



Agenda Item 6

CX/NFSDU 12/34/9

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Thirty-fourth Session
Bad Soden am Taunus, Germany
3 – 7 December 2012

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

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

Governments and interested international organizations are invited to submit comments on the Proposed Draft Revision, as presented in Appendix A, Table 3 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 **15 November 2012**.

(References: REP12/NFSDU, paragraphs 77-80; CX/NFSDU 11/33/7; REP11/NFSDU, paragraphs 51 to 74 and Appendix VII; CX/NFSDU 10/32/5; ALINORM 10/33/26, paragraphs 88-97 and Project Document, Appendix V)

**Charge to the Electronic Working Group by the 33rd session of the Codex Committee On Nutrition
And Foods For Special Dietary Uses (Rep11/NFSDU):**

At the 33rd Session, the Committee received the report of the physical working group that met just prior to the session and noted that it could not consider the item due to time constraints. It agreed to return the proposed draft revision for redrafting by an eWG chaired by Canada and co-chaired by New Zealand and working in English, circulation for comments at Step 3, and consideration at the next session.

The terms of reference were as follows:

- Obtain agreement on the structure (format) of the General Principles considering both headings and subheadings where these are required.
- Consider sections 3 to 7 of the General Principles (CAC/GL 9-1987) and obtain agreement on which principles are overarching or of general applicability, which principles are additional for specific types of additions, and which principles could be considered guidance factors rather than principles. This would include discussion of which principles are to be retained and which may not be needed.
- Consider whether the purposes of addition should be stated in the Introduction with principles for these included in the overarching or general principles section.
- Consider which definitions are required.
- Consider the level of demonstration of public health need required to support mandatory versus that required for voluntary addition of essential nutrients.

Background:

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

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

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

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

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

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

Another objective of the review would be to consider the need to expand the definition of fortification to encompass the purpose of meeting recommended nutrient intakes and reducing the risk of inadequate intake as demonstrated by relevant scientific data, as well as the current purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups.

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

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

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

Previous Work:

The previous work on this item can be reviewed by reference to the documents listed below the title on page one of this report. It is also summarized in the second consultation document that is attached to this report, in English only, as Appendix B, as well as in the Appendix II to that document which is attached as Appendix C. The previous work was challenged in part by a lack of agreement on the structure of the document. Therefore one focus of the 2011-2012 eWG has been to seek general agreement on the overall structure to enable the group to move on to a detailed discussion of the content.

2011-2012 Electronic Working Group

It was decided to conduct two rounds of consultation with eWG members and focus on the structure of the document in the first round while leaving discussion of the actual text of the principles or guidance until the second round.

Participation

In December 2011, New Zealand invited all members of the CCNFSDU to participate in the eWG. 26 Codex Member Countries (CMC) (Argentina, Australia, Belgium, Belize, Brazil, Canada, China, Costa Rica, Cuba, Denmark, Ecuador, Egypt, France, Ghana, India, Japan, Korea, Malaysia, Moldova, New Zealand, Norway, Sri Lanka, Sudan, Sweden, United States, Uruguay), one Codex Member Organization (CMO) (European Union), and 9 Codex Observers (CO) (CEFS, CRN, EUSALT, FoodDrink Europe, GMA, IADSA, IDF, IFT, IFU) indicated interest in participating. A first consultation document was circulated for comment on February 6, 2012. This consultation focussed on the structure of the document.

Responses to the first consultation of 2012 were received from 9 CMC (Australia, Brazil, Costa Rica, Ghana, India, Moldova, Norway, Uruguay and the United States), 1 CMO (the European Union) and 5 CO (CRN, EUSalt, IADSA, ICGMA, and IFU).

Responses to the second consultation of 2012 were received from 10 CMC (Argentina, Australia, Brazil, Canada, Ecuador, Malaysia, Moldova, Norway, Uruguay and United States), 1 CMO (European Union) and 6 CO (CEFS, EUSalt, FoodDrink Europe, ICBA, IDF and IFU).

Canada and New Zealand would like to express their sincere gratitude to the eWG participants who submitted comments. These were considered by the Chair and Co-chair in preparing this discussion document and revised text options to be circulated by the Secretariat for comments at Step 3.

