another opportunity (next year’s meetings) for further input and based on this year’s plenary discussions it will be clearer what the options for consideration are.

| Section of the General Principles                                                                                                                                                                                                                                                                                                       | Proposed ICGMA comments                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------|
| <p><b>3.2 Selection of Nutrients and Determination of amounts</b></p>                                                                                                                                                                                                                                                                   | <p><b>3.2 Selection of Nutrients and Determination of amounts</b></p> |
| <p><b>3.2.1 The amount of an added</b> <i>or</i> [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</p> |                                                                       |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| <p>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>This is a blending of two potential options and is to be discussed in plenary</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  |
| <p><b>3.2.2 The Upper Level of Intake</b> 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><b>3.2.3 Potential change to population intakes</b> 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><b>Alternative for 3.2.2 and 3.2.3</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  |
| <p><i>National authorities may establish maximum limit for the addition of essential nutrients to foods to reduce any potential risk for adverse effects on health. Maximum limits for the addition of essential nutrients to foods should be based on the following criteria:</i></p> <ul style="list-style-type: none"> <li>(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></li> <li>(ii) <i>The daily intake of essential nutrients from other dietary sources</i></li> </ul> <p><i>When the maximum levels are set, due account may be taken of the reference intake values of essential nutrients for the population.</i></p> <p><i>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><b>3.2.4 Where an Upper Level of Intake</b> 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></p> <p><sup>1</sup> HOI – 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><b>3.2.5</b> 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 The [amount of an essential nutrient added] /</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |  |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                      |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| [addition of an essential nutrient] to a food should not result in an adverse effect on the metabolism of any other nutrient                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <p><b>3.2.7 National authorities may establish minimum limits</b> for the addition of essential nutrients 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>To be discussed in plenary: whether or how to refer to the conditions of use for “source of” claims</p>                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <p><b>3.3 Selection of Foods</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <p><b>3.3.1 [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.]</b><br/>Or<br/>[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]<br/>Or<br/>[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>ICGMA SUPPORTS STATEMENT 3:</p> <p>[The selection of food(s) to which to add an essential nutrient(s) should primarily be based on achieving appropriate purposes of nutrition addition as identified in 3.1.1]</p> <p>Note: In support of not going with Option 1: An example of where use of a ubiquitous food was of value and meets intent of above statement is the addition of folate to flour products</p> |
| <p><b>This principle is to be deleted</b><br/>[Consideration should be given to the nutrient profile of the food before [fortification] [nutrient addition] to ensure that nutritionally appropriate foods are selected for [fortification] [nutrient addition]</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <p><b>3.3.2 The selection of appropriate foods</b> [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.]</p> <p>Note: with this option 3.3.4 and 3.3.5 no longer needed and w/b deleted</p>                                                                                                                                                                                                         | <p>ICGMA SUPPORTS THE FOLLOWING WORDING:</p> <p>The selection of foods to which essential nutrients may be added should <del>take into account the nutritional value of the foods and</del> is best determined by National Authorities</p> <p>Which is 3.3.1 complementary to ICGMA’s preferred wording for 3.3.1</p>                                                                                                |
| <p><b>3.3.4 Essential nutrients should not be added to unprocessed foods, including but not limited to fruit, vegetables, meat, poultry and fish</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <p>ICGMA WILL MONITOR DISCUSSION ON THIS ITEM</p>                                                                                                                                                                                                                                                                                                                                                                    |
| <p><b>3.3.5 Essential nutrients should not be added to alcoholic beverages</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <p>ICGMA asks the question: Are alcoholic beverages covered under Codex Alimentarius?</p>                                                                                                                                                                                                                                                                                                                            |
| <p><b>Section of the General Principles</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <p><b>Proposed ICGMA comments</b></p>                                                                                                                                                                                                                                                                                                                                                                                |
| <p><b>3.4 Technological Aspects</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <p>ICGMA SUPPORTS the basic principles captured in this section as they relate to:</p> <ol style="list-style-type: none"> <li>1. Natural or synthetic</li> <li>2. Safety, bioavailability</li> <li>3. Stability throughout customary conditions</li> <li>4. Undesirable characteristics, shelf life\</li> <li>5. Processing techniques that assure proper</li> </ol>                                                 |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | distribution, stability, consistency, availability of nutrient.                                                                                                                                                                                                                                                                                                                   |
