

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
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Agenda Item 5

CX/NFSDU 10/32/5  
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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES 32<sup>nd</sup> Session

Santiago, Chile  
1 – 5 November 2010

#### PROPOSED DRAFT REVISION OF THE CODEX GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS (CAC/GL 9-1987) AT STEP 4

*Report of the Electronic Working Group (EWG)*

*Chaired by Canada and co-chaired by Chile and New Zealand*

Governments and interested international organizations are invited to submit comments on the above document at Step 3 in writing preferably by email to the Secretariat, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy, Fax +39-06-5705-4593, e-mail [codex@fao.org](mailto:codex@fao.org) with copy to Mr Georg Müller, Federal Ministry of Food, Agriculture and Consumer Protection, Rochusstraße 1, 53123 Bonn, Germany, Fax: +49 (228) 99 529 49 65, e-mail: [ccnfsdu@bmelv.bund.de](mailto:ccnfsdu@bmelv.bund.de) by **27 October 2010**.

(Reference: ALINORM 10/33/26, paragraphs 88-97 and Project Document, Appendix V)

#### **CHARGE TO EWG BY 31<sup>TH</sup> SESSION OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES**

At its 31st session the Codex Committee on Nutrition and Foods for Special Dietary Uses (Committee) agreed to establish an Electronic Working Group (EWG), chaired by Canada and co-chaired by New Zealand and Chile, to prepare a draft revised document of the General Principles for the Addition of Essential Nutrients to Foods (the *Principles*) for circulation at Step 3 and consideration by the next session of the Committee.

The Committee stated that the revision of the *Principles* should be in line with the agreed Project Document (Appendix V, Alinorm 10/33/26). The Committee agreed to stress that the review of the general principles would evaluate the totality of the current document to ensure coherence and consistency of the principles and the guidance in the first section of Project Document.

## **BACKGROUND**

At its 31st Session the Committee recalled that at its 30th Session it had agreed that an electronic Working Group led by Canada should revise the Discussion Paper and Project Document proposing new work for the Committee to amend the *Codex General Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 09-1987) in line with the comments made at the 30th Session.

The Delegation of Canada introduced the Discussion paper together with the revised Project Document and emphasized that to acknowledge current practices and to ensure that the addition of essential nutrients to food is rational and does not result in indiscriminate additions which may pose a health hazard due to excesses, deficiencies or imbalance of such nutrients, the Principles should be reviewed by the Committee. The Delegation indicated that the comments made by the Electronic Working Group had been focussed on the following points: need to clarify whether the intent of proposal was to affirm that the current principles apply to both mandatory and discretionary addition of essential nutrients and whether similar purpose apply to both; consider revising the definition of “fortification” in the current general principles such that its purpose is not limited to preventing or correcting a demonstrated deficiency of an essential nutrient but also to encompass other public health benefits such as meeting recommended nutrient intakes and reducing the risk of inadequate intakes as demonstrated by relevant scientific data. The Delegation also pointed out that with regard to the selection of nutrients to be added, a risk-based approach would have to take into consideration all sources of exposure, including intake from supplements and Upper Level of intakes when these have been established.

The Project Document, as revised and adopted by the 31st Session of the Committee (Appendix V, Alinorm 10/33/26) states that the “purpose” of the new work would be

“to extend the “Basic Principles” to also include principles for the safe voluntary addition of essential nutrients for the purpose of meeting recommended nutrient intakes and reducing the risk of inadequate intakes as demonstrated by relevant scientific data, in addition to “preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups.” These principles would acknowledge and encourage rational and safe voluntary addition of essential nutrients to foods. The review of the general principles would evaluate the totality of the current document to ensure coherence and consistency of the principles and the guidance.”

The “Main Aspects” to be covered by the new work are stated in the Project Document as follows:

“The work would involve a review of the Codex General Principles for the Addition of Essential Nutrients to Foods to consider the addition of essential nutrients to foods for purposes beyond those currently stated in the current *Principles*, including an examination of how to protect consumers against excesses, deficits or imbalances.