Outcomes from The eWG:

The first round of consultation focused on the structure of the document considering both headings and subheadings where these are required with the aim of forming a place of agreement to move forward with the detailed text. There was an overall preference for the document to be referred to as **General Principles** as opposed to Guidelines and this was taken forward in the second round of consultation. The various positions and preferences for terminology in relation to the structure can be found in the discussions in Appendix A and B but for the majority there was enough agreement to continue with a structure that included the broad areas of :

1. Scope;
2. Definitions;
3. Principles; and
4. Principles for Specific Types of Nutrient Addition

Final decisions on naming of sections 3 and 4 remains to be taken.

All respondents to the first discussion paper agreed that most if not all the points were principles. Also, there was general agreement about the usefulness of sub-headings under section 3. Where there was the most disagreement was on the need for sub-sections on the specific types of addition.

The first round of consultation also allowed for some further development of the detail of what issues should be addressed under each of the sections. This considered the sections 3-7 of the original General Principles (CAC/GL 9-1987) to ensure that key concepts continued to be addressed or were modified where necessary. The texts that the Chair and Co-chair proposed for the second round were grounded in the text of the existing General Principles as much as possible. New text was thus directly presented in relation to the existing text to ensure that it had that context and to seek to minimize changes.

In considering the **Introduction** section in the second round of consultation, most members of the eWG believed that it should only describe the purpose of the document with elaboration of the purposes of addition of essential nutrients under Section 3, Principles. Regarding the **Definitions** section, there was a strong position that a number of the definitions in this section are not required but also very strong positions for keeping them, with specific comments provided in relation to many of the proposed definitions.

Regarding Sections 3 and 4, while there was considerable agreement that the different points were principles rather than guidance factors, in a number of cases there was not agreement on which ones should stay in the document, in that for some members they might not be appropriate for an international standard, or, if kept, where in the document they should be placed. Further, the second round results highlighted that there was not yet agreement in all cases on which principles are overarching or of general applicability or which principles are additional for specific types of additions.

Consideration of the level of demonstration of public health need required to undertake mandatory versus voluntary addition was also discussed in the second round of consultation under sub-section 3.1.3. There was strong support that the decision to adopt mandatory addition should be determined at a national level. The proposed text also included reference to the decision being based on severity and the extent of public health need. Almost all eWG members agreed that the text proposed provide sufficient guidance on level of demonstration of public health need required to support mandatory versus that required for voluntary addition although a number of edits were proposed. However, the CMO indicated that it is not necessary to specify the conditions to take into account when choosing the type of nutrient addition and since there was proposed to be a section on mandatory addition, they suggested that the principle be deleted. **It may be noted that for sub-section 4.1.** there was general agreement that there should be a demonstrated public health need for increasing the intake of an essential nutrient in one or more populations through mandatory addition. Exactly how to define how a need might be demonstrated and the strength of the evidence required still needs to be agreed upon.

To advance discussion, it may be desirable during the Committee Session to first discuss the merits of having principles for restoration, nutritional equivalence of substitute foods and special purpose foods and make decisions regarding these, and then the positioning of Section 4.1 as to whether this deals only with mandatory addition of essential nutrients to foods or more generally to addition of essential nutrients to address a demonstrated public health need, prior to proceeding through the document clause by clause.

The overall results of the two rounds of consultation with the eWG and proposed revisions to the General Principles based on those consultations are presented in Appendix A. This is presented as a table with 3 columns to help the reader follow the comments and discussions on each clause of the document and the proposed way forward. The first column shows the text as proposed to the eWG in the second round of consultation. The second column summarizes the comments received from the eWG and proposes a recommendation for the Committee to consider. The third column shows the proposed draft text for consideration by members of the CCNFSDU at Step 3 with changes from column one shown in red and retaining text in square brackets or as strike through where there may be a need to focus further discussion and choose from different options.

For reference, the 2nd consultation document in English only is also attached as Appendix B. Appendix C is the Appendix II table from that consultation with notes on the previous discussions on each item and questions posed to the eWG, and Appendix D is the distribution list for the eWG .