| <p><b>3.4.1 The sources of the added</b> 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]:<br/>FAO / WHO standards, international Pharmacopoeias or recognized international standards or national legislation.</p>                                                                                                                                                                                                                                                                                                       | <p>ICGMA SUPPORTS the following<br/>3.4.1 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.</p> <p>And<br/>Removal of balance of sentence referring to purity criteria which is covered in other Codex text (i.e. General Standards on Food Additives)</p> |
| <p><b>3.4.2 The added essential nutrient</b> should be sufficiently stable in the food under customary conditions of processing, packaging, storage, distribution and use.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | ICGMA SUPPORTS                                                                                                                                                                                                                                                                                                                                                                    |
| <p><b>3.4.3 The added essential nutrient</b> should [have minimal impact on the original food characteristics] / [not impart undesirable characteristics to the food] (e.g. colour, taste, flavor, texture, cooking properties) and should not unduly shorten shelf life</p>                                                                                                                                                                                                                                                                                                                                                                                                                           | <p>ICGMA SUPPORT THE FOLLOWING VERSION<br/>The added essential nutrient should have minimal impact on the original food characteristics and should not unduly shorten shelf life.</p>                                                                                                                                                                                             |
| <p><b>3.4.4 Technology and processing facilities</b> should be available to permit the [standardized] addition of the essential nutrient to a food in a [manner to ensure nutrient [bioavailability, consistency, distribution and stability]</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                      | ICGMA WILL MONITOR PLENARY DISCUSSIONS                                                                                                                                                                                                                                                                                                                                            |
| <p><b>3.5 Monitoring</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                   |
| <p><del>Former 3.10 Methods of measuring, controlling and/or enforcing the levels of added essential nutrients in foods should be available to monitoring bodies to facilitate efficient monitoring of those products.</del></p> <p>To be deleted as it expresses a basic expectation underlying Codex standards and does not need to be repeated.</p>                                                                                                                                                                                                                                                                                                                                                 | ICGMA SUPPORTS DELETION OF THIS PRINCIPLE                                                                                                                                                                                                                                                                                                                                         |
| <p><b>3.5.1 [It is important that National Authorities]</b> [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><b><u>To be discussed in plenary:</u></b><br/>Does this change the meaning to surveillance of all nutrient intakes – <i>Note: previous iteration said from all sources of the nutrients added to foods</i><br/>Is this principle an obligation or something important to do?</p> | <p>ICGMA SUPPORTS FOLLOWING VERSION:<br/>National Authorities should monitor population intakes from all sources including [essential] nutrients added to foods in order to assess the extent to which the purposes identified in 3.1.1 are addressed and to ensure that any risk of excessive intakes is minimized.</p>                                                          |
| <p><b>3.5.2 Monitoring of total nutrient intakes</b> should use the same [method] [approach] as used in deciding the nutrient addition</p> <p><b>To be discussed in plenary:</b><br/>Is it valid to say “should” use the same approach for assessment and monitoring. Note – some countries want this principle removed</p>                                                                                                                                                                                                                                                                                                                                                                            | <p>ICGMA SUPPORTS THE FOLLOWING WORDING<br/><br/>Monitoring of total nutrient intakes should use the same [approach] <b>[if possible]</b> as used in deciding the nutrient addition</p>                                                                                                                                                                                           |
| <p><b>4.0[Principles for] [Specific]Types of Nutrient Addition</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | ICGMA SUPPORTS INCLUSION OF SPECIFIC IN TITLE                                                                                                                                                                                                                                                                                                                                     |
| <p><b>4.1 Addition of Essential Nutrients</b> [to Address a Demonstrated Public Health Need] [and Mandatory Addition] <del>Mandated For Purpose of fortification [Correcting/Reducing] Inadequate Intakes</del></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <p>ICGMA SUPPORTS THE FOLLOWING WORDING<br/>4.1 Addition of Essential Nutrients for Purposes of Reducing Inadequate Intakes in a Population</p>                                                                                                                                                                                                                                   |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>For plenary: discussion</b> on title will be in context of the feedback within eWG that suggests two different takes on purpose of this section:</p> <ol style="list-style-type: none"> <li>1. Applies only to mandatory addition to support public health need</li> <li>2. Applies to a mandatory or voluntary approach to address a public health need</li> </ol>                                                                                                                                                                                                                                                                                                                                                                                    | <p>ICGMA SUPPORTS Option 2 under Plenary Discussion<br/>That the purpose of this section is as it applies to mandatory or voluntary ....</p>                                                                                                                                                          |