One objective of the review of the *Principles* would be to re-affirm that these encompass voluntary fortification. The Committee could also consider the need to first clarify the similarities and differences in principles for mandatory versus voluntary fortification. For example, certain principles, such as the desirability of using scientific risk assessment to guide decision-making, may be applicable to all, whereas the nature and extent of the public health need would likely differ for voluntary versus mandatory addition.

Another objective of the review would be to consider the need to expand the definition of fortification to encompass the purpose of meeting recommended nutrient intakes and reducing the risk of inadequate intake as demonstrated by relevant scientific data, as well

as the current purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups.

To preserve the intent of the *Principles*, potential new work would also consider scientific advances in nutrient risk assessment. Such an approach would include consideration of criteria or principles related to:

- selection of appropriate foods to fortify (e.g., establishment of qualifying and /or disqualifying criteria),
- selection of nutrients to be added, and
- determination of levels to which permitted nutrients could be added according to scientific relevant data.

Finally, consideration would have to be given to whether the consumer could be misled as to the nutritional quality of the fortified food, and whether additional principles are needed to address this (e.g., principles related to labelling and claims)."

### ***ELECTRONIC WORKING GROUP***

In February 2010 Canada invited all members of CCNFSDU to participate in the EWG. Expressions of interest were received from Argentina, Australia, Belgium, Brazil, Colombia, Costa Rica, the European Community, Ghana, Iceland, Iran, Israel, Japan, Libya, Malaysia, Mexico, Netherlands, New Zealand, South Africa, Thailand, United States of America, FAO, CIAA (Confederation of the Food and Drink Industries of the EU), CRN (Council for Responsible Nutrition), IADSA (International Alliance of Dietary/Food Supplement Associations), ICBA (International Council of Beverage Associations), IDF (International Dairy Federation), International Foundation for Health, ISDI (International Special Dietary Foods Industries).

EWG participants were requested to provide comments on what, if any, additions or changes were required to the *Principles* to reflect the "Purpose and Scope of the Proposed New Work" as well as the "Main Aspects to be Covered" set out in the Project Document, Appendix V, Alinorm 10/33/26. Participants were also reminded that the Committee stated that the totality of the current document would be evaluated to ensure coherence and consistency of the principles and the guidance.

To help EWG participants in addressing the main aspects to be covered in the review of the *Principles* to reflect the "Purpose and Scope of the Proposed New Work" and the "Main Aspects to be Covered", a revised *Principles* was drafted which included these aspects within the text as well as questions intended to solicit comments on these and any other considerations that could be considered necessary. Comments on the first draft were requested by April 15, 2010.

### **First Round of Comments**

Comments on the first draft of proposed revisions to *the Principles* and associated questions were received from Argentina, Australia, Brazil, Chile, Costa Rica, European Community, Iran, Japan, Libya, Mexico, Netherlands, Norway, New Zealand, United States of America, IADSA (International Alliance of Dietary/Food Supplement Associations), ICBA (International Council of Beverage Associations), and IDF (International Dairy Federation).

The seventeen members and observers who provided comments were generally supportive of moving ahead with a revision to the Codex General Principles for the Addition of Essential Nutrients to Foods (General Principles). As evidenced by the comments received, one of the areas that required further

consideration by the EWG was related to the need to establish separate principles for voluntary versus mandatory fortification, and the substance of these principles.

A number of suggestions were submitted proposing revisions to the draft General Principles to provide additional clarity as to the proposed intent as well as to bring into consideration additional factors. In particular the following comments were made:

1. Proposal to change the document to “Guidelines” from “General Principles” in line with other such Codex documents (e.g., Guidelines for Vitamin and Mineral Supplements).
2. The majority of respondents agreed that the General Principles should exclude food supplements since these are covered in a separate Codex document and a proposal to include the reference to the Codex Guidelines for Vitamin and Mineral Supplements (CAC/GL 55-2005) as a footnote.
3. Proposal to specifically exclude non-traditional or indirect addition of essential nutrients.
4. Proposal to change the heading of section 2 to “Definitions” since this more appropriately reflects its contents.
5. Proposal to include in the definition of “nutrient” the text “or excess” in paragraph (c), i.e., “a deficit or excess”.
6. Proposal to delete in the definition of “substitute food” the words “flavour” and “odour” since their inclusion is restrictive in the production of substitutes and is of questionable benefit.
7. Proposal to use the term “fortification” alone, i.e., delete “enrichment”. This is the more commonly used term in other WHO and FAO documents, for example the WHO/FAO “Guidelines on food fortification with micronutrients” (2006).
8. Proposal to include definitions for “mandatory fortification” and “voluntary fortification” as used in the document WHO/FAO “Guidelines on food fortification with micronutrients” (2006).
9. Proposal to create two separate sections on mandatory and voluntary fortification, i.e., the content proposed in sub-sections 6.2 and section 6.3 would be included in sections 6 and 7.
10. Comments questioning the need to establish at the international level specific provisions related to the selection of foods which may be fortified voluntarily since this would be best determined at national/regional/local levels taking into account diets, socioeconomic factors and the need to avoid risks to health.
11. Comments proposing that nutrients permitted for voluntary fortification be determined on safety and risk assessment grounds and not solely on the severity of the adverse effect that is the basis of Upper Intake Levels (ULs).
12. Proposal to consider parallel text to that used in the Codex Guidelines for Vitamin and Mineral Food Supplements regarding minimum and maximum levels of vitamins and minerals, i.e.,
  1. *The minimum level of each vitamin and/or mineral contained in a vitamin and mineral food supplement per daily portion of consumption as suggested by the manufacturer should be 15% of the recommended daily intake as determined by FAO/WHO.*
  2. *Maximum amounts of vitamins and minerals in vitamin and mineral food supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking*

*the following criteria into account:*

- (a) upper safe levels of vitamins and minerals 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;*
- (b) the daily intake of vitamins and minerals from other dietary sources.*

*When the maximum levels are set, due account may be taken of the reference intake values of vitamins and minerals for the population.*

13. A request that the EWG consider the possibility that the scope of this document be extended to include, as well as essential nutrients, non-essential nutrients and related substances (a constituent of food (other than a nutrient) that has a favourable physiological effect), pointing to the fact that products containing such non-essential nutrients and related substances are available in the global market place. And their addition to foods could be managed under the same risk-based approach being proposed for essential nutrients. The request was accompanied by a proposal that the Principles could be divided into two sections: a Section A addressing principles for the addition of essential nutrients and a Section B addressing principles for the addition of non-essential nutrients and related substances, and suggests this as future work for the EWG after consideration by the Committee.

The above comments, as well as other suggestions made by EWG participants regarding language and clarity, were considered in revising the draft General Principles which were circulated to all EWG participants for a second round of comments on July 9, 2010.

### **Second Round of Comments**

Comments on the Draft Revised *Principles* were received from Australia, Brazil, the European Community, Libya, Malaysia, Mexico, Netherlands, Norway, United States of America, and the IDF.

In addition to very helpful editorial comments as well as suggestions for further clarity, the comments included those listed below:

1. With regard to the proposal to change the title of the document to “Guidelines” from “General Principles” in line with other such Codex documents (e.g., Guidelines for Vitamin and Mineral Supplements), the support for this it was not unanimous. The two options “Principles” and “Guidelines” are placed in square brackets for further discussion.
2. The Introduction now includes three paragraphs. The first continues to address the intent of the *Principles*. There was a suggestion that the 2nd bullet could be eliminated and replaced by an additional clause at the end of the first bullet: “...through the establishment of a uniform set of principles”. It was considered that the concept of rational addition is addressed in the second paragraph. Another respondent however stated that the 2nd bullet should be retained with added text that uses terminology consistent with the Codex nutritional risk analysis principles: “...for the purpose of reducing risk of adverse health effects due to inadequate intake.” Both options are retained in square brackets for discussion by the Committee.

The second paragraph in the Introduction includes the principles for nutrient addition that are in section 3.1. of the current document with some additional explanatory text. This paragraph was accepted with the majority favouring the 1st option that had been proposed for its revision.

