

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
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Agenda Item 5

CX/NFSDU 11/33/7

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Thirty third Session

Bad Soden am Taunus, Germany

14 – 18 November 2011

PROPOSED DRAFT REVISION OF THE GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS (CAC/GL 09-1987)

Report of the Electronic Working Group (EWG)
Chaired by Canada and co-chaired by Mexico 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 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 by **21 October 2011**.

(REP11/NFSDU, paragraphs 51 to 74 and Appendix VII
ALINORM 10/33/26, paragraphs 88-97 and Project Document, Appendix V)

CHARGE TO EWG BY 32nd SESSION OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES (REP11/NFSDU)

The 32nd Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) agreed to consider further the development of the draft revised *General Principles for the Addition of Essential Nutrients to Foods (General Principles)*, specifically considering principles, their application to mandatory and/or voluntary fortification, and how the principles should be presented and organized within the Codex document.

The Committee agreed that an Electronic Working Group (EWG), chaired by Canada and co-chaired by Mexico and New Zealand, would work between the 32nd and 33rd Sessions of the Committee, taking into account the discussion at the 32nd session and the amendments to the text presented in Appendix VII, to:

- consider the principles and which of these in sections 3, 4, 5 and 6 of the current draft revised document (CX/NFSDU 10/32/5) are applicable to mandatory and/or voluntary addition of essential nutrients,
- make proposals for the structure of the document based on the review of the principles.
- consider the options for definitions discussed by the Committee at its 32ⁿ Session.

The EWG would propose options, items, and a revised text to be circulated for additional comments at Step 3. The revised text and the related comments will be addressed by the physical working group that would work immediately before the 33rd Session of the Committee.”

BACKGROUND

Project Document

The Project Document, as revised and adopted by the 31st Session of the Committee (Appendix V, Alinorm 10/33/26) stated that the “purpose” of the new work with regard to the *General Principles for the Addition of Essential Nutrients to Foods* 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

Participation

In January 2011 Canada invited all members of CCNFSDU to participate in the EWG to consider further the development of the draft revised *General Principles for the Addition of Essential Nutrients to Foods*.

In correspondence from the Chair and Co-Chairs, dated February 28, 2011, the interested EWG participants were requested to provide comments by April 15, 2011, on what, if any, additions or changes are required to the *General Principles* to reflect the “Purpose and Scope of the Proposed New Work”, the “Main Aspects to be Covered” set out in the Project Document (Appendix V, Alinorm 10/33/26) and cited above, as well the discussions at the 32nd Session of the Committee and the charge to the EWG, (REP 11/NFSDU, paragraphs 51 to 74, and Appendix VII). Participants were also reminded that the Committee had previously stated that

the totality of the current document would be evaluated to ensure coherence and consistency of the principles and the guidance. The February document reflected the text as shown in Appendix VII with some further proposals by the chair and co-chairs for consideration by the EWG.

Comments on the proposed revisions to the *General Principles* and associated questions were received from Argentina, Australia, Bolivia, Canada, Costa Rica, Denmark, the European Community, Japan, Malaysia, New Zealand, Norway, Republic of Korea, Singapore, United States of America, Uruguay, ICBA (International Council of Beverage Associations), and IDF (International Dairy Federation).

Canada, Mexico and New Zealand would like to express their gratitude to the EWG participants who submitted comments which were considered by the Chair and Co-chairs in preparing the discussion document and revised text options to be circulated by the Secretariat for comments at Step 3. The revised text and additional comments that will be received during the Step 3 consultations will be addressed by the physical working group that will work immediately before the 33rd Session of the Committee.

CONCLUSIONS BASED ON EWG INPUT

In terms of the specific charge to the EWG and based on the feedback received from the EWG, the Chair and Co-Chairs offer the following conclusions:

1. In considering the principles and which of these in sections 3, 4, 5 and 6 of the current draft revised document (CX/NFSDU 10/32/5) are applicable to mandatory and/or voluntary addition of essential nutrients, there was general consensus that the principles in section 3 are applicable to all types of appropriate addition of nutrients to foods and that specific principles in sections 4, 5 and 6 are equally applicable to mandatory and voluntary additions. Some respondents stated that where principles do not apply to both mandatory and voluntary additions these can be so identified but that separate sections for mandatory and voluntary additions are not required.

2. With regard to the structure of the document, in general there seemed to be agreement that the format of the current *General Principles* (CAC/GL 09-1987) should be retained, with a number of modifications and additions within sections proposed. One respondent suggested deletion of sections 4 and 5 since these were considered to be covered by the principles in section 3. This same respondent also suggested that section 7 may not be needed since special purpose foods were addressed in other Codex documents. The main options for formats are presented below and have been considered in the draft revised *General Principles* that are attached.

3. A large number of comments were received on the Definition section. The most substantial of these included a suggestion to delete all definitions with the exception of those for “nutrient” and “essential nutrient” since the purpose and certain basic principles of addition of nutrients in the Introduction of the *General Principles* were considered to address these. Another substantial change proposed was to the definition of “fortification” to make it applicable to the addition of essential nutrients in general. The respondent proposing this change also proposed that section 6 be renamed to “*Addition of Essential Nutrients for Purposes of Increasing Population Nutrient Intakes*”.

4. A substantial number of suggestions for edits and amendments were received regarding Section 6, Nutrient Addition for the Purposes of Fortification. There seemed to be general agreement that there was a lot of duplication of principles with many commenting on specific principles that should be deleted. However, there was a lack of consensus on the structure, level of detail and content required in this section. Some respondents took a reductive approach, and proposed deleting many of the voluntary fortification provisions or transferring them to Section 3 on Basic Principles. Whereas other respondents proposed reorganising the document to combine the mandatory and voluntary principles and structuring the document based on the purpose of the principles.

SUMMARY OF MAIN COMMENTS FROM EWG (Appendix 1)

A summary of the key comments received from the EWG in response to the request dated February 28, 2011, is attached as Appendix 1. Copies of actual comments received from EWG participants are available on request.

DRAFT REVISED *GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS* (Appendix 2)

Based on the comments received from the EWG, Canada, Mexico and New Zealand are pleased to provide draft revised *General Principles for the Addition of Essential Nutrients to Foods*, for comments at Step 3 by the Codex Committee on Nutrition and Foods for Special Dietary Uses (Appendix 2). The table that is attached as Appendix 2 includes 3 versions of the draft revised *General Principles* in a side-by-side presentation as follows

1. The version of the draft revised *General Principles* that was sent to the EWG for comment on February 28, 2011. This version was generally based on Appendix VII (REP11/NFSDU) and also incorporated other comments received from members prior to the 32nd Session of the Committee. It is provided mainly for ease of reference as the document on which comments were made by the EWG.
2. A version of the draft revised *General Principles* that uses the format in the current format of the *General Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 09-1987) with changes made within the sections based on comments received during the 32nd Session as well as from the EWG. This version presents options for many of the sections and subsections where there was no consensus. This version takes into account comments that the choice of mandatory or voluntary addition applies to all types of nutrient additions and not solely to addition for the purpose of fortification.
3. A version of the draft revised *General Principles* based on a different structure that was suggested to reduce duplication. In this version, specific principles are retained only for “Fortification”, including mandatory and voluntary subsections, and “Special Purpose Foods”. The principles associated with restoration and nutritional equivalence of substitute foods are moved into Section 2 which is named “Description” to allow for inclusion of the purpose of the specific types of nutrient addition. Principles that are considered applicable to all types of nutrient addition are placed in Section 3 including many of the principles from within Section 6 of the EWG version for “Voluntary Fortification”.

Please note that in the versions of the draft revised *General Principles* in Appendix 2 new text is underlined. The numbering and re-numbering of sections posed a challenge, in particular since with the format revisions sections sometimes do not align. It was decided to leave the numbering of sections until decisions are made about which sections will remain and exactly where these will be placed. For ease of reference, the table in Appendix 2 includes item numbers corresponding to each discrete row of the table. We have also included, at the end of the table, the structure of the formats in each of the three versions (item 48 in the table in Appendix 2).

COMMENTS REQUESTED AT STEP 3

Comments are requested from Members and Observers on the attached versions of the draft revised *General Principles*. In considering comments, Members and Observers should focus primarily on versions 2 and 3 since these are based on feedback from the EWG. Analysis of the comments that are received during the Step 3 consultation will be used to decide on the focus of the Physical Working Group on the *General Principles* that is planned to take place immediately before the 33rd Session of the CCNFSDU.

Appendix 1

Proposed Draft Revision of the Codex *General Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 09-1987)

Report of the Electronic Working Group (EWG) Chaired by Canada and co-chaired by Mexico and New Zealand

SUMMARY OF MAIN COMMENTS FROM the ELECTRONIC WORKING GROUP

I. GENERAL

The general comments on the *General Principles* received from the EWG participants included the following:

- Starting Point for EWG Work: The report of the 32nd Session of the CCNFSDU states (Paragraphs 58 and 67 of the 32nd CCNFSDU session report (REP 11/NFSDU)):

58. “After some discussion, the Committee agreed to combine the first and second indents of the current text, with a few amendments, in order to describe the purposes of the document and to transfer the rest of the section, except the last paragraph, to Section 3, Principles....”

67. The Committee agreed that the section should be divided into two parts, one on fundamental principles that would include mainly the sections transferred from the original Introduction, and the other on basic principles applicable to all types of addition of nutrients to foods.

No opposition to the Committee’s decisions was recorded in the report thus these agreements and Appendix VII should be the starting point for the EWG work. However, the EWG Co-chairs commented in the February document to the EWG that, on consideration, the transferred text from the Introduction describes the purpose and outcome of the *General Principles* and was retained in the Introduction (rather than transferred to the Principles section) for further comment by the EWG.

Given that the report refers to Committee agreement on the above amendments, it would have been more appropriate and more likely to facilitate progress on this agenda item to ask questions to all EWG members about the transferred text rather than to present revised text that is inconsistent with the outcome of the Committee’s discussion as identified in the above paragraphs and in Appendix VII.

- The *General Principles* should provide guidance to regulate fortification but should not encourage indiscriminate fortification.
- The key terms used in the document could be considered as follows: the purposes of the document are set out in the Introduction (public health need and trade); the means by which the first of these relating to public health need is achieved is through the four different strategies for which there are General Principles in section 3, and Specific Principles in sections 4-7.
- The 2006 WHO publication on micronutrient fortification should be referenced (i.e., *Guidelines on food fortification with micronutrients*, WHO/FAO 2006) as it is a valuable source of detailed information on all aspects of nutrient addition to foods, e.g., dietary modelling and the use of the UL.
- The choice of mandatory or voluntary addition should apply to all nutrient additions including restoration, nutritional equivalence and special purpose foods, and not just to fortification.
- Only one set of Specific Principles need to be given for each of restoration, nutritional equivalence, fortification and special purpose foods and there should not be separation of principles into mandatory and voluntary fortification.
- The document should apply to all types of addition of essential nutrients. Since voluntary fortification is more common than mandatory fortification, those principles that are specifically applicable to mandatory fortification could be identified in a separate section. This would also contribute to the aim of simplifying the document.

- Further guidance is needed in section 3 on the factors for consideration in deciding whether to apply mandatory or voluntary fortification.
- The *Principles* need to be clear that assessment of dietary intakes needs to occur as part of decision making as well as in monitoring.
- The initiative of revising the *General Principles* creates an opportunity to review the totality of the document. Such a revision is important in the context of the socio-economic changes and the life styles of the population that have led to changes in the energy and nutrient requirements of various groups of the population and to intakes of certain vitamins and minerals for these groups that would be below those recommended. In addition, there has been considerable progress in scientific knowledge concerning intakes of some nutrients that are necessary for maintaining optimal health and well-being.
- The *General Principles* should not define detailed conditions which should be fulfilled in the case of the addition of nutrients to foods. Specific provisions, such as those related to the selection of foods which may be fortified and essential nutrients which may be added should not be set at international level. These would be best determined, when necessary, at regional/national/local level taking into account dietary habits, socioeconomic situations and the need to avoid any risks to health.
- The Codex Guidelines for Vitamin and Mineral Food Supplements (CAC/GL 55-2005) provide for the basic principles of a risk-based approach to set minimum and maximum amounts of vitamins and minerals contained in food supplements. The same principles should apply to foods to which essential nutrients have been added and therefore it is not necessary to establish detailed criteria and conditions to be followed to determine amounts of essential nutrients that may be added to foods.
- A single term, “national authorities” should replace the terms: “national authorities”, “governments” and “those responsible for developing guidelines and legal texts”.