Attachments:

Appendix A: Draft Revised General Principles with summary of EWG comments and recommendations

Appendix B: Second EWG Consultation Paper

Appendix C: Appendix II of Second EWG Consultation Paper

Appendix D: Distribution List for EWG

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

Sept 26, 2012

Contents:

Table 1: Comments and proposed revised text of *GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS (CAC/GL 09-1987 amended 1989, 1991)*

Table 2: Proposed Revised Text showing changes (from Column 3 of Table 1).

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

Explanatory note: This Table contains, in the first column, the text as circulated to the electronic working group in the left column. This text is based on the existing document (CAC/GL 09-1987, amended 1989, 1991) and shows possible changes to that document that reflected results of previous eWG and Committee discussions. The second column contains the questions posed to the eWG during the second round, wherever specific questions were posed, as well as a summary of the comments received and a recommendation by the Chair and Co-Chair to the Committee. The third column contains the proposed changes and options drawn from the eWG comments by the Chair and Co-Chair.

At the end of the table, the text from Column 3 is reproduced as a complete document, for ease of review. Below that, a clean text version is inserted.

Abbreviations used: CMC: Codex Member Country CMO: Codex Member Organization CO: Codex Observer

Table 1: Comments and proposed revised *GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS (CAC/GL 09-1987 amended 1989, 1991)*

Text circulated to EWG in June 2012	Question posed to eWG (if any) and Summary of eWG Comments	Proposed revised text
<p>INTRODUCTION</p> <p><i>(Revised) The [General Principles] [Guidelines] for the Addition of Essential Nutrients to Foods (the Principles) [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 pertaining to the addition of essential nutrients to foods to establish a uniform through the establishment of a set of principles that serve as a basis for the rational and safe pertaining to the addition of essential nutrients to foods.</i></p> <ul style="list-style-type: none"> ● To maintain and improve the overall nutritional quality of foods. ● To prevent the indiscriminate addition of essential nutrients to foods thereby 	<p>Question: Does this revised paragraph provide a sufficient introduction describing the purpose of the document, keeping in mind that the purposes for addition of essential nutrients to foods are proposed to be moved to Section 3? Do you agree with the deletions and relocations of text? If not, please explain and provide alternative text.</p> <p>Summary: Most of the EWG members who responded agreed that this revised introduction provided sufficient information describing only the purpose of the document and moving the purpose of addition to section 3. One CMO and one CO suggested keeping the purpose of addition in the introduction. One CMO also suggested reverting back to “those responsible” instead of</p>	<p>INTRODUCTION</p> <p><i>(Revised) The [General Principles] [Guidelines] for the Addition of Essential Nutrients to Foods (the Principles) [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 pertaining to the addition of essential nutrients to foods to establish a uniform through the establishment of a set of principles that serve as a basis for the rational and safe pertaining to the addition of essential nutrients to foods.</i></p> <ul style="list-style-type: none"> ● To maintain and improve the overall nutritional quality of foods. ● To prevent the indiscriminate addition of

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<p>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.</p> <ul style="list-style-type: none"> To facilitate acceptance in international trade of foods which contain added essential nutrients. 	<p>“national authorities”. One CMC suggested a minor edit to make 2 sentences instead of one.</p> <p>Recommendation: Keep text as proposed but discuss further at plenary if there is a rationale for placing the purposes for addition in Section 3. While it was proposed that the term “The Principles” be used as an abbreviated form for the title throughout the rest of the document, this may not be possible if Section 3 is just called “Principles” as was also proposed. This will be left in place for later confirmation.</p>	<p>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.</p> <ul style="list-style-type: none"> To facilitate acceptance in international trade of foods which contain added essential nutrients.
<p>(new) <u>The [General Principles] [Guidelines] for the Addition of Essential Nutrients to Foods</u> 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>	<p>Summary: All EWG members were supportive of retaining this revised principle. One CMC stated that they preferred the term “are consistent and used in conjunction with” instead of “take into consideration provisions in”.</p> <p>Recommendation: Keep text as is with minor edits for consistency with rest of documents. Use of “take into consideration provisions in” is retained as this point was discussed at the 32nd session of the Committee and it was clarified that the <i>Nutritional Risk Analysis Principles</i> apply in the framework of Codex while the <i>Principles for the Addition of Essential Nutrients to Foods</i> are intended for governments and so the proposed text was revised to clarify that the relevant provisions would be “taken into consideration” “where applicable”.</p>	<p>(new) <u>The [General Principles] [Guidelines] for the Addition of Essential Nutrients to Foods</u> 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>
<p>(new) <u>The <i>General Principles for the Addition of Essential Nutrients to Food</i> are applicable, as appropriate, to both mandatory and voluntary addition of essential nutrients unless otherwise indicated.</u></p>	<p>Question: Do you agree with this statement? Is it in the right place? If not, where would you suggest it be placed?</p> <p>Summary: All EWG members agreed with this principle. Two CMCs suggested it might be better positioned under scope while one CMO suggested</p>	<p>(new) <u>The [General Principles] <i>for the Addition of Essential Nutrients to Food</i> are applicable, as appropriate, to both mandatory and voluntary addition of essential nutrients unless otherwise indicated.</u></p>