The third paragraph in the Introduction includes the reference to the need to consider the Codex Nutritional Risk Analysis Principles and Guidelines for the Work of the CCNFSDU.

3. There was no consensus regarding the new proposed bullet “To allow a wider choice of fortified foods” in the first part of the Introduction, as well as in the Basic Principles, with a variety of reasons given pro and con its retention, for example, that it reflects the intent of the general principles; that it only applies to voluntary fortification; that it is not a main purpose of Guidelines and that its relevance is questionable. One participant suggested some additional text: “to contribute to the improvement of health and/or the nutritional status of the population or specific population groups.” This bullet is being retained in square brackets for further discussion.
4. With regard to the reference to the Codex Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the CCNFSDU, there was not consensus on the use of the text “take into consideration” versus “are consistent and used in conjunction with” in the 3rd paragraph of the Introduction, thus both were retained in square brackets for further discussion.

The Committee may wish to discuss the need for further consideration of the Codex Nutritional Risk Analysis Principles during the drafting of these *Principles* and in particular in their implementation.

5. The majority of respondents agreed to the exclusion of vitamin and mineral food supplements for the Scope of these [Principles][Guidelines].
6. With regard to the replacement of the heading “Description” by “Definitions”, all those commenting favoured “Definitions” since this more appropriately reflects the contents of this section.
7. Most respondents were opposed to the inclusion of the text “or excess” in paragraph (c) of subsection 2.1 as it was considered to extend the scope of the definition of a nutrient and is not characteristic of a nutrient.
8. With regard to the proposed new text in section 2.2, “Essential nutrient includes but is not limited to vitamins and mineral nutrients”, this was considered redundant by some EWG participants. It was supported by others and one participant suggested leaving for further discussion. The text is therefore retained in square brackets for further consideration.
9. With regard to the definitions in sections 2.3 to 2.9, one participant questioned the need for these definitions since these would appear to be covered in the Introduction section.
10. Generally there was support for the use of the term “fortification” in place of “enrichment” One participant indicated that in their understanding there was a difference between the two terms: fortification referring to addition of nutrients not present in a food or to levels beyond those present inherently, whereas enrichment referred to addition to complement levels in a food.
11. With regard to subsection 2.3, it is proposed to delete the second sentence since that appears as a principle for the addition of essential nutrients in section 5.2 on nutritional equivalence.
12. There was some support for the inclusion of definitions for “Mandatory” and “Voluntary” fortification. However it was suggested that these should be placed in section 3 under Basic Principles.
13. Two changes were proposed to the order of the definitions: make 2.2 a subsection of 2.1 and reverse the order of 2.3. and 2.4 since 2.3 makes reference to a substitute food which is only