| <p><b>4.1.1 There should be a demonstrated public health</b> need for increasing the intake of an essential nutrient in one or more populations [<del>through mandated addition</del>] [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 intake of nutrients, and/or by estimates of possible deficiencies because of changes in food habits.</p> | <p>ICGMA SUPPORTS THE FOLLOWING SUCCINCT AND CLEAR WORDING</p> <p>4.1.1 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 the mandatory or voluntary addition of essential nutrients.</p> |
| <p><b>4.1.2 The foods selected</b> as a vehicle for the added essential nutrient(s) should be consumed by the population at risk [of inadequate intake]</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <p>ICGMA SUPPORTS</p>                                                                                                                                                                                                                                                                                 |
| <p><b>4.1.3 The amount of the essential</b> nutrient added to the food should aim to be sufficient to [<del>reduce inadequate intakes</del>] [<del>correct or prevent the deficiency</del>] meet the public health need.<br/><b>For discussion in plenary</b><br/>Stating meet the public health need is sufficient...</p>                                                                                                                                                                                                                                                                                                                                                                                                                                   | <p>ICGMA SUPPORTS</p>                                                                                                                                                                                                                                                                                 |
| <p><b>4.1.4 The intake of the food selected</b> as a vehicle should be stable and uniform and the [<del>lower and upper levels of intake</del>] [amount of the food consumed by the lower and upper percentiles of the populations] should be known.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <p>ICGMA SUPPORTS</p>                                                                                                                                                                                                                                                                                 |
| <p><b>4.1.5 The cost effectiveness</b> of the addition of essential nutrients to foods for the intended consumer should be considered<br/><b>For plenary discussion:</b><br/>does this belong in Section 3.1 Fundamental Principles</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <p>ICGMA WILL MONITOR DISCUSSIONS</p> <p>On how cost effectiveness is factored into a demonstrated need for addition of an essential nutrient(s)</p>                                                                                                                                                  |
| <p><b>4.2 Nutrient Addition for Purposes of Restoration</b><br/><b>For Plenary discussion</b><br/>Whether this section is needed?<br/>Majority of countries responses were in support of maintaining</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <p>ICGMA SUPPORTS INCLUSION</p>                                                                                                                                                                                                                                                                       |
| <p><b>4.2.1 Where the food has been</b> identified as a significant [source] [contributor to intake] of [energy and/or] 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>ICGMA SUPPORTS principle but will look for opportunity to suggest wording that makes the principle clearer.</p>                                                                                                                                                                                    |
| <p><b>4.2.2 A food should be considered</b> 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 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</p>                                                  | <p>ICGMA SUPPORTS Nutrient Reference Value (NRV), already established in Codex text and therefore does not need further definition.</p>                                                                                                                                                               |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                         |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>level of this nutrient need not be restored.]</p> <p>Note: The question posed to the eWG was which type of reference value should the 10% calculation be based on?</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                         |
| <p><b>4.3 Nutrient Addition for Purposes of Nutritional Equivalence</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <p>ICGMA SUPPORTS RETENTION OF THIS PRINCIPLE</p>                                                                                                                                       |
| <p><b>4.3.1 Where a substitute food is intended</b> 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] / [<del>considered</del>]</p>                                                                                                                                                                                                                                                                                                                                                                                                                                               | <p>ICGMA SUPPORTS wording that includes [contributor to intake]<br/>And [recommended]</p>                                                                                               |
| <p><b>4.3.2 A food being substituted or partially</b> 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]</p> <p><b>For the plenary discussion:</b><br/>Should the principle be removed and leave the decision to National Authorities</p>                                                                                                                                                                                                                                    | <p>ICGMA SUPPORTS REMOVAL OF PRINCIPLE with the decision left to National Authorities</p>                                                                                               |
| <p><b>4.3.3 Where there is a clear public</b> health reason to moderate the intake of a specific nutrient, the level of this nutrient need not be equivalent.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <p>ICGMA WOULD LIKE THIS PRINCIPLE TO BE REMOVED.<br/>In concert with removal of 4.3.2 Both are instructional in nature</p>                                                             |
| <p><b>4.4 Nutrient Addition to Special Purpose Foods</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <p>ICGMA SUPPORTS INCLUSION OF THIS SECTION</p> <p>Special purpose foods are broader than Foods for Special Dietary Uses, therefore a section specific to these foods is necessary.</p> |
| <p><b>4.4.1 [Essential]</b> 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>Alternative<br/>[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>ICGMA SUPPORTS the alternative principle for its clarity</p>                                                                                                                         |