II. TITLE OF DOCUMENT

There was no clear consensus for the title of this document with a split between those who prefer “General Principles” and those that prefer “Guidelines”. As indicated at its 32nd Session, once the Committee has finished its deliberations on this document the more appropriate title may become clearer. Please note that the term “*General Principles*” will be used in this discussion document.

III. FORMAT for THE *GENERAL PRINCIPLES*

In their charge to the EWG, the 32nd Session of the CCNFSDU specifically requested that the EWG make proposals for the structure of the document based on the review of the principles.

Several comments were received from the EWG on the format of the *General Principles*. These are summarized below. It was assumed that those not commenting on the format per se did not object to what was proposed to the EWG in the February 28, 2011 request for comments.

Generally respondents did not object to maintaining the overall structure of the current General Principles (i.e., CAC/GL 09-1987) but a number of proposals were made for modifications within the Sections.

A number of respondents stated that the Committee should focus on updating relevant sections of these Codex *General Principles* but the basic structure of CAC/GL 09-1987 should be retained.

One respondent stated that only one set of Specific Principles need to be given for each of restoration, nutritional equivalence, fortification and special purpose foods, i.e., that there should not be separation of principles into mandatory and voluntary fortification noting that this creates duplication. This respondent suggested retention of the current format of the *General Principles*, (i.e., CAC/GL 09-1987) with clear guidance provided in section 3 on the factors for consideration in deciding whether to apply mandatory or voluntary fortification.

Purposes for each section in the *General Principles* were suggested by one respondent as follows:

“INTRODUCTION (*To briefly identify the purpose of this guidance as providing a set of principles for the rational and safe addition of essential nutrients to foods, and to acknowledge that these principles take into consideration the Codex Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the CCNFSDU.*)

1. SCOPE (*To identify the applicability of the principles to all foods except vitamin and mineral food supplements*)
2. DEFINITIONS
3. OVERARCHING PRINCIPLES (*To identify overarching principles applicable to all types of mandatory and voluntary addition of nutrients to foods*)
- 4- 7. (*To identify principles that are specific to different types of nutrient addition*)”

With regard to Section 6, the same respondent stated that according to the Committee report documented that several delegations expressed the view that the majority of principles for mandatory and voluntary fortification apply to both and where differences exist, they could be identified within the relevant sections, whereas other delegations supported two separate sets of principles (para 68, REP 11/NFSDU). The respondent noted the difficulty in evaluating these two options if only text for the latter option is presented and suggested that the final EWG report include also an option showing how text could be organized in Sec. 6 as a consolidated set of principles. This respondent’s proposed reorganization allows the identification of separate principles in cases where the Committee agrees a principle does not apply to both mandatory and voluntary fortification. This respondent’s suggested format was as follows:

Introduction

1. *Scope*
2. *Definitions*
3. *Overarching Principles*
 - 3.1 *Fundamental principles*
 - 3.2 *Additional principles to consider for nutrient addition*
4. *Addition of Essential Nutrients for Purposes of Restoration*
5. *Addition of Essential Nutrients for Purposes of Nutritional Equivalence*
6. *Addition of Essential Nutrients for Purposes of Increasing Population Nutrient Intakes*
 - 6.1 *Demonstration of need*
 - 6.2 *Selection of foods to fortify*
 - 6.3 *Determination of amounts of nutrients that may be added*
 - 6.4 *Cost considerations*
7. *Nutrient Addition to Special Purpose Foods*

Another respondent indicated that since most nutrient addition to foods is in the voluntary category the majority of principles should apply to this type of addition and that specific principles for mandatory fortification should be identified in a separate section. This respondent also stated that since the Introduction would include the purpose of the document it is not necessary to maintain certain definitions and basic principles in the document. The respondent considered that a reduction in the number of definitions and basic principles would simplify and clarify the text. In this regard this respondent proposed the following revised format for the *General Principles*:

Introduction

1. *Scope*
2. *Definitions (include only definitions for “nutrient” and “essential nutrient”)*
3. *Basic Principles (apply to all additions)*
 - . *Foods which may be fortified*
 - . *Selection of essential nutrients that may be added*
 - . *Determination of amounts of essential nutrients to be added*
4. *Mandatory Fortification*

IV. TEXT FOR GENERAL PRINCIPLES

1. Introduction

During the discussions at the 32nd Session some members had pointed out that the Introduction section should focus on the purpose of the document. In this regard, the Committee agreed to combine the first and second indents of the current text, with a few amendments, in order to describe the purpose of the document and to transfer the rest of the section, except the last indent, to Section 3 (Principles).

The Committee was not able to come to a consensus regarding the text “to allow a wider choice for fortified foods” but agreed that the addition of nutrients to food should not only be safe but also “rational”, as this term was well understood and was already included in the current *Principles*.

In preparing questions to be addressed by the EWG, the Chair and Co-Chairs of the EWG considered whether the text in the 2nd indent (as deleted in Appendix VII) actually did describe the purpose and outcome of the General Principles rather than principles per se and asked the EWG to comment on the placement of this text. The EWG was also requested to comment on whether the Introduction section should include any additional text or whether any of the current text needed to be removed in order that the Introduction would be clearly focused on the purpose of the *General Principles*.

Whereas in the original Codex Principles, a basic principle was that there are 4 appropriate *purposes* for addition of essential nutrients to foods, i.e. restoration, nutritional equivalence of substitute foods, fortification and ensuring the appropriate nutrient composition of a special purpose food, the concept of what constitutes an appropriate purpose for addition is evolving in this revision process to become one of achieving certain impacts on health or on the nutritional quality of the food supply. Thus, the Committee proposed that a basic or fundamental *principle* is that there are only certain *purposes* that should be recognized as appropriate bases for addition of essential nutrients, these being, 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; maintaining or improving the overall nutritional quality of foods; and [allowing 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.]]. One member has further recommended that what used to be referred to as *purposes* for addition in the original document, i.e. restoration, nutritional equivalence of substitute foods, fortification (proposed to be changed to nutrient addition to increase population nutrient intakes) and ensuring the appropriate nutrient composition of a special purpose food, be considered simply *mechanisms* by which the purposes are achieved. The document then offers “principles” to guide their implementation. The Committee has also proposed to clarify and simplify what the purpose of the Guidelines/General/Principles themselves is, i.e. "to provide guidance through the establishment of a set of principles that serve as a basis for the rational and safe addition of essential nutrients to foods.

Responses/Comments from EWG on the “Introduction” Section

One respondent agreed that the Introduction should include the purpose of the General Principles, and that actual principles should be addressed under sections 3 to 6. The respondent also agreed with the decisions made at the last session (as identified in paragraphs 58, 67 and Appendix VII) to: 1) retain text in the Introduction that refers to the purpose of this guidance as providing a set of principles that serve as a basis for the rational and safe addition of essential nutrients to foods; and 2) transfer the first four bullets of the second indent to a new section on Fundamental Principles in Section 3. This respondent disagreed with the co-chairs that the transferred text does not describe principles and believed that the first four bullets do identify important fundamental principles for when nutrients may be appropriately added to foods, but acknowledged that it may be helpful to insert “appropriately” in the introductory text to Sec. 3.1 for clarification. That is, a fundamental principle is that essential nutrients may be *appropriately* added to foods for the purpose of (correcting a demonstrated deficiency...., contributing to meeting requirements...., contributing to the maintenance or improvement of health....; and/or maintaining or improving the overall nutritional quality of foods.)

The same respondent did not support the new proposed text in brackets in the fifth bullet of the second indent that refers to “allowing a wider choice of fortified foods”. They noted that this may be a consequence of revising the existing guidelines for some (but not necessarily all) governments using them, but it should not be identified as a main purpose or a principle of this guidance. Moreover, “allowing a wider choice of fortified foods” *per se* would not necessarily result in improvement of the health and/or nutritional status of a population in the absence of a demonstrated need by a population group(s) and rational nutrient addition that takes into account potential consumption of the fortified food(s) by all population groups including infants. The respondent also noted that the second bracketed text in the fifth bullet is a repetition of text in the third bullet.

This respondent’s comments were supported by several other respondents who recommended that at the second indent, the text in the first four bullets (which the respondent considers addresses fundamental

overarching principles for why nutrients should be added to foods) be moved to Section 3, consistent with the outcome of the discussion at last session (paras 58 and 67 and Appendix VII). One respondent recommended deletion of the 2nd bullet point of the first indent consistent with the outcome of discussion at last session (Appendix VII) and that an explicit reference to a goal of Codex provisions to facilitate fair international trade should not be needed.

One respondent agreed with the modifications to the overall structure of the document as proposed in the document to the EWG, in particular the laying down of general provisions stating the intentions of the document in the Introduction including the purpose of allowing a wider choice of fortified foods. This respondent also considered the insertion of the reasons for the addition of essential nutrients to foods in the introductory section of the document to be appropriate and in light of such a revision and additions to the Introduction section, considers that it is not necessary to maintain certain definitions and basic principles in the document.

One respondent suggested adding the words “*to address a public health need*” to the first bullet in the first indent, i.e., “*serve as a basis for the rational and safe addition of essential nutrient to foods to address a public health need*”. This respondent further recommended that the second indent pull together various proposed and existing statements of purpose and link them to the public health consideration:

“A public health need could be addressed by:

- improving the overall nutritional quality of foods*
- contributing to meeting requirements of one or more essential nutrients and reducing the risk of inadequate intakes, poor nutritional status and prevalence of deficiency in the population*
- preventing the indiscriminate addition of essential nutrient to foods thereby reducing the risk to health of nutrient excesses or imbalances.”*

This respondent also recommended that a reference to the 2006 FAO/WHO Guidelines on food fortification with micronutrients should be included as these provide considerably more detail on the subject than can be covered in Codex Guidelines.

In the 2nd indent, some respondents wanted clarification of the term “nutritional quality” in the 3rd bullet point and suggested replacement with the term “nutrient profile”.

With regard to the second set of square brackets at bullet point 5, most of respondents would like it deleted. Although many respondents indicated that the whole of bullet point 5 should be deleted there was not consensus. One respondent suggested that the text in the first set of square brackets should be changed to “*allowing consumers to make informed decisions when choosing a fortified food*”.

Conclusions/Further Discussion

The suggested edits to this section are presented in the attached texts in Appendix 2 for additional discussion by the Committee.

2. Section 1: SCOPE

Generally it was considered that the proposed text sufficiently describes the scope of the document. Several respondents noted that the footnote to the Codex Guidelines on vitamin and mineral food supplements (CAC/GL 55-2005) had been deleted and should be reintroduced.

3. Section 2: DEFINITIONS

During its 32nd Session the Committee discussed the “Definition” section at great length. The text which specifies that essential nutrients were not limited to vitamins and minerals was retained in square brackets. The Committee agreed to include the WHO definition of nutritional equivalence as an alternative to the current definition in square brackets for further consideration. The Committee also considered the WHO definition of fortification but it was pointed out that it was preferable to use the current Codex terminology, which was more consistent with the *Nutritional Risk Analysis Principles* and that the WHO definition includes the concept of biofortification which the Committee had specifically agreed to exclude from consideration in the discussions of the *General Principles*. It was also noted that the Task Force on Foods Derived from Biotechnology had developed specific guidance in this area and had acknowledged the applicability of CAC/GL 9-1987 in Annex 2 of their Guidelines. The Committee agreed to insert in square brackets at the end of the paragraph the proposal from the European Union concerning contribution to the improvement of health and/or nutritional status and the wording from the WHO definition to the effect that

fortification should be “with minimal risk to health”. The Committee also considered an alternative proposal to limit the text to the definition only and to delete any reference to the purpose of the fortification in the definition. The Committee could not come to a conclusion and agreed that the definition should be considered further at the next session

The Committee requested that the EWG consider definitions. In this regard the EWG had been requested to comment on the text in square brackets and make recommendations with regard to any definitions that could be deleted (e.g., “nutrients” and “essential nutrients”), as well as new definitions that should be considered. A specific question with regard to the definition of fortification was whether it should include its purpose. The EWG was also requested to comment on the placement of the definitions for voluntary and mandatory fortification.

Responses/Comments from EWG on Section 2

A wide variety of comments was received from the EWG on this Section. There was consensus that the heading of this section should be changed to “Definitions”.