- defined in 2.4. It was decided to leave the order as it appears in the current text and recommend that the Committee consider the above suggestions and also the possibility of putting the definition in alphabetical order.
14. One participant requested clarification of the rationale for the inclusion of provision for nutrient addition for the purpose of nutritional equivalence of substitute foods expressing concern that this could mislead consumers and discourage the consumption of traditional foods. Although the Committee may wish to discuss this concern, there are in fact a number of substitute foods currently available that are intended for consumers with specific health or cultural requirements, for example plant-based beverages as substitutes for milk; plant protein-based meat substitutes; and margarine as a substitute for butter.
  15. The need for a definition of “standardization” was questioned since there is no reference to it in the text of the *Principles*. This text was placed in square brackets for further discussion.
  16. There were a number of comments regarding the Basic Principles in Section 3. It was considered by some that these should continue to apply to all types of nutrient addition. In this regard a number of proposed revisions were made in the text.
  17. The Committee should discuss whether in section 3.3 (former 3.2) “scientifically justified” should be further clarified by “nutritionally justified” (i.e., “The addition of an essential nutrient should be scientifically and nutritionally justified.....”).
  18. A respondent questioned the need to specify within the *Principles* whether fortification is mandatory or voluntary as well as the need for specific criteria and conditions for mandatory and voluntary fortification. This respondent stated that mandatory fortification should remain the responsibility of national authorities and that the *Principles* should apply only to voluntary fortification. With regard to voluntary fortification, however, this respondent stated that specific provisions for the selection of foods and essential nutrients should be determined at the national, regional or local levels.
  19. A respondent suggested that the basic principles of a risk-based approach to set minimum and maximum amounts of vitamins and minerals in food supplements should also apply to foods to which essential nutrients have been added (please see point 12 in the comments on the first round). This suggestion has not been incorporated into the text of the *Principles* but is left for discussion by the Committee.
  20. Section 3.10 (former 3.8) now includes some additional text to strengthen the principle that fortification should not be used to mislead consumers as to the nutritional merit of the food.
  21. The different options are presented for the Committee’s discussion for section 3.12 with regard to monitoring. These were drafted based on comments received. The first option is specific to nutrients added to foods and includes the concept of monitoring to assess the impact of the addition of a nutrient in meeting public health needs. In regard to the latter, the previously proposed text in this option, “to justify national/regional measures”, has been replaced by “to assess to assess the extent to which public health needs are being addressed”. The second option refers to broader monitoring of intakes from all sources for those nutrients that are most likely to pose a risk of inadequate or excessive intakes for the population(s). In discussing this section, the Committee should clarify whether “total intakes” and “all dietary sources” would include supplements and whether or not this term needs to be added to the text.

22. Revisions were suggested to Sections 4 and 5 for clarification and to include the concept of frequency of consumption in addition to nutrient content. In addition, it was suggested to include the “INL” in addition to “recommended nutrient intake” as the basis for determining the need for nutrient addition for the purpose of restoration or nutritional equivalence. The Committee should clarify the intended meaning of “recommended nutrient intake”, whether it already encompasses INL<sub>98</sub>, whether a population weighted value should be used, or whether the Nutrient Reference Value should be used for this purpose.
23. As indicated in the discussion of the comments received in the first round, one of the areas that required further consideration by the EWG was related to the need to establish separate principles for voluntary versus mandatory fortification, and the substance of these principles. In this regard there were a number of comments. These are addressed both under section 3 and section 6.
- Respondents generally considered that the *Principles* should allow for any nutrient addition to be either mandatory or voluntary based on national assessment and needs.
- There were a number of comments with regard to the proposed structure of Section 6. Some respondents supported in general the proposed structure with separate sections setting out requirements for mandatory and voluntary fortification.
- Other respondents suggested that the basis for differentiating between mandatory and voluntary fortification should be the degree of public health need., and that either may be used as a tool to achieve the same goal, i.e., preventing or correcting a demonstrated deficiency or risk of deficiency.
- The proposed revisions to sections 6.1 take into consideration and attempt to coordinate comments that there are many similarities between principles for mandatory and voluntary fortification to address the risk of adverse health effects.
24. Section 6.3 from the previous draft (now renumbered 6.2) which set out conditions for voluntary fortification is being retained in square brackets for additional discussion since a number of respondents in the second round of comments supported inclusion of these specific conditions and included some additional proposed text.
25. With regard to the suggestion that the EWG consider the possibility that the scope of this document be extended to include, as well as essential nutrients, non-essential nutrients and related substances (a constituent of food (other than a nutrient) that has a favourable physiological effect), it was considered that this was beyond the scope established and approved for this new work.
26. In response to the suggestion that the *Principles* explicitly exclude “non-traditional” or “indirect” addition of nutrients, it was considered that this appeared inconsistent with the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) which states that the *Principles* apply to foods from plants modified by increasing the amount of a nutrient(s) or related substance(s).

***Draft Revised General Principles for the Addition of Essential Nutrients to Foods***

Based on the additional comments received during the second round, Canada, Chile and New Zealand are pleased to provide the draft revised *General Principles for the Addition of Essential Nutrients to Foods*, for discussion at the 32nd Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses.