**IDF - International Dairy Federation**

| <p><b>Proposed Draft Revised GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS (CAC/GL 09-1987 amended 1989, 1991)</b></p> | <p>IDF COMMENTS</p>                                             |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|
| <p><b>2.3 (former 2.4) Substitute food</b> is a food which is designed</p>                                                                   | <p>IDF considers that the use or application of the food is</p> |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>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>important. IDF suggests that if the definition is retained that the text reads ‘resemble a common food in appearance, texture and application/use, and is intended to be used as a complete or partial...’. IDF does not support the use of the example as the description is self-explanatory and no example is provided in the description of restoration.</p>                                                                                                                                                                                                                                            |
| <p><b>2.4 (former 2.3) Nutritional equivalence</b> means <del>being of</del> the addition of one or more essential nutrient to a substitute food to achieve a similar nutritive value to its <del>normal</del> counterpart in terms of quantity and quality of protein and in terms of kinds, quantity and bioavailability of essential nutrients. <del>For this purpose, nutritional equivalence means that essential nutrients provided by the food being substituted, that are present in a serving or portion or 100 kcal of the food at a level of 5% or more of the recommended intake of the nutrient(s) are present in the substitute or partially substituted food (extender) in comparable amounts. [It is achieved when one or more essential nutrients are added to a product that is designed to resemble a common food in appearance, texture, flavour and odour in amounts such that the substitute product has a similar nutritive value, [in terms of the amount and bioavailability of the added essential nutrient.]]</del></p> | <p>IDF supports the proposed definition.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <p><b>If retained, Proposed revised definition for option 3):</b><br/> <b>2.5 Fortification</b> as used in these <del>[guidelines/principles]</del> means the addition of one or more essential nutrients to a food [whether or not it is normally contained in the food]. <del>for the purpose of preventing or correcting improving population health by addressing a demonstrated deficiency of one or more nutrients in the population or specific population group(s).</del></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <p>IDF supports the proposed definition. As Codex definitions are used by national authorities more broadly, the definition needs to be wide enough to encompass the fortification (addition of a substance) to a food for an additional health benefit (e.g. phytosterol esters for cholesterol absorption; Folic acid for NCD risk reduction). We also support definitions be included for mandatory and voluntary fortification as types of fortification and with restoration and nutritional equivalence as justifications for where fortification might be required.</p>                                 |
| <p><b>2.8 Restoration</b> means the addition to a food of essential nutrient(s) <del>which are in amounts to replace those</del> 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.] <del>in amounts which will result in the presence in the food of the levels of the nutrient(s) present in the edible portion of the food before processing, storage or handling.</del></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <p>IDF is of the opinion that the definition of restoration should be retained and supports the amendments in respect of natural variations.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <p><b>3. PRINCIPLES</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <p><b>3.3.1 (new)</b> [Certain foods [may have to] [should] be excluded from voluntary <b>[fortification] [nutrient addition]</b> 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, 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</p>                                                                                                                                                                                                                                                                                                                             | <p>Whilst the comment was made that the “new wording here allows more flexibility as there may be cases where a country may decide to permit addition of nutrients to a staple food on a voluntary basis to help ensure reaching the target population.” IDF does not support the use of the word “ubiquity” because of the subjective nature of the term. 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 data.</p> |



|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>purposes</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                     |
| <p>(new) <del>Consideration should be given to the nutrient profile of the food before [fortification] [nutrient addition] to ensure that nutritionally appropriate foods are selected. for [fortification] [nutrient addition].</del></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <p>IDF supports the removal of the reference to nutrient profiles</p>                                                                                                                                                                                                               |
| <p>4.1.1 <i>Former 6.2.1</i> There should be a demonstrated <u>public health</u> need for increasing the intake of an essential nutrient in one or more populations <del>groups</del> <del>[through mandated addition]</del> [which may be accomplished by <u>mandatory addition of essential nutrients</u>. A demonstrated public health need, however, may also be addressed through voluntary addition.] <del>[through fortification]</del>. This <del>may be in the form of need may be demonstrated by actual-clinical or subclinical</del> evidence of deficiency, subclinical evidence of deficiency, [suboptimal nutritional status], [evidence from valid biochemical indicators], estimates indicating <del>low-inadequate or potentially inadequate</del> intake of nutrients, estimates indicating potentially inadequate intakes of nutrients, and/or <u>by estimates of</u> possible deficiencies <del>likely to develop</del> because of changes <del>taking place</del> in food habits. <del>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</del></p> | <p>IDF is concerned that this purpose does not adequately reflect situations where the addition of a vitamin or mineral would benefit individuals within a population and not just the entire population. Diet and lifestyle, circumstances and needs vary within a population.</p> |
| <p><b>4.2 Nutrient Addition for Purposes of Restoration</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <p>IDF is of the opinion that these criteria should be maintained as a subset of fortification.</p>                                                                                                                                                                                 |
| <p><b>4.3 Nutrient Addition for Purposes of Nutritional Equivalence</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <p>IDF is of the opinion that this definition should be maintained as a subset of fortification</p>                                                                                                                                                                                 |