General

One respondent stated that in the light of the proposed inclusion of the purposes and certain basic principles of addition of nutrients in the Introduction of the *General Principles*, it is considered that it is not necessary to keep the following definitions:

- 2.3 Nutritional equivalence*
- 2.4 Substitute food*
- 2.5 Fortification*
- 2.6 Restoration*
- 2.7 Special purpose foods*
- 2.8 Nutrient density*
- 2.9 Standardization*

In particular, this respondent noted that the inclusion of a definition of "fortification or enrichment" could risk resulting in unnecessary repetition and possible contradiction with the general principles included in the Introduction Section, more so as the text in the definition differs from the purposes and basic principles in the Introduction Section.

2.1 Nutrient and 2.2 Essential nutrient

Some respondents considered that the inclusion of definitions for both “nutrient” and “essential nutrient” was unnecessary. Generally respondents considered that the second sentence in section 2.2. was redundant and may be misinterpreted. One respondent suggested a revision of the structure of the definition for “essential nutrient” to parallel that of the definition for “nutrient”, i.e.,

“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; or
(b) a deficit of which will cause characteristic bio-chemical or physiological changes to occur.”

Other comments here included the recommendation that the concept of excessive nutrient intake should be included in the definition of “nutrient” in 2.1 (c) and that the term “healthy life” in 2.1 (b) be changed to either “health” or “healthy body”.

2.3 Nutritional equivalence and 2.4 Substitute foods

A number of respondents suggested incorporation of the term “substitute food” within the definition of “nutritional equivalence”. One respondent suggested merging the definitions of nutritional equivalence and substitute food to create a new definition of nutritional equivalence of substitute foods as this introduces a purpose into the definition as is the case with the definitions of restoration and fortification. Another respondent stated that “Nutritional equivalence” is a comparative term and should be used in relation to a reference food, in this case the substitute food. The following text was suggested:

*“**Nutritional equivalence** is achieved when an essential nutrient is added to a substitute food in amounts such that the substitute food has a similar nutritive value to the food being substituted, in terms of the amount and bioavailability of the added essential nutrient.”*

Yet another respondent suggested that the definition of nutritional equivalence should combine aspects of the original definition and the WHO/FAO alternative (Guidelines on food fortification with micronutrients) as this introduces a purpose into the definition to be consistent with the definitions of fortification and restoration:

“Nutritional equivalence means the addition of one or more essential nutrients to a substitute food to achieve a similar nutritive value to its normal counterpart in terms of quantity and quality of protein, and kinds, quantity and bioavailability of essential nutrients.”

A third option proposed to include the nutritional value of the food within the definition of nutritional equivalence and to delete the definition of substitute food.

“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. It can be 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.”

If the definition of nutritional equivalence includes substitute food, it was proposed that “Substitute food” be defined before “Nutritional equivalence”. There was no consensus on retaining or deleting the text on flavour and odour in sections 2.3 and 2.4. It was suggested that examples should not be included in the definition of substitute food.

2.5. Fortification

There was no consensus on retaining the purpose of fortification within its definition. Several respondents stated that the purpose of fortification is stated elsewhere in the text and should be removed from the definition.

Options suggested for the definition of “fortification [or enrichment], in addition to that in the February 2011 EWG draft revision, included:

- “fortification” should be defined as nutrient addition and the purposes of different types of fortification/nutrient addition should be addressed in related principles, i.e., *“Fortification (or enrichment) as used in these [guidelines/principles] means the addition of one or more essential nutrients to a food [whether or not it is normally contained in the food].”*
- “fortification” should include its impact in improving health (goal) by addressing deficiency or reducing the risk of poor nutritional status or inadequate nutrient intake (means of achieving goal), i.e., *“Fortification (or enrichment) means the addition of one or more essential nutrients to a food, whether or not it is normally present in the food, for the purpose of improving population health by addressing a demonstrated deficiency or reducing the risk of poor nutritional status or inadequate nutrient intake.”*

There was no clear consensus on the retention of or the placement of the definitions of “mandatory” and “voluntary” fortification, however many respondents supported moving the definitions from section 3 to section 2, either specifically under 2.5 “Fortification” or as stand alone definitions. One respondent suggested that the words “for a specific purpose” be included in the definitions of voluntary and mandatory fortification (i.e., *“Mandatory fortification occurs when governments require food manufacturers to add specified nutrients to particular foods or categories of food for a specific purpose. Voluntary fortification occurs when a food manufacturer chooses to add specified nutrients to particular foods or food categories for a specific purpose.”*)

One respondent suggested that the descriptions for voluntary and mandatory fortification provided by WHO/FAO (2006) might be adapted for this section and could either replace the proposed definition for fortification or be placed after the amended current definition:

“Voluntary fortification when a food manufacturer freely chooses to fortify particular foods in response to permission given in food law, or under special circumstances, is encouraged by a

national authority to do so (World Health Organization, Food and Agriculture Organization. Guidelines on food fortification with micronutrients. First ed. Geneva, Switzerland: World Health Organization; 2006, p33).”

“**Mandatory fortification** when a national authority legally obliges food producers to fortify particular foods or categories of foods with specified micronutrients. (World Health Organization, Food and Agriculture Organization. Guidelines on food fortification with micronutrients. First ed. Geneva, Switzerland: World Health Organization; 2006, p31).”

2.6 Restoration

A suggestion was made to merge the definitions of “standardization” and “restoration” since the concept of standardization was seen as linked to restoration, i.e.,

“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, or in order to compensate for natural variations in essential nutrients, in amounts which will result in the presence in the food of the levels of the nutrients(s) present in the edible portion of the food before processing, storage or handling.”

2.7 Special purpose foods

There appeared to be agreement that the square brackets around “and also include foods for infants and young children” should be removed.

2.8 Nutrient density

A suggestion was made to replace MJ with KJ.

2.9. Standardization

There appeared to be general agreement that the definition of “standardization” should be deleted since the term is not used in the document. However, a suggestion was made to merge the definitions of “standardization” and “restoration” since the concept of standardization was seen as linked to restoration (see 2.6 above).

Other comments on the Definition Section included recommendations that the order of the definitions should reflect the order of the document.

One respondent suggested a definition for “*Population*” to cover both national populations and population subgroups to streamline the text wherever the cumbersome reference to *population or a population subgroup* appears. Doing this enables “population” to be used as an adjective.

“Population refers to a national population or a specific population group(s) as appropriate.”

Conclusions/Further Discussion

The suggested edits to this section are presented in the attached texts in Appendix 2 for additional discussion by the Committee.

4. Section 3: [BASIC] [GENERAL] [OVERARCHING] PRINCIPLES

At its 32nd Session the Committee could not come to a conclusion with regard to this section and agreed to consider further the development of principles, their application to mandatory and/or voluntary fortification, and how these principles should be presented and organized. The Committee’s discussions included:

- a new introductory paragraph that would apply to all principles under the section
- a proposal to divide the section into two parts, one on “fundamental” principles that would include mainly the sections transferred from the original Introduction, and the other on “basic principles” which would be applicable to all types of addition of nutrients to foods.
- application of the principles to mandatory and voluntary fortification. Several delegations expressed the view that the majority of principles for mandatory and voluntary fortification apply to both and where differences exist, they could be identified within the relevant sections. Other delegations pointed out that, while some common principles existed, there were significant differences and two separate sets of principles should be developed. The Delegation of the European Union expressed the view that scientific evidence, dietary habits and socio-economic conditions had evolved since the

adoption of the current Principles in 1987 and that voluntary fortification was now very widespread and more frequent than mandatory fortification in some regions. Some delegations indicated that they used mandatory fortification at the national level and needed guidance in this respect. The Committee could not come to a conclusion and agreed to consider further the development of principles, their application to mandatory and/or voluntary fortification, and how these principles should be presented and organized.

The Committee requested that the EWG specifically reconsider the text included in the proposed sections 3.1 “Fundamental principles” and 3.2 “Basic principles”.

In the February 2011 document, the EWG was asked to consider the following with regard to this Section:

- the retention of the heading “Basic Principles” or alternately the term “Overarching Principles” since it appeared that “fundamental” and “basic” were synonymous.
- whether the principles within this section apply to all types of additions and whether specific principles for the various types of additions should continue to be included in separate sections that address the specific type of addition.
- text to be deleted and new text to be included

Responses/Comments from EWG on Section 3

There was general consensus that the principles in this Section are applicable to all types of appropriate addition of nutrients to foods. There was no consensus on the heading for this Section: some preferred Basic Principles whereas others preferred General Principles. There was also some support for the proposed “Overarching Principles”. In addition, there was also no agreement on whether this section needs to have subheadings. One respondent suggested that if all the principles in this Section are considered to apply to all additions they should all be equally weighted and there should be no hierarchy as implied by subheadings 3.1 Fundamental and 3.2 Additional. Another respondent proposed to retain the subheading “Fundamental Principles” for Section 3.1 but to modify the subheading proposed in Section 3.2 in Appendix VII to “Additional Principles to Consider for Nutrient Addition”.

As in comments on the Introduction Section, respondents generally considered that the text “to allow a wider choice of fortified foods” was not a principle for the addition of essential nutrients to foods although it may be an outcome of fortification.

Introductory paragraph

A number of comments and suggestions for edits were made with regard to the introductory paragraph.

One respondent agreed with regard to the Committee’s decision to transfer the bullets on purposes of fortification from the Introduction section to Section 3. This respondent supported the removal of brackets and proposed that the additional text be added to more comprehensively reflect the nature of the principles in Section 3 (i.e., to encompass not only the risk of fortification but also the benefits):

“The following principles are applicable, as appropriate, to mandatory and/or voluntary addition of essential nutrients. These principles are intended to address when nutrient addition is justified and 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. This will also help to prevent practices which may mislead or deceive the consumer.”

Another respondent considered that the main differences for mandatory fortification should be identified in a separate section and therefore proposed rewording of the first sentence as follows: *“These principles are applicable, as appropriate, to all types of addition of essential nutrients.”*

Two respondents stated that the second and third sentences in the introductory paragraph should be deleted as the intentions set out in the second sentence are already laid down in the Introduction of the *General Principles* and the third sentence is covered by paragraph 3.10.

One respondent stated that the term “health hazard” in the second sentence is not defined and proposed its replacement with “adverse health effect” as defined in the Codex Alimentarius Nutritional risk analysis principles and guidelines for application to the work of the CCNFSU. This respondent also suggested replacement of the text “essential nutrient excesses, deficits or imbalances” with *“their inadequate and/or excessive intake”*.

Some respondents questioned whether to “prevent practices which may mislead or deceive the consumer” is a principle and whether it is outside the scope of these principles and better considered in guidelines on nutrition claims, e.g., CAC/GL 23-1997 (amended 2001 and 2004). Further discussion was suggested by the Committee.

One respondent suggested adding the text “where nutrient addition is voluntary” at the end of the last sentence for additional clarity since it was considered that the last sentence applies to voluntary additions.

Section 3.1

A range of comments were received in regard to this section. Several respondents indicated preference for the 2nd option of 3.1., i.e.,

“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.”

One respondent suggested that since “purpose” is now included in the Introduction, the various additions may be regarded as “strategies” to achieve the purpose, i.e.,

“3.1 Essential nutrients may be added to foods by means of restoration, nutritional equivalence of substitute foods, fortification, and ensuring appropriate nutrient composition of a special purpose food.”

Another respondent suggested introduction of the term “achieving” immediately before “nutritional equivalence” for further accuracy and clarity.

A respondent who supported maintaining the subheading “Fundamental principles” also suggested insertion of additional text and modifications as follows for additional clarity and to further characterize “fortification” should fortification be defined to mean simply nutrient addition:

“3.1 Fundamental Principles

Essential nutrients may be appropriately added 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 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;*

The above principles may be achieved by restoration, nutritional equivalence of substitute foods, nutrient addition to increase population nutrient intakes, and ensuring the appropriate nutrient composition of a special purpose food.]”

There appeared to be consensus that 3.1.5 should be deleted, a number of reasons being given: because it is already mentioned in the Introduction; consumer choice is not the mandate of Codex or it is not a principle for the addition of essential nutrients.