In line with the “Purpose” and “Main Aspects to be Covered” in the Project Document, the EWG addressed the following:

- § the need to ensure that the *Principles* continue to protect consumers against excesses, deficits or imbalances;
- § the extension of the “Basic Principles” to include principles for the safe voluntary addition of essential nutrients for the purpose of meeting recommended nutrient intakes and reducing the risk of inadequate intakes in addition to preventing or correcting a demonstrated deficiency;
- § the application of the *Principles* to voluntary as well as mandatory fortification and clarification of the similarities and differences in principles for mandatory versus voluntary fortification;
- § the scientific advances in nutrient risk assessment including consideration of criteria or principles related to:
  - selection of appropriate foods to fortify (e.g., establishment of qualifying and /or disqualifying criteria),
  - selection of nutrients to be added, and
  - determination of levels to which permitted nutrients could be added according to scientific relevant data.
- § the need for additional principles to ensure that the consumer is not misled as to the nutritional quality of the fortified food.

In the Draft Revised General Principles document that follows all new text is underlined and in [square brackets]. Text that has been deleted is shown ~~struck-out~~.

For ease of reference, an unmarked version of the Draft Revised General Principles is also being provided.

**revised draft [GENERAL PRINCIPLES] [GUIDELINES] FOR THE ADDITION OF  
ESSENTIAL NUTRIENTS TO FOODS  
CAC/GL 09-1987 (amended 1989, 1991)**

## INTRODUCTION

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

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

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

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

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

## 1. SCOPE

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

## 2. DESCRIPTION [DEFINITIONS]

[Definitions]

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

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

**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 bio-chemical or physiological changes to occur.

**2.2 Essential nutrient** means any substance normally consumed as a constituent of food which is needed for growth and development and the maintenance of healthy life and which cannot be synthesized in adequate amounts by the body. [Essential nutrient includes but is not limited to vitamins and mineral nutrients.]

**2.3 Nutritional equivalence** means being of similar nutritive value in terms of quantity and quality of protein and in terms of kinds, quantity and bioavailability of essential nutrients. ~~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.~~

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

**2.6 Restoration** means the addition to a food of essential nutrient(s) which are lost during the course of good manufacturing practice, or during normal storage and handling procedures, 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.

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

**2.8 Nutrient density** means the amount of nutrients (in metric units) per stated unit of energy (MJ or kcal).

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

### 3. BASIC PRINCIPLES

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

~~3.1.1 restoration;~~

~~3.1.2 nutritional equivalence of substitute foods;~~

3.1.3 fortification [or enrichment];

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

~~3.1.5 to allow a wider choice of fortified foods]~~

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

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

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

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

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

**3.4 (Former 3.3)** The addition, of an essential nutrient to a food should not result in an adverse effect on the metabolism of any other nutrient.

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

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

**3.7 (Former 3.5)** The essential nutrient should be biologically available from the food.

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

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

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

~~[3.9 The additional cost of addition [of essential nutrients to foods] should be reasonable for the intended consumer.]~~ applicable to mandatory fortification; moved to section 6.2 as 6.2.7

**3.11** Methods of measuring, controlling and/or enforcing the levels of added essential nutrients in foods should be available.

**3.12** When provision is made in food standards, regulations or guidelines for the addition of essential nutrients to foods, specific provisions should be included identifying the essential nutrients to be considered or to be required and the levels at which they should be present in the food to achieve their intended purpose.

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

OR

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

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

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

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

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

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

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

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

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

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

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

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

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

6.1.2 (*former 6.2.2*) The food selected as a vehicle for the essential nutrient(s) should be consumed by the population at risk.

6.1.3 (*former 6.2.3*) The intake of the food selected as a vehicle should be stable and uniform and the lower and upper levels of intake should be known.

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

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

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

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

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

6.2.1 Foods which may be fortified:

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

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

**OR**

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

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

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

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

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

6.2.2 Selection of essential nutrients that may be added:

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

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

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

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

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

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

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

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

a) demonstration of an upper level or a range of intake that is unlikely to result in adverse health effects, and

b) intake data and a careful modelling approach adopted by national authorities should be used to provide evidence to ensure that aggregate exposure to the essential nutrient in question is within acceptable limits.]

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

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