Section 3.2

A recommendation was made to amend the heading for section 3.2 from “Basic Principles” as it appears in Appendix VII to “Additional Principles to Consider for Nutrient Addition” and to modify and renumber 3.2 as follows:

“3.2.1 ~~3.2~~ (modified former 6.1) The mandatory and voluntary addition of essential nutrients to foods should take into account the kinds and amounts of essential nutrients to be added, the foods to be fortified, the particular nutritional problems to be corrected, the characteristics of the target populations, and the food consumption patterns of the area.”

Another respondent suggested a number of edits to the text as well as inclusion of bullet points and more considerations related to the choice of mandatory or voluntary nutrient addition:

“3.2 The choice of mandatory or voluntary addition of essential nutrients to foods should take into account:

- the severity and extent of public health need and the kinds and amounts of essential nutrients to be added*

- *the local food consumption patterns and other characteristics of the population at risk and the target foods for nutrient addition*
- *the relative importance of consumer choice*
- *the extent of uptake of voluntary permissions by food manufacturers.”*

A suggestion was made to move text from the introductory paragraph of section 6 into a new 3.2.2., and that a new 3.2.3 should indicate that voluntary nutrient addition should be regulated at the national level. i.e.,

“3.2.2. (New) 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.

3.2.3 (New) Voluntary addition of essential nutrients is when a food manufacturer chooses to add specified nutrients to particular foods or food categories and should be regulated at the national level.”

A respondent indicated that it was not necessary to include the definitions of "mandatory" and "voluntary" fortification in the section on Basic Principles and that a separate section identifying the principles for mandatory fortification would be sufficient.

Several respondents suggested deleting the last two sentences of the introductory text either because they feel that these points are covered in Section 3.10 and/or because it is unclear whether this is a basic principle.

Section 3.3

There was some agreement to remove the two sets of square brackets in the first sentence in section. One respondent stated that sections 3.3 and 3.4 appear to be describing basic components of nutrient-risk characterization. As such, a modified section was proposed which draws on the necessary 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.

“3.3 (former 3.2) [The addition of essential nutrients to food should be risk-based and not result in either inadequate and/or excessive intakes of the added essential nutrients, considering the nature of the adverse health effects being addressed, total dietary intake of the added nutrients from foods as well as intake from other relevant sources, upper levels of intake and identification of special sub populations at risk.]”

A suggestion was made to amend the first sentence to allow for other nutrient sources such as supplements to be taken into account, i.e., replace “amounts from other sources in the diet” with “amounts from all dietary and supplement sources.”

For clarity, a suggestion was made to edit the second sentence in this section as follows: “Upper levels of intake based on scientific risk assessment should be used to identify the need for any restrictions on the quantity of the addition or on the types of foods to be fortified.”

Some respondents stated that the concept of "upper levels of intake" is already covered by the first sentence in paragraph 3.3 and by the principles in paragraph 6.2.2.1 and suggested deletion of the second sentence. It was also stated that if the purpose of addition of nutrients is stated in the Introduction section the text in square brackets in the first sentence is not necessary.

Section 3.4

Clarification was requested on the relevance of a reference to adverse effects on the metabolism of other nutrients particularly since it may be difficult in practice to ascertain any interactions.

One respondent suggested including “and absorption” immediately after metabolism, i.e., “...on the metabolism and absorption of any other nutrient”.

Section 3.5

Generally there was agreement to retain this new section. One respondent proposed a streamlined version, i.e.:

“3.5 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 in the following order FAO/WHO standards, international Pharmacopoeias, recognized international standards or national legislation.

Section 3.6

Generally there was agreement to retain this section as is. One respondent suggested deletion since this was not relevant in the context of international guidelines. One respondent suggested addition of “processing”, i.e.,

“3.6 The essential nutrient should be sufficiently stable in the food under customary conditions of processing, packaging, storage, distribution and use.”

Section 3.7

Retention of this section was generally supported.

A suggestion was made to change the term “biologically available” to “*bioavailable*” and inclusion of text to require that the added source of an essential nutrient should be safe. However, respondents also noted that there may be a duplication of scope in paragraphs 3.5 and 3.7 and asked that deletion of one of these paragraphs be considered.

Section 3.8

Retention of this section was generally supported.

It was not considered necessary to specify that the addition of essential nutrients should not have any undesirable impact on the characteristics of the food.

For clarity, a respondent suggested adding the word “added” immediately before “essential nutrient” in sections 3.6, 3.7 and 3.8.

Section 3.9

Retention of this section was generally supported.

It was suggested that the text “satisfactory manner” at the end of this section is not specific and should be removed. For clarity, the following text was proposed:

“3.9 (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 availability, consistency, distribution and stability.”

One respondent suggested deletion of this section as it is not relevant within the context of international guidelines.

Section 3.10

Retention of this section was generally supported. However, a respondent stated that the inclusion of “health benefit” as an alternative to “nutritional merit” introduces a new concept that is not currently reflected in section 3: General Principles or the first part of section 6. If the term is to be retained here, the CCNFSU would need to consider appropriate General Principles and specific principles for fortification that would serve as the basis for providing for a health benefit other than one of only nutritional merit.

A suggestion was made that this section should apply to all forms of consumer communications and that there is no need to single out labelling. Another suggestion was to include the advertising of food fortified with essential nutrients for the benefit of the consumer.

A question was raised as to whether the principle in this section is outside the scope of this document and would be better considered in guidelines on nutrition claims e.g., CAC/GL 23-1997 (amended 2001 and 2004).

Section 3.11

There was support for retention of this section although one respondent suggested transposing sections 3.11 and 3.12 for better flow. A suggestion was made to incorporate the concept that methods should be made available to monitoring bodies, i.e.,

“3.11 Methods of measuring, controlling and/or enforcing the addition of essential nutrients in foods should be made available to monitoring bodies to facilitate efficient monitoring of those products.”

A respondent stated that additional text is needed to assist decision making on nutrient addition for each strategy. This respondent stated that while there is much text relating to safety in the fortification section, it focuses too heavily on safety. In this regard a new general principle was proposed and applied to the decision making process.

“(new) Potential change to population intakes should be estimated as part of the decision making about nutrient addition. Such estimation 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 reference daily intake values for adequacy and safety.”

Section 3.12

Generally there was support for retaining this section. A number of edits were suggested for clarity including the following:

“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~~ that may be added and the minimum levels at which they should be present in the food to achieve their intended purpose.”

One respondent suggested that this section should incorporate the need for minimum and possibly maximum levels in regulations. The suggested edit in this regard included:

“~~When provision is made in~~ National food standards, regulations or guidelines for the addition of essential nutrients, ~~specific provisions should be included~~ identifying the target foods, the essential nutrients ~~to be considered or to be required~~ or permitted to be added and the minimum and where appropriate, maximum levels at which they should be present.”

Sections 3.13 and 3.14

There was a range of comments on these two sections including retention of both as well as a suggestion to combine them, i.e.,:

“3.13 [Monitoring total intakes of the added essential nutrients in population(s) by national authorities is necessary to assess the extent to which public health needs are being addressed and to ensure that the risk of adverse health effects are minimized to the greatest extent possible.]

One respondent indicated preference for retaining section 3.13 only with amendments to streamline the text linking national monitoring to permitted or required nutrient addition. This respondent also stated that since improvement in nutritional status and prevalence of deficiency are previously mentioned as purposes of nutrient addition, it was considered that these should also be monitored and referred to this through the use of “public health need”. This respondent suggested that any risk of excessive intake should be minimized rather than absent. The proposed text:

“3.13 National authorities should ~~monitoring~~ ~~populations~~ ~~total intakes of the added essential nutrients added to foods from all dietary and supplement sources~~ ~~in the populations is essential particularly~~ and to assess the extent to which the public health needs are being is addressed and to ensure that a any risk of excessive intakes is ~~absent~~ minimized. Monitoring of total nutrient intakes should use the same approach as used in deciding the nutrient addition.”

It was suggested that the monitoring of population intakes should be performed for all nutrients and not only for those which are likely to pose a risk of inadequate or excessive intakes for the population(s). However, it was suggested that the monitoring of total intakes is *important* rather than *essential*. Another respondent stated that monitoring of total intakes of nutrients should take place on all foods, not only the foods that are fortified with added nutrients.

Paragraphs 6.2.1 to 6.2.3

A suggestion was made to move section 6.2 to Section 3.

Conclusions/Further Discussion

The suggested edits to this section are presented in the attached texts in Appendix 2 for additional discussion by the Committee.

5. Section 4: ADDITION OF ESSENTIAL NUTRIENTS FOR THE PURPOSE OF RESTORATION

The Committee requested that the EWG consider the principles and which of these in sections 3, 4, 5 and 6 of the current draft revised document (CX/NFSDU 10/32/5) are applicable to mandatory and/or voluntary addition of essential nutrients, taking also into account the discussion at the present session of the CCNFSDU, and the amendments to the text (presented in Appendix VII for ease of reference). The EWG would make proposals for the structure of the document based on this review of the principles.

The EWG was specifically requested to indicate whether this section requires any additional text and comment on the text in square brackets. In addition to the text in square brackets at the end of section 4.1, is there a need to include any other text with regard to mandatory versus voluntary nutrient addition for the purpose of restoration?

Responses/Comments from EWG on Section 4

A number of comments were received in regard to this section, including support for the removal of the square brackets.

A suggestion was made that the title of this section should be changed to “Restoration”. A suggestion was also made that this section, as well as the following three should have an introductory paragraph that refers to Specific Principles, i.e., “The following Specific Principles apply to the addition of essential nutrients for the restoration of the nutritional value of foods.”

It was recommended that the last sentence in section 4.1 should be moved to a new first Specific Principle with the remainder of the text renumbered as 4.2. The definition of restoration mentions addition of essential nutrient so there is no need to repeat it here.

It was suggested that a food which contributes to energy intake without contributing to essential nutrient intake should not be subject to restoration; therefore reference to energy is deleted.

It was considered essential to differentiate nutrient intake from food consumption to provide clarity.

One respondent reiterated that in the light of the inclusion of the intent and general principles in the Introduction, and their request to delete the Definitions of this basis for the addition of essential nutrients, there was no need to provide detailed principles for nutrient addition for the purpose of restoration and nutritional equivalence in the Guidelines, and proposed to delete these two sections.

With regard to the determination of whether a food is a “significant source” of an essential nutrient, i.e., greater than or equal to 10% INL₉₈ it was pointed out that no guidance is given with regard to the determination of significant source based on energy. Moreover, it was questioned on what basis the greater than or equal to 10% INL₉₈ figure is chosen and why is it different to sub-section 5.2 that offers guidance on equivalence? It was also noted that the text also fails to note which age-gender group should be used in selecting a reference INL₉₈. Without an identified rationale for why a food is considered a significant source of an essential nutrient at greater than or equal to 10% INL₉₈ for restoration but greater than or equal to 5% INL₉₈ for equivalence, it was proposed to place these values in square brackets for further consideration by the Committee. In addition a footnote was proposed on the term INL₉₈.

In section 4.3, one respondent proposed revising this text to take into account both the frequency of consumption and nutrient content of a food, and to refer to NRVs rather than to recommended nutrient intake (RNI) values, considering among other things that FAO/WHO RNIs vary by age and sex group and current work to revise and expand NRVs.

Conclusions/Further Discussion

The suggested edits to this section are presented in the attached texts in Appendix 2 for additional discussion by the Committee.

6. Section 5: ADDITION OF ESSENTIAL NUTRIENTS FOR THE PURPOSE OF NUTRITIONAL EQUIVALENCE

The Committee requested that the EWG consider the principles and which of these in sections 3, 4, 5 and 6 of the current draft revised document (CX/NFSDU 10/32/5) are applicable to mandatory and/or voluntary addition of essential nutrients, taking also into account the discussion at the present session of the CCNFSDU, and the amendments to the text (presented in Appendix VII for ease of reference). The EWG would make proposals for the structure of the document based on this review of the principles.

The EWG was specifically requested to indicate whether this section requires any additional text and comment on the text in square brackets. In addition to the text in square brackets at the end of section 5.1, is there a need to include any other text with regard to mandatory versus voluntary nutrient addition for the purpose of nutritional equivalence?

Responses/Comments from EWG on Section 5

A number of comments were received in regard to this section, including support for the removal of the square brackets. Comments were similar to those made on Section 4.

A suggestion was made that the title of this section should be changed to “Nutritional Equivalence of Substitute Foods”.

A suggestion was also made that this section, as well as sections 4, 5 and 6 should have an introductory paragraph that refers to Specific Principles, i.e., “The following Specific Principles apply to the addition of essential nutrients for the addition of essential nutrients to achieve nutritional equivalence of substitute foods.”

It was recommended that the last sentence in section 5.1 should be moved to a new first Specific Principle with the remainder of the text renumbered as 5.2. The definition of nutritional equivalence refers to the addition of essential nutrients so there is no need to repeat it here.

One respondent reiterated that in the light of the inclusion of the intent and general principles in the Introduction, and their request to delete the Definition of this basis for the addition of essential nutrients, there was no need to provide detailed principles for nutrient addition for the purpose of restoration and nutritional equivalence in the Guidelines, and proposed to delete these two sections.

There were questions regarding the use of the “INL” including the need to provide the rationale for the difference between the determination of a significant source of a nutrient for restoration and for equivalence. Some suggested that [INL₉₈] should be deleted and/or replaced with NRVs. It was proposed to place these values in square brackets for further consideration by the Committee.

It was suggested that a normal counterpart food which contributes to energy intake without contributing to essential nutrient intake should not be the basis of nutritional equivalence of a substitute food.

Conclusions/Further Discussion

The suggested edits to this section are presented in the attached texts in Appendix 2 for additional discussion by the Committee.

7. Section 6: ADDITION OF ESSENTIAL NUTRIENTS FOR THE PURPOSE OF FORTIFICATION

The Committee requested that the EWG consider the principles and which of these in sections 3, 4, 5 and 6 of the current draft revised document (CX/NFSDU 10/32/5) are applicable to mandatory and/or voluntary addition of essential nutrients, taking also into account the discussion at the present session of the CCNFSDU, and the amendments to the text (presented in Appendix VII for ease of reference). The EWG would make proposals for the structure of the document based on this review of the principles.

The EWG was specifically requested to comment on the structure of this section and whether there need to be separate principles for mandatory and voluntary fortification. Comments are also requested on the specific principles under each section.

Responses/Comments from EWG on Section 6

There was a wide range of responses received on this section with a large number of suggestions for edits and substantial amendments.

Introductory paragraph

One respondent suggested that the introductory paragraph should refer to Specific Principles. Several respondents stated that this Section should be clear that fortification can be either mandatory or voluntary. Although several respondents did not support separation of the specific principles in this Section into mandatory and voluntary fortification, there was no clear consensus on this. Some considered that if the two were merged it may be necessary to include text indicating that the principles apply to both mandatory and voluntary fortification unless otherwise specified. Some respondents suggested that the introductory paragraph included principles and that these should be presented as such (see below). One respondent who supported the introductory paragraph suggested the additional text “and/or scientific evidence that

demonstrates the positive contribution of a nutrient to growth, development or maintenance of health” at the end of the second sentence of the paragraph.

Another respondent stated that only principles addressing mandatory fortification should be included in this section and that the title to this section should be changed to *“Mandatory fortification”*. In this regard it was proposed to delete the last sentence of the introductory paragraph as the differences between mandatory and voluntary fortification should be addressed in the separate Section on Mandatory Fortification.

A respondent suggested that the text “a demonstrated public health need” implies that there exists a (potential) deficiency. This is the purpose of mandatory fortification, and also of voluntary fortification when used as a tool by governments to achieve similar purposes as mandatory fortification. This respondent stated that “a demonstrated public health need” would not encompass the majority of cases of voluntary fortification that are initiated by the industry, for other reasons than to prevent or correct a demonstrated deficiency. Since it is important that the guidelines include principles for all types of addition of nutrients to foods, in order to ensure that all foods with added nutrients can be eaten safely by all parts of the population as a part of a normal diet, and that consumers are not misled, this respondent suggested inserting the following text after the existing text:

“Fortification for the purposes of preventing or correcting a demonstrated deficiency in the population 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.”

The respondent who proposed defining “fortification” as “nutrient addition” and not to refer to all the purposes of fortification in this definition, also proposed that Section 6 be renamed as *“Nutrient addition for purposes of increasing population nutrient intakes”* and to use the following structure for the Section to clarify that principles therein apply to both mandatory and voluntary fortification unless otherwise indicated thus allowing the identification of separate principles for voluntary versus mandatory fortification in cases where the Committee agrees that a principle does not apply to both. This respondent provided suggestions for the re-organization of the sections in the current text to fit the proposed new structure for Section 6:

*“6.1 Demonstration of Need
6.2 Selection of Foods to Fortify (current 6.2.1)
6.3 Determination of Amounts of Nutrients that May Be Added (current 6.2.3)
6.4 Cost Considerations (in current 6.1)”*

There were a large number of comments of an editorial nature and proposals for additional text or deletions for clarity on this section. The key ones are captured below.

Section 6.1

It was recommended that Section 6 should clarify that fortification can be either mandatory or voluntary and that this should be the first specific principle in this Section. It was also recommended that this section include the last sentence in the introductory paragraph of the EWG document, i.e.,:

“6.1 National authorities should determine whether fortification should be mandatory or voluntary. Mandatory fortification is appropriate in addressing a serious public health need such as clinical deficiency whereas voluntary fortification may be appropriate in addressing a lower order risk of inadequate nutrient intakes.”

6.1.1 There should be demonstrated public health need for increasing the intake of an essential nutrient in a population. This need may be demonstrated by actual clinical evidence or subclinical evidence of deficiency, estimates indicating inadequate levels of intake of nutrients or evidence for possible deficiencies likely to develop because of changes taking place in food habits.”

Respondents who did not support separate sections for mandatory and voluntary fortification had the following suggested changes:

- Sections 6.2.1.3 & 6.2.1.6 are a consideration for both mandatory and voluntary fortification and should be retained as specific principles. Consideration of nutrient profiling should be sufficient to determine appropriate composition of target foods so all other principles relating to selection or otherwise of target foods are not required. Nutrient profiling could cover alcoholic beverages but this remains for clarification.

- With the exception of 6.2.1.3 and 6.2.1.6, it was suggested to delete the principles in section 6.2 for voluntary fortification since it duplicates some of the mandatory section or is unduly focused on technical aspects of risk assessment which should be covered under Section 3.

The respondent suggesting that Section 6 address only mandatory fortification proposed the following additional text for the introductory paragraph of this new section that includes the text in paragraph 3.2.1 and some additional text:

"Mandatory fortification occurs when governments require food manufacturers to add specified essential nutrients to particular foods or categories of foods. Mandatory fortification should remain the responsibility of the national authorities as they are in the best position to address specific public health concerns at local level."

With regard to the demonstration of need for fortification, one respondent suggested deleting the reference to "potential inadequate intakes" as it appears inconsistent with demonstrating need and it is also unclear how *potential* inadequate intake levels would be demonstrated. This same respondent proposed to clarify that fortification to address "possible deficiencies" should be supported by evidence (e.g., modeling of changes in food habits).

Subsection 6.1.3

It was proposed to replace the term "upper level of intake" by "amount of the food consumed by the lower and upper percentiles of the population" since "upper level of intake" is a fixed term defined as the maximum level of daily nutrient intake that is likely to pose no risk of adverse effects.

Subsection 6.1.4

One respondent supported the broad theme of addressing public health need and accepted the text in the first square brackets in 6.1.4 with deletion of the text in the second square brackets. The term "*habitual*" was preferred to "*normal*" since this term links to "*stable and uniform consumption*" in 6.1.3.

Subsection 6.1.5

A respondent stated that all references to UL throughout the document should be deleted because they are too prescriptive for use as principles and that the FAO/WHO resource (Guidelines on food fortification with micronutrients) cited in the Introduction provides guidance on all aspects of risk assessments including when a country does not have sophisticated dietary modelling capacity based on contemporary national nutrition surveys.

Subsection 6.1.6

It was suggested to delete this section since it is already in Section 3 and applies to all strategies for addition.

Subsection 6.1.7

It was suggested to delete this section since the cost impacts of voluntary fortification are also passed on to consumers and that rather than additional cost, the cost effectiveness of fortification should be considered, i.e.,:

"6.1.7 The cost effectiveness of the addition of essential nutrients to foods for the intended consumer should be considered."

Section 6.2

The respondent suggesting that Section 6 address only mandatory fortification proposed to move paragraph 6.2 and its subparagraphs to Section 3 Basic Principles. In addition, this respondent also stated that it is not necessary to define detailed conditions which should be fulfilled for the addition of essential nutrients to food, i.e., that specific provisions, such as those related to the selection of foods which may be fortified, essential nutrients which may be added and their amounts should not be set at international level. The respondent also stated that the selection of appropriate foods and essential nutrients would be best determined, when necessary, at the regional/national/local level taking into account dietary habits, socioeconomic situations and the need to avoid any risks to health. The respondent suggested that subsections 6.2.1 to 6.2.3 be moved to Section 3 and edited as follows:

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

Subsection 6.2.1

A respondent pointed out that the Global Strategy states that unhealthy diets are one of the leading causes of the major non-communicable diseases, and that elevated consumption of energy-dense and nutrient-poor foods that are high in fat, sugar and salt, is a factor that increases the risk. The respondent also noted that in a public health perspective, fortification with essential nutrients of energy-dense and nutrient-poor foods with a high content of risk-increasing nutrients like sugar, saturated fat and salt since this could convey the impression that they are now healthier. To counter this undesirable effect, the respondent supported the inclusion of principles that restrict fortification as presented in this section.

Subsections 6.2.1.2 and 6.2.1.4

There was no clear preference for the 1st or 2nd optional text for 6.2.1.2.

A respondent stated that there is no rationale for the inclusion of either of the two proposed versions for 6.2.1.2 or 6.2.1.4 since the addition of essential nutrients should be based on safety and meeting the nutrient needs of the target population. This respondent stated that nutrient profiles have not been established at the Codex Alimentarius level, and there is little or no experience in their use at the national or international levels; it is therefore inappropriate to introduce the concept of nutrient profiles into this text. This respondent also stated that consumer education, including fact-based nutrition labeling, is the appropriate place to address issues related to the excessive intake of any food or beverage, no matter its nutrient composition.

Another respondent objected to the use of the term “ubiquitous” in 6.2.1.2 since some staple foods are often considered ubiquitous, yet they are often under consumed in many countries. The evidence of a risk of excessive intakes leading to adverse health effects, and not the ubiquitous nature of a food, should be the factor to consider.

Some respondents indicated that both 6.2.1.3 and 6.2.1.4 were not need since both addressed the principle of nutrient profiles. There was not clear preference for one over the other.

Subsections 6.2.1.3 and 6.2.1.4

A respondent stated that the nutrient profile of a food should not be used as a basis for exclusion of a food from fortification but that the nutrient profile may be taken into consideration when restricting the types of food to be fortified in those cases where there is a high risk of excessive intake of the added nutrient. This respondent requested that 6.2.1.4 be deleted and that 6.2.1.3 should not be stated as an obligation. The following text was suggested to replace 6.2.1. 3:

"[Additional] Foods or categories of foods to which particular groups of vitamins and minerals may not be added may be determined by the competent authorities taking into account their nutritional value."

With regard to 6.2.1.3 another respondent stated that “nutritional profile” should be replaced by “nutritional merits” since it is important to consider the complete nutritional contribution of foods (the food matrix) to the diet as opposed to only considering a certain nutritional profile or a selective number of nutrients. Some nutrient-rich foods that contain potential “risk-increasing nutrients” may also contain other nutrients that have a beneficial effect on health, or may counter balance the effect of the risk-increasing nutrients. This respondent also suggested deletion of 6.2.1.4.

Subsections 6.2.1.5 and 6.2.1.6

A respondent proposed to delete these sections as such a level of detail is not necessary in an international Guideline, and in addition, the selection of appropriate foods to be fortified is covered by paragraph 3.10. Another respondent stated that the term “unprocessed” in 6.2.1.5 was vague and unclear and should be clarified or this section should be deleted.

Subsection 6.2.2

A suggestion was made to rename this section as “Selection of essential nutrients that may be added through voluntary fortification”.

A respondent stated that iff restrictions on the voluntary addition of essential nutrients to foods are required, they should be determined on safety and risk assessment grounds, and not solely on the severity of the

adverse effect upon which the Upper Intake Level (UL) is based. This respondent stated that the selection of essential nutrients to be added to foods may be done on the basis of the basic principles of a risk-based approach that takes into account the UL and the intake of the nutrient from other dietary sources. The following wording for 6.2.2.1 was suggested:

"The Upper Intake Level (UL), as well as the intake of the nutrient from other dietary sources should be the basis for a risk assessment by national authorities and should inform restrictions on essential nutrients permitted to be added to foods on a voluntary basis."

Subsection 6.2.3

A suggestion was made to rename this section as "Determination of amounts of essential nutrients that may be added on a voluntary basis".

A respondent stated that the selection of essential nutrients and their amounts that may be added to foods should be determined at national/regional/local level taking into account dietary habits, socioeconomic situations and the need to avoid any risks to health. This respondent also stated that the amounts of essential nutrients that may be added to food should be done on the basis of certain basic principles of a risk-based approach as provided for by the Codex Guidelines for Vitamin and Mineral Food Supplements (CAC/GL 55-2005). In the light of this, the following changes to section 6.2.3 were proposed:

Subsection 6.2.3.1

It was suggested to delete "...or on the metabolism of any nutrient."

Subsection 6.2.3.2

"National authorities may establish minimum limits for the addition of essential nutrient to foods to ensure that consumers are not misled and that the foods offer a benefit to consumers. 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) "

Subsection 6.2.3.3

It was proposed that, since the amount of an essential nutrient added to a food should not result in excessive intakes in all individuals and not only in those with a potentially high intake of a fortified food, the following additional text be added to this paragraph including the criteria for the setting of maximum amounts of nutrients added to foods which are based on the principles provided by the Codex Guidelines for Vitamin and Mineral Food Supplements (CAC/GL 55-2005):

"The amount of the essential nutrient added to a food, should not result in excessive intakes by individuals. 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 safe levels 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 vitamins and minerals for the population.

When maximum amounts are close to the upper level of intake 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."

Subsection 6.2.3.4

It was suggested that this is covered by the criteria proposed in 6.2.3.3 and should be deleted.

Subsection 6.2.3.5

It was suggested to delete this text as the basic principles of a risk-based approach are in 6.2.3.3.

Subsection 6.2.3.6

It was suggested to delete point (b) since it is already addressed by 6.2.3.3.

Conclusions/Further Discussion

There was a wide range of responses received on this section with a large number of suggestions for substantial amendments and edits. A significant number of respondents did not consider that this section needed to be separated into principles for mandatory and voluntary additions consistent with the comments on previous sections that, generally, specific principles within the sections on the various additions would apply equally to voluntary and mandatory additions. It was suggested that a consolidated set of principles be prepared for consideration by the Committee.

The suggested edits to this section are presented in the attached texts in Appendix 2 for additional discussion by the Committee.

8. Section 7: ADDITION OF ESSENTIAL NUTRIENTS TO SPECIAL PURPOSE FOOD

In view of the directions from the Committee that the totality of the current document would be evaluated to ensure coherence and consistency of the principles and the guidance, the EWG were asked to comment on section 7 including the text in square brackets.

Responses/Comments from EWG on Section 7

There was general support for this section including support for removal of the square brackets.

A recommendation was made to change the heading to “Special Purpose Foods”.

A number of edits were suggested by one respondent to further clarify the text including addition of a sentence requiring specific consideration of the needs of the target population. Another respondent further suggested that reference should be specifically to the principles in section 3 (i.e. the general or overarching or basic principles). The suggested edits to this section are as follows:

“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 density of such foods. Consideration should be given to the target population and their nutrient requirements based on general reference intakes such as RNIs.”

One respondent stated that this section should be deleted as special purpose foods are covered by other Codex standards and guidelines.

It was also suggested that further discussion is required by the Committee on the extent to which these principles apply to special purpose foods intended for infants.

Conclusions/Further Discussion

The suggested edits to this section are presented in the attached texts in Appendix 2 for additional discussion by the Committee.

Appendix 2 – Draft Revised *General Principles for the Addition of Essential Nutrients to Foods*

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1	<p>INTRODUCTION</p> <p>The <i>[General Principles] [Guidelines] for the Addition of Essential Nutrients to Foods</i> provide a framework for the addition of essential nutrients to food and are intended to provide guidance to those responsible for developing guidelines and legal texts through the establishment of a set of principles that</p> <ul style="list-style-type: none"> • serve as a basis for the rational and safe addition of essential nutrients to foods. • facilitate acceptance in international trade of foods which contain added essential nutrients. <p>[The <i>General Principles for the Addition of Essential Nutrients to Foods</i> aim at providing a framework for the addition of essential nutrients to foods for the purpose of:</p> <ul style="list-style-type: none"> • 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. • maintaining or improving the overall nutritional quality of foods; • [allowing 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.]¹ 	<p>INTRODUCTION</p> <p>OPTION 1</p> <p>The <i>[General Principles] [Guidelines] for the Addition of Essential Nutrients to Foods</i> provide a framework for the addition of essential nutrients to food and are intended to provide guidance to those responsible for developing guidelines and legal texts through the establishment of a set of principles that serve as a basis for the rational and safe addition of essential nutrients to foods.</p> <p>OPTION 2</p> <p>The <i>[General Principles] [Guidelines] for the Addition of Essential Nutrients to Foods</i> provide a framework for the addition of essential nutrients to food and are intended to provide guidance to those responsible for developing guidelines and legal texts through the establishment of a set of principles that:</p> <ul style="list-style-type: none"> • serve as a basis for the rational and safe addition of essential nutrients to foods. • facilitate acceptance in international trade of foods which contain added essential nutrients. <p>[The <i>General Principles for the Addition of Essential Nutrients to Foods</i> aim at providing a framework for the addition of essential nutrients to foods for the purpose of:</p> <ul style="list-style-type: none"> • correcting a demonstrated deficiency of one or more essential nutrients in the population or specific 	<p>INTRODUCTION</p> <p>The <i>[General Principles] [Guidelines] for the Addition of Essential Nutrients to Foods</i> [provide a framework for the addition of essential nutrients to food and] are intended to provide guidance to [National authorities] [those] responsible for developing guidelines and legal texts through the establishment of a set of principles that</p> <ul style="list-style-type: none"> • serve as a basis for the rational and safe addition of essential nutrients to foods. • facilitate acceptance in international trade of foods which contain added essential nutrients. <p>[The <i>General Principles for the Addition of Essential Nutrients to Foods</i> aim at providing a framework for the addition of essential nutrients to foods for the purpose of:</p> <ul style="list-style-type: none"> • maintaining or improving the overall nutritional quality of foods; • contributing to meeting requirements of one or more essential nutrients and reducing the risk of inadequate intakes • preventing the indiscriminate addition of essential nutrient to foods thereby reducing the risk to health of nutrient excesses or imbalances] <p>[The <i>[General Principles] [Guidelines] for the Addition of Essential Nutrients to Foods</i> [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</p>

¹ In their discussion the Committee had agreed to the following text to replace the first two indents. “The *[General Principles] [Guidelines] for the Addition of Essential Nutrients to*

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	<p>[The <i>General Principles</i>] <i>Guidelines</i> for the <i>Addition of Essential Nutrients to Foods</i> 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>population groups;</p> <ul style="list-style-type: none"> • 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. • maintaining or improving the overall nutritional quality nutrient profile] of foods; • [allowing a wider choice of fortified foods] <p>OPTION 3</p> <p>The <i>General Principles</i> <i>Guidelines</i> for the <i>Addition of Essential Nutrients to Foods</i> provide a framework for the addition of essential nutrients to food and are intended to provide guidance to national authorities through the establishment of a set of General and Specific Principles that:</p> <ul style="list-style-type: none"> • serve as a basis for the rational and safe addition of essential nutrients to foods to address a public health need • facilitate acceptance in international trade of foods which contain added essential nutrients. <p>A public health need could be addressed by:</p> <ul style="list-style-type: none"> • improving the overall nutritional quality of foods 	<p>on Nutrition and Foods for Special Dietary Uses (CAC Procedural Manual), where applicable.</p>

Foods provide a framework for the addition of essential nutrients to food and are intended to provide guidance to those 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.” The EWG Co-Chairs in their comments to the EWG requested that the EWG consider whether the 2nd indent covers the purpose of the *General Principles* and should therefore remain in the Introduction section.

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		<ul style="list-style-type: none"> • contributing to meeting requirements of one or more essential nutrients and reducing the risk of inadequate intakes, poor nutritional status and prevalence of deficiency in the population • preventing the indiscriminate addition of essential nutrient to foods thereby reducing the risk to health of nutrient excesses or imbalances. <p>[The <i>[General Principles]</i> <i>[Guidelines]</i> for the <i>Addition of Essential Nutrients to Foods</i> [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.</p>	
2	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. ²	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.	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.
3	2. DEFINITIONS For the purpose of these [principles] [guidelines]:	2. DEFINITIONS For the purpose of these [Principles] [Guidelines]:	2. DESCRIPTION For the purpose of these [Principles] [Guidelines]:
4	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.	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.	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.
5	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	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	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

² Codex Guidelines for Vitamin and Mineral Food Supplements (CAC/GL 55-2005)

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	adequate amounts by the body. [Essential nutrient includes but is not limited to vitamins and mineral nutrients.]	amounts by the body. or 2.2 <i>Essential nutrient</i> means any substance normally consumed as a constituent of <u>food which cannot be synthesized in adequate amounts by the body and</u> (a) which is needed for growth and development and the maintenance of healthy life; or (b) <u>a deficit of which will cause characteristic biochemical or physiological changes to occur.</u>	amounts by the body.
6	2.3 <i>Nutritional equivalence</i> 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. [<i>Nutritional equivalence</i> is achieved when an essential nutrient is 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.]	2.4 (former 2.3) <i>Nutritional equivalence</i> means <u>the addition of one or more essential nutrient to a substitute food to achieve a similar nutritive value to its normal counterpart</u> in terms of quantity and quality of protein and in terms of kinds, quantity and bioavailability of essential nutrients. 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.] or <i>Nutritional equivalence</i> is achieved when an essential nutrient is added to <u>a substitute food in amounts such that the substitute food has a similar nutritive value to the food being substituted, in terms of the amount and bioavailability of the added essential nutrient.</u>	2.5 (former 2.3) <i>Nutritional equivalence</i> means <u>the addition of one or more essential nutrient to a substitute food to achieve a similar nutritive value to its normal counterpart</u> in terms of quantity and quality of protein and in terms of kinds, quantity and bioavailability of essential nutrients. <u>Where the food being substituted has been identified as a significant contributor³ of intake and particularly where there is demonstrated evidence of public health need, nutritional equivalence should be strongly recommended.</u>

³ For the purposes of nutritional equivalence a food being substituted or partially substituted is considered a significant contributor of an essential nutrient if a serving or portion or 100kcal of the food contains the essential nutrient in amounts equal to or greater than 5% of the recommended nutrient intake [or INL 98].

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		<p>or</p> <p><i>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. It can be 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.</i></p>	
7	<p>2.4 <i>Substitute food</i> 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.</p>	<p>2.3 (former 2.4) <i>Substitute food</i> 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.</p>	<p>2.4 <i>Substitute food</i> 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.</p>
8	<p>2.5 <i>Fortification</i> [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) or for the purpose of contribution to the improvement of health and/or nutritional status of the population or specific population groups [with minimal risk to health].]</p>	<p>2.5 <i>Fortification</i> 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) or for the purpose of contribution to the improvement of health and/or nutritional status of the population or specific population groups [with minimal risk to health].]</p> <p>or</p> <p><i>Fortification</i> means the addition of one or more essential nutrients to a food, whether or not it is normally present in the food, for the purpose of improving population health by addressing a demonstrated</p>	<p>2.6 <i>Fortification [or enrichment]</i> [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) or for the purpose of contribution to the improvement of health and/or nutritional status of the population or specific population groups [with minimal risk to health].]</p>

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		<p><u>deficiency</u> or reducing the risk of <u>poor</u> nutritional status or <u>inadequate nutrient intake</u>.</p> <p>or</p> <p>Fortification as used in these [guidelines/principles] means the addition of one or more essential nutrients to a food [whether or not it is normally contained in the food].</p>	
9	<p>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.</p>	<p>2.8 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, <u>or in order to compensate for natural variations in essential nutrients</u> 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.</p>	<p>2.3 (former 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. <u>Where the food has been identified as a significant contributor⁴ of intake and particularly where there is demonstrated evidence of public health need, restoration should be strongly recommended.</u></p>
10		<p>2.6 (moved from 3.2.1) <u>[Mandatory nutrient addition occurs when governments require food manufacturers to add specified essential nutrients to particular foods or categories of foods.][for a specific purpose.]</u></p>	<p>2.7 <u>[Mandatory nutrient addition occurs when governments require food manufacturers to add specified essential nutrients to particular foods or categories of foods.]</u></p>
11		<p>2.7 (moved from 3.2.2) <u>[Voluntary nutrient addition is when a food manufacturer chooses to add specified nutrients to particular foods or food categories.][for a specific purpose.]</u></p>	<p>2.8 <u>[3.2.2][Voluntary nutrient addition is when a food manufacturer chooses to add specified nutrients to particular foods or food categories.]</u></p>
12	<p>2.7 Special purpose foods are foods that have been designed to perform a specific function, such as to</p>	<p>2.9 Special purpose foods are foods that have been designed to perform a specific function, such as to</p>	<p>2.7 Special purpose foods are foods that have been designed to perform a specific function, such as to</p>

⁴ For the purposes of restoration a food is considered a significant contributor to intake of an essential nutrient if the edible portion of the food prior to processing, storage or handling contains the essential nutrient in amounts equal to or greater than 10% of the recommended nutrient intake [or INL 98] in a reasonable daily intake.

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	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].	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.	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].
13	2.8 Nutrient density means the amount of nutrients (in metric units) per stated unit of energy (MJ or kcal).	2.10 Nutrient density means the amount of nutrients (in metric units) per stated unit of energy (MJ [KJ] or kcal).	2.8 Nutrient density means the amount of nutrients (in metric units) per stated unit of energy (MJ [KJ] or kcal).
14	[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.]		
15		2.11 (new) Population refers to a national population or a specific population group(s) as appropriate.	
16	3. BASIC PRINCIPLES [The following principles are applicable, as appropriate, to mandatory and/or voluntary addition of essential nutrients.] [These principles are 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.] [This will also help to prevent practices which may mislead or deceive the consumer.]	3. [BASIC] [OVERARCHING] [GENERAL] PRINCIPLES [The following principles are applicable, as appropriate, to mandatory and/or voluntary addition of essential nutrients.] [These principles are intended to address when nutrient addition is justified and to prevent the indiscriminate addition of essential nutrients to foods thereby decreasing the risk of [health hazard] [adverse health effect] due to [essential nutrient excesses, deficits or imbalances][<u>their inadequate and/or excessive intake</u>]. [This will also help to prevent practices which may mislead or deceive the consumer.] <u>[National authorities should determine whether fortification should be mandatory or voluntary. 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.] [Voluntary fortification should be regulated at the national level.] (IF ACCEPTED, SHOULD THIS</u>	3. [BASIC] [OVERARCHING] PRINCIPLES [The following principles are applicable, as appropriate, to mandatory and/or voluntary addition of essential nutrients.] [These principles are 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.] [This will also help to prevent practices which may mislead or deceive the consumer.]

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17	<p>[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]]</p> <p>or</p> <p>[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.]</p>	<p>PARAGRAPH BE HERE OR IN SECTION 6 ?</p> <p>[3.1 Essential nutrients may be added to foods for the purpose of restoration, [achieving] nutritional equivalence of substitute foods, fortification and ensuring the appropriate nutrient composition of a special purpose food.]</p> <p>or</p> <p>[3.1 Fundamental Principles <u>Essential nutrients may be appropriately added to foods for the purpose of:</u></p> <ul style="list-style-type: none"> • <u>correcting a demonstrated deficiency of one or more essential nutrients in the population or specific population groups;</u> • <u>contributing to meeting requirements of one or more essential nutrients and reducing the risk of their deficiency;</u> • <u>contributing to the maintenance or improvement of health and/or nutritional status of the population or specific population groups and/or</u> • <u>maintaining or improving the overall nutritional quality of foods;</u> <p><u>The above principles may be achieved by restoration, nutritional equivalence of substitute foods, nutrient addition to increase population nutrient intakes, and ensuring the appropriate nutrient composition of a special purpose food.]”</u></p>	<p>[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.]</p>
18	<p>3.2 (modified former 6.1) The mandatory and voluntary addition of essential nutrients to foods should be in accordance with food law and other policies established by national authorities and take into account the kinds and amounts of essential nutrients to be added, the foods to be fortified, the particular nutritional problems</p>	<p>[3.2 <u>The choice of mandatory or voluntary addition of essential nutrients to foods should take into account:</u></p> <ul style="list-style-type: none"> • <u>the severity and extent of public health need and the kinds and amounts of essential nutrients to be added</u> • <u>the local food consumption patterns and other characteristics of the population at risk and the</u> 	<p>[3.2 <u>The choice of mandatory or voluntary addition of essential nutrients to foods should take into account:</u></p> <ul style="list-style-type: none"> • <u>the severity and extent of public health need and the kinds and amounts of essential nutrients to be added</u> • <u>the local food consumption patterns and other characteristics of the population at risk and the target</u>

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	<p>to be corrected, the characteristics of the target populations, and the food consumption patterns of the area.</p> <p>3.2.1 (<i>New</i>) [Mandatory nutrient addition occurs when governments require food manufacturers to add specified essential nutrients to particular foods or categories of foods.]</p> <p>3.2.2 (<i>New</i>) [Voluntary nutrient addition is when a food manufacturer chooses to add specified nutrients to particular foods or food categories.]</p>	<p><u>target foods for nutrient addition</u></p> <ul style="list-style-type: none"> • <u>the relative importance of consumer choice</u> • <u>the extent of uptake of voluntary permissions by food manufacturers]</u> <p>or</p> <p>[Additional Principles to Consider for Nutrient Addition]</p> <p>3.2 (<i>modified former 6.1</i>) The mandatory and voluntary addition of essential nutrients to foods should be in accordance with food law and other policies established by national authorities and take into account the kinds and amounts of essential nutrients to be added, the foods to be fortified, the particular nutritional problems to be corrected, the characteristics of the target populations, and the food consumption patterns of the area.</p>	<p><u>foods for nutrient addition</u></p> <ul style="list-style-type: none"> • <u>the relative importance of consumer choice</u> • <u>the extent of uptake of voluntary permissions by food manufacturers]</u> <p>3.3 (<i>modified former 6.1</i>) The mandatory and voluntary addition of essential nutrients to foods should be in accordance with food law and other policies established by national authorities and take into account the kinds and amounts of essential nutrients to be added, the foods to be fortified, the particular nutritional problems to be corrected, the characteristics of the target populations, and the food consumption patterns of the area.</p>
19	<p>3.3 (<i>Former 3.2</i>) 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.]</p>	<p>3.4 (<i>Former 3.2</i>) 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.]</p> <p>or</p> <p>3.3 “3.3 (<i>former 3.2</i>) [<u>The addition of essential nutrients to food should be risk-based and not result in either inadequate and/or excessive intakes of the added essential nutrients, considering the nature of the adverse health effects being addressed, total dietary intake of the added nutrients from foods as well as intake from other relevant sources, upper levels of intake and identification</u>]</p>	

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20	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.	of special sub populations at risk. /” 3.5 (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.	
21	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 (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, 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.]	3.5 (former 6.2.2) Selection of essential nutrients that may be added: 3.5.1 (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.] 3.5.2 (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. 3.5.3 (former 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.
22	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 3.4) The [added] essential nutrient should be sufficiently stable in the food under customary conditions of <u>processing</u> , packaging, storage, distribution and use.	3.6 (former 6.2.1) Foods which may be fortified: 3.6.1 (former 6.2.1.2) Certain foods should be excluded from voluntary [fortification] [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. or 3.6.1 [Certain foods may not be appropriate for voluntary [fortification] [nutrient addition] , e.g., foods with the potential to result in exposure to high intakes associated

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			<p>with a risk of adverse health effects.]</p> <p>3.6.2 [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>3.6.3 [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] [nutrient addition].]</p> <p>3.6.4 [Essential nutrients should not be added to unprocessed foods, including, but not limited to, fruit, vegetables, meat, poultry and fish.]</p> <p>3.6.5 [Essential nutrients should not be added to beverages containing more than 1.2% by volume of alcohol.]</p>
23	<p>3.7 (<i>Former 3.5</i>) The essential nutrient should be biologically available from the food.</p>	<p>3.8 (<i>Former 3.5</i>) The [added] essential nutrient should be [biologically available] [bioavailable] from the food.</p>	<p>3.7 Technological aspects</p> <p>3.7.1 (<i>new</i>) 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.</p> <p>3.7.2 (<i>Former 3.4</i>) The essential nutrient should be sufficiently stable in the food under customary conditions of packaging, storage, distribution and use.</p> <p>3.7.3 (<i>Former 3.6</i>) 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.</p> <p>3.7.4 (<i>Former 3.7</i>) Technology and processing facilities should be available to permit the addition of the essential</p>

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			nutrient to a food in a satisfactory manner.
24	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 3.6) The <u>added</u> 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.	
25	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 3.7) Technology and processing facilities should be available to permit the <u>standardized</u> addition of the essential nutrient to a food in [a satisfactory manner] [<u>a manner to ensure nutrient availability, consistency, distribution and stability</u>].	
26	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.	3.11 (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.	3.4 (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.
27	3.11 Methods of measuring, controlling and/or enforcing the levels of added essential nutrients in foods should be available.	3.12 Methods of measuring, controlling and/or enforcing the levels of added essential nutrients in foods should be available <u>to monitoring bodies to facilitate efficient monitoring of those products</u> .	
28	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 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 and the levels at which they should be present in the food to achieve their intended purpose. or [3.13. When provision is made in National food standards, regulations or guidelines for the addition of essential nutrients, specific provisions should be included identifying the target foods, the essential nutrients to be considered or to be required <u>or permitted to be added and the minimum and where appropriate,</u>	

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29	<p>[3.13 (new) 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.]</p>	<p><u>maximum</u> levels at which they should be present.]</p> <p>[3.14 (new) 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 <u>the</u> risk of [excessive intakes is absent] [adverse health effects is minimized to the greatest extent possible].</p> <p>or</p> <p>[National authorities should monitor <u>population</u> total intakes of the <u>essential</u> nutrients <u>added to foods from all dietary and supplement sources</u> and -assess the extent to which <u>the</u> public health need <u>is</u> addressed and ensure that <u>any</u> risk of excessive intakes is <u>minimised</u>. <u>Monitoring of total nutrient intakes should use the same approach as used in deciding the nutrient addition.</u>]</p>	<p>3.8 Monitoring</p> <p>3.7.1 Methods of measuring, controlling and/or enforcing the levels of added essential nutrients in foods should be available.</p> <p>3.8.2 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.</p> <p>3.8.3 [(new) <u>National authorities should carry out monitoring activities of the</u> total intakes of the added nutrients in population(s) particularly to assess the extent to which public health needs are being addressed and to ensure that a risk of excessive intakes is absent.]</p> <p>or</p> <p>3.8.3 [(new) 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).]</p> <p>3.8.4 (former 6.5.1.2) 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.</p> <p>3.8.5 (former 6.5.1.3) The Upper Level of Intake should be used to assess exposure to excessive intakes and to estimate safe limits of addition for essential nutrients.</p> <p>3.8.6 (former 6.5.1.4) Where an Upper Level of Intake is not available, the scientific evidence to support the safe addition of an essential nutrient should include:</p>

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			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 to provide evidence to ensure that aggregate exposure to the essential nutrient in question is within acceptable limits.]
30	[3.14 (new) 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).]	[3.15 (new) 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).] or (new) <u>Potential change to population intakes should be estimated as part of the decision making about nutrient addition. Such estimation 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 reference daily intake values for adequacy and safety.</u> ”	
31	4. [NUTRIENT] ADDITION [OF ESSENTIAL NUTRIENTS] FOR PURPOSES OF RESTORATION	4. ADDITION OF ESSENTIAL NUTRIENTS FOR PURPOSES OF RESTORATION <u>[The following specific principles apply to the addition of essential nutrients for the restoration of the nutritional value of foods.]</u>	
32		<u>[4.1 National authorities should determine whether restoration should be mandatory or voluntary.]</u>	
33	4.1 Where the food has been identified as a significant [contributor to intake] of energy and/or essential nutrients in the [population group(s)], and particularly where there is demonstrated evidence of public health need, restoration of the essential nutrients of concern lost during processing, storage or	4.2 Where the food has been identified as a significant [contributor to intake] of energy and/or essential nutrients in the [population group(s)], and particularly where there is demonstrated evidence of public health need, restoration of the essential nutrients of concern lost during processing, storage or handling, should be	

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	handling should be strongly recommended. [National authorities should determine whether addition of essential nutrients for the purpose of restoration should be mandatory.]	strongly recommended. [National authorities should determine whether addition of essential nutrients for the purpose of restoration should be mandatory.]	
34	4.2 A food should be considered a significant [contributor to intake] of an essential nutrient if the edible portion of the food prior to processing, storage or handling contains the essential nutrient in amounts equal to or greater than 10% of the recommended nutrient intake [or INL 98] 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])].	4.3 A food should be considered a significant [contributor to intake] of an essential nutrient if the edible portion of the food prior to processing, storage or handling contains the essential nutrient in amounts equal to or greater than 10% of the recommended nutrient intake [NRV] [or INL 98] in a reasonable daily intake [of the food (or in the case of an essential nutrient for which there is no recommended intake [NRV], 10% of the average daily intake [of the nutrient])].	
35	5. [NUTRIENT] ADDITION [OF ESSENTIAL NUTRIENTS] FOR PURPOSES OF NUTRITIONAL EQUIVALENCE	5. ADDITION OF ESSENTIAL NUTRIENTS FOR PURPOSES OF NUTRITIONAL EQUIVALENCE <u>[The following specific principles apply to the addition of essential nutrients for nutritional equivalence of substitute foods.]</u>	
36		<u>[5.1 National authorities should determine whether nutritional equivalence of substitute foods should be mandatory or voluntary.]</u>	
37	5.1 Where a substitute food is intended to replace a food which has been identified as a significant [contributor to intake] of energy and/or essential nutrients in the [population group(s)], and particularly where there is demonstrated evidence of public health need, nutritional equivalence in terms of the essential nutrients of concern should be strongly recommended. [National authorities should determine whether addition of essential nutrients for the purpose of nutritional equivalence should be mandatory.]	5.2 Where a substitute food is intended to replace a food which has been identified as a significant [contributor to intake] of energy and/or essential nutrients in the [population group(s)], and particularly where there is demonstrated evidence of public health need, nutritional equivalence in terms of the essential nutrients of concern should be strongly recommended. [National authorities should determine whether addition of essential nutrients for the purpose of nutritional equivalence should be mandatory.]	
38	5.2 A food being substituted or partially substituted should be considered a significant [contributor] of an essential nutrient if a serving or portion or 100 kcal of the food contains the essential nutrient in amounts equal	5.3 A food being substituted or partially substituted should be considered a significant [contributor] of an essential nutrient if a serving or portion or 100 kcal of the food contains the essential nutrient in amounts equal	

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	to or greater than 5% [or INL 98] of the recommended nutrient intake.	to or greater than 5% [or INL 98] of the recommended nutrient intake.	
39	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.	5.4 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.	
40	<p>6. [NUTRIENT] ADDITION [OF ESSENTIAL NUTRIENTS] FOR PURPOSES OF FORTIFICATION There should be a demonstrated [public health] need for increasing the intake of n 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.</p>	<p>6. ADDITION OF ESSENTIAL NUTRIENTS FOR PURPOSES OF FORTIFICATION</p> <p>or</p> <p>6. ADDITION OF ESSENTIAL NUTRIENTS FOR THE PURPOSE OF INCREASING POPULATION NUTRIENT INTAKES</p> <p><u>[National authorities should determine whether fortification should be mandatory or voluntary. 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.] [Voluntary fortification should be regulated at the national level.]</u> (IF ACCEPTED, SHOULD THIS PARAGRAPH BE HERE OR IN 3.0 ?)</p> <p>[6.1 Mandatory Fortification]</p> <p>or</p> <p>[6.1 Demonstration of Need] There should be a demonstrated [public health] need for increasing the intake of an essential nutrient in one or more population groups [through fortification]. This need may be demonstrated by actual clinical or subclinical evidence of deficiency, estimates indicating inadequate or potentially inadequate levels of intake of nutrients or <u>evidence of</u> possible deficiencies likely to</p>	<p>4. [NUTRIENT] ADDITION OF ESSENTIAL NUTRIENTS] FOR PURPOSES OF FORTIFICATION There should be a demonstrated [public health] need for increasing the intake of an essential nutrient in one or more population groups [through fortification]. This need may be demonstrated by actual clinical or subclinical evidence of deficiency, estimates indicating inadequate or potentially inadequate levels of intake of nutrients or possible deficiencies likely to develop because of changes taking place in food habits. Mandatory fortification is appropriate in addressing serious public health needs such as clinical deficiency whereas voluntary fortification may be appropriate in addressing lower order risk of inadequate nutrient intakes <u>[or plausible beneficial effects of essential nutrients consistent with maintaining or improving health.]</u></p>

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		<p>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.</p> <p>[Fortification for the purposes of preventing or correcting a demonstrated deficiency in the population 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.]</p>	
41	<p>6.1 Mandatory Fortification (<i>former 6.2</i>) The following conditions should be fulfilled [when fortifying foods][for any fortification programme]:</p> <p>6.1.2 (<i>former 6.2.2</i>) The food selected as a vehicle for the essential nutrient(s) should be consumed by the population at risk.</p> <p>6.1.3 (<i>former 6.2.3</i>) 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.</p> <p>6.1.4 (<i>former 6.2.4</i>) 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.</p> <p>6.1.5 (<i>former 6.2.5</i>) 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].</p> <p>6.1.6 (<i>former 3.7</i>) Technology and processing facilities</p>		<p>4.1 (<i>former 6.2.3</i>) The <u>level of consumption</u> of the food selected as a vehicle should be stable and uniform and the lower and upper levels of intake should be known.</p> <p>4.2 (<i>former 6.2.5</i>) 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].</p> <p>4.3 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</p> <p>4.4 (former 6.5.1.2) 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.</p> <p>4.5 Mandatory Fortification</p>

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	<p>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.]]</p>		<p>4.5.1 (former 6.2.2) The food selected as a vehicle for the essential nutrient(s) should be consumed by the population at risk. 4.5.2 (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. 4.5.3 (former 3.9) The additional cost [of mandatory addition of essential nutrients to foods] should be reasonable for the intended consumer.]]</p>
42	<p>6.2 Voluntary Fortification 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</p>	<p>6.2 (former 6.1) [Foods which may be fortified][Selection of foods to fortify] 6.2.1 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. 6.2.2 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] [<u>amount of the food consumed by the lower and upper percentiles of the population</u>] should be known. 6.2.3 6.1.3 Certain foods should be excluded from voluntary fortification, because of their ubiquity in the food supply and thus e.g., foods with the potential to result in exposure to high intakes of nutrients associated with a risk of adverse health effects. 6.2.4 6.1.4 Consideration should be given to the nutrient profile of the food before fortification to ensure that nutritionally appropriate foods are selected for fortification.] 6.2.5 6.1.6 Essential nutrients should not be added to unprocessed foods, including, but not limited to, fruit, vegetables, meat, poultry and fish.] 6.2.6 6.1.7 Essential nutrients should not be added to</p>	

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	<p>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.]</p> <p>[6.2.1.5 Essential nutrients should not be added to unprocessed foods, including, but not limited to, fruit, vegetables, meat, poultry and fish.]</p> <p>[6.2.1.6 Essential nutrients should not be added to beverages containing more than 1.2% by volume of alcohol.]</p>	<p>beverages containing more than 1.2% by volume of alcohol.]</p>	
43	<p>6.2.2 Selection of essential nutrients that may be added:</p> <p>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.</p>	<p>6.3 6.2.2 [Selection of essential nutrients that may be added]:</p> <p>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.</p> <p>6.1.5 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.]</p>	
44	<p>6.2.3 Determination of amounts of essential nutrients that may be added:</p> <p>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.</p> <p>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</p>	<p>6.4 6.2.3 Determination of amounts of essential nutrients that may be added:</p> <p>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.</p> <p>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 <u>[habitual]</u> amounts by</p>	

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	<p>amounts by the population.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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:</p> <p>a) demonstration of an upper level or a range of intake that is unlikely to result in adverse health effects, and</p> <p>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.]</p>	<p>the population.</p> <p>or</p> <p><u>[6.2.3.2 National authorities may establish minimum limits for the addition of essential nutrient to foods to ensure that consumers are not misled and that the foods offer a benefit to consumers. 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).]</u></p> <p>6.3.1 (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.</p> <p>6.3.2 (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 all other dietary sources including food supplements]. [by individuals with a high intake of a fortified food].</p> <p>6.3.3 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.</p> <p>6.3.5 The Upper Level of Intake should be used to assess exposure to excessive intakes and to estimate safe limits of addition for essential nutrients.</p> <p>or</p>	

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		<p><u>[The Upper Intake Level (UL), as well as the intake of the nutrient from other dietary sources should be the basis for a risk assessment by national authorities and should inform restrictions on essential nutrients permitted to be added to foods on a voluntary basis.]</u></p> <p>6.3.6 Where an Upper Level of Intake is not available, the scientific evidence to support the safe addition of an essential nutrient should include:</p> <p>a) demonstration of an upper level or a range of intake that is unlikely to result in adverse health effects, and</p> <p>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.]</p>	
45		<p>6.5 Cost considerations (former 3.9) The additional cost [of mandatory addition of essential nutrients to foods] should be reasonable for the intended consumer.]]</p> <p>or</p> <p><u>new 6.1.7 The cost effectiveness of the addition of essential nutrients to foods for the intended consumer should be considered.</u></p>	
46	7. NUTRIENT ADDITION TO SPECIAL PURPOSE FOODS	7. NUTRIENT ADDITION TO SPECIAL PURPOSE FOODS	5. NUTRIENT ADDITION TO SPECIAL PURPOSE FOODS
47	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.	7.1 <u>[Essential]</u> nutrients may be added to special purpose foods, including foods for special dietary uses, to ensure an appropriate and adequate nutrient content <u>[for their intended use]</u> [based on the principles in this guidance wherever applicable]. Where appropriate, such addition should be made with due regard to the nutrient <u>[composition]</u> [density] of such foods. <u>Consideration should be given to the target population and their nutrient requirements based on general reference intakes</u>	5.1 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.

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48	<p>Structure of version 1, above: <i>Introduction</i></p> <ol style="list-style-type: none"> 1. <i>Scope</i> 2. <i>Definitions</i> 3. <i>[Basic] [Overarching] Principles</i> 4. <i>Addition of Essential Nutrients for Purposes of Restoration</i> 5. <i>Addition of Essential Nutrients for Purposes of Nutritional Equivalence</i> 6. <i>Addition of Essential Nutrients for Purposes of Fortification</i> 6.1 <i>Mandatory Fortification</i> 6.2 <i>Voluntary Fortification</i> 7. <i>Nutrient Addition to Special Purpose Foods</i> 	<p><i>such as RNIs</i></p> <p>Structure of above version 2, above: <i>Introduction</i></p> <ol style="list-style-type: none"> 1. <i>Scope</i> 2. <i>Definitions</i> 3. <i>[Basic] [Overarching] [General] Principles</i> 3.1 <i>Fundamental principles</i> 3.2 <i>Additional principles to consider for nutrient addition</i> 4. <i>Addition of Essential Nutrients for Purposes of Restoration</i> 5. <i>Addition of Essential Nutrients for Purposes of Nutritional Equivalence</i> 6. <i>Addition of Essential Nutrients for Purposes of Fortification <u>or</u> for the Purposes of Increasing Population Nutrient Intakes</i> 6.1 <i>Mandatory Fortification <u>or</u> Demonstration of need</i> 6.2 <i>[Foods which may be fortified] [Selection of foods to fortify]</i> 6.3 <i>[Selection of essential nutrients that may be added]</i> 6.4 <i>Determination of amounts of nutrients that may be added</i> 6.5 <i>Cost considerations</i> 	<p>Structure of above version 3, above: <i>Introduction</i></p> <ol style="list-style-type: none"> 1. <i>Scope</i> 2. <i>Description</i> 3. <i>[Basic] [Overarching] Principles</i> 3.x <i>Selection of essential nutrients that may be added</i> 3.x <i>Foods which may be fortified</i> 3.x <i>Technological aspects</i> 3.x <i>Monitoring</i> 4. <i>[Nutrient] addition of essential nutrients] for purposes of fortification</i> 5. <i>Nutrient Addition to Special Purpose Foods</i>

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		<i>7. Nutrient Addition to Special Purpose Foods</i>	