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	including it in an introductory paragraph to section 3. A CMC and CMO suggested edits some of which were incorporated in the proposed revised principle. Recommendation: Retain statement with revisions proposed by members of the EWG. The Committee may wish to discuss further the placement of this principle in the document.	
(new) National authorities should also consult the <i>FAO/WHO Guidelines on food fortification with micronutrients</i> (WHO, 2006) for further information.	Question: Do you agree that there should be reference to guidance on food fortification in other WHO/FAO texts? If so, is the text proposed acceptable? Summary: Most of the EWG members who responded agreed with retaining this principle with a few suggesting using “may” instead of “should” and that the statement should refer more broadly to WHO/FAO documents since the 2006 document may become outdated or other FAO/WHO documents may become relevant. Recommendation: Retain statement with revisions proposed by members of the EWG.	(new) National authorities should may also consult the FAO/WHO publications <i>Guidelines on food fortification with micronutrients</i> (WHO, 2006) for further guidance on nutrient addition. information.
1. SCOPE These {principles} {Guidelines} are intended to apply to all foods to which essential nutrients are added, <u>not including vitamin and mineral food supplements</u> ¹ . ¹ See the Codex <i>Guidelines for Vitamin and Mineral Food Supplements</i> (CAC/GL-55-2005)	Summary: All members agreed with retaining this principle with a few suggesting minor edits for clarity. As noted earlier, two CMC suggested incorporating into the scope the text, “The General Principles for the Addition of Essential Nutrients to Food are applicable, as appropriate, to both mandatory and voluntary addition of essential nutrients unless otherwise indicated.” Recommendation: Retain statement as is with minor edits proposed by members of the EWG. As noted above, the Committee may wish to discuss further the placement in the document of the principle on applicability of principles to both mandatory and voluntary addition.	1. SCOPE These {Principles} {Guidelines} are intended to apply to the addition of all foods to which essential nutrients to foods are added, not including vitamin and mineral food supplements ¹ . ¹ See the Codex <i>Guidelines for Vitamin and Mineral Food Supplements</i> (CAC/GL-55-2005)
2. [DEFINITIONS] [DESCRIPTION] For the purpose of these {Principles} {Guidelines}:	Summary: A few members suggested adding the following terms in the definition section: Foods	2. [DEFINITIONS] [DESCRIPTION] For the purpose of these {Principles} {Guidelines}:

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	<p>for special dietary uses, Upper level of Intake, RNI, NRV and INL 98 if they are used in the document.</p> <p>Recommendation: Include additional definitions proposed by EWG members if they are used in the document. Where applicable, cite Codex documents where these terms are already defined.</p>	
<p>2.1 Nutrient means any substance normally consumed as a constituent of food:</p> <p>(a) which provides energy; or</p> <p>(b) which is needed for growth and development and maintenance of healthy life; or</p> <p>(c) a deficit of which will cause characteristic biochemical or physiological changes to occur.</p>	<p>Summary: Most of the EWG members who responded agreed with the revised definition and deleting the word “healthy” to be consistent with the Guidelines on Nutrition Labelling. One CMC did not agree with deletion of healthy as their regs make reference to maintenance of health. One CMC suggested deleting this definition as only the term “essential nutrients” is used in the document.</p> <p>Recommendation: Since the term is not used in the document, the Committee may wish to consider its deletion. Otherwise, it may be retained with the possible deletion of the term “healthy”. It should be noted that the Codex document, <i>Nutritional Risk Analysis Principles</i> cites these General Principles as the source of the definition of nutrient and essential nutrient.</p>	<p>[2.1 Nutrient means any substance normally consumed as a constituent of food:</p> <p>(a) which provides energy; or</p> <p>(b) which is needed for growth and development and maintenance of healthy life; or</p> <p>(c) a deficit of which will cause characteristic biochemical or physiological changes to occur.]</p>
<p>2.2 Essential nutrient means any substance normally consumed as a constituent of food which is needed for growth and development and the maintenance of healthy life and which cannot be synthesized in adequate amounts by the body.</p> <p>or</p> <p>2.2 Essential nutrient means any substance normally consumed as a constituent of food which <u>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 <u>and cannot be synthesized in adequate amounts by the body;</u> or</p>	<p>Summary: Most EWG members supported the 2nd option for the definition with some members suggesting to use the word nutrient instead of substance. One CMC also suggested to exclude (b) because (a) covers all concerning state of health. This comment raises a point in that, on further inspection, it can be seen that the second option materially changes the definition in that it includes “<u>or (b) a deficit of which will cause characteristic bio-chemical or physiological changes to occur.</u>” which is not in the original definition of Essential nutrient. It is not clear why the original drafters of the General Principles</p>	<p>2.2 Essential nutrient means any substance normally consumed as a constituent of food which is needed for growth and development and the maintenance of healthy life and which cannot be synthesized in adequate amounts by the body.</p>

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(b) a deficit of which will cause characteristic bio-chemical or physiological changes to occur.	<p>excluded this from the definition of “Essential Nutrient” but included it in the definition of “Nutrient.” Regarding the suggestion to replace “substance” by “nutrient”, noting that the three sub-clauses in the definition of “nutrient” are separated by “or”, this would also materially change the definition in that “essential nutrient” would now encompass substances which only provide energy.</p> <p>Recommendation: Retain the existing definition with the possible deletion of the word “healthy”. The Committee may wish to discuss whether an essential nutrient could be one whose only attribute is that a deficit of it “will cause characteristic bio-chemical or physiological changes to occur”.</p>	
<p>2.3 (former 2.4) <i>Substitute food</i> is a food which is designed to resemble a common food in appearance and texture, flavour and odour, and is intended to be used as a complete or partial replacement for the food it resembles, <u>e.g., plant protein-based beverages as a replacement for milk.</u></p>	<p>Summary: All EWG members except for one CMO and one CO supported retaining this definition. Some members suggested edits: Two CMC suggested retaining flavour and odour, one stating they believed it is an important organoleptic characteristic of food and the other noting that any food intended as a replacement must be as close as possible to the food being substituted. One CMC and one CO propose to remove the example of plant-based beverage as it is not appropriate and they believe the definition is self-explanatory. The CO also noted that no example is provided for restoration. The CMO has indicated a preference to remove the definitions and principles related to the concepts of nutritional equivalence of substitute foods, restoration and special purpose foods from the General Principles but is interested in a discussion concerning the merits of retaining them.</p> <p>Recommendation: Retain definition but it is</p>	<p>2.3 (former 2.4) <i>Substitute food</i> is a food which is designed to resemble a common food in appearance and texture, flavour and odour, and is intended to be used as a complete or partial replacement for the food it resembles, <u>e.g., plant protein-based beverages as a replacement for milk.</u></p>

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	suggested that the committee discuss the possibility of retaining “flavour and odour” and deleting the plant-based beverage example.	
<p>2.4 (former 2.3) <i>Nutritional equivalence</i> means being of the addition of one or more essential nutrient to a substitute food to achieve a similar nutritive value to its normal counterpart in terms of quantity and quality of protein and in terms of kinds, quantity and bioavailability of essential nutrients. For this purpose, nutritional equivalence means that essential nutrients provided by the food being substituted, that are present in a serving or portion or 100 kcal of the food at a level of 5% or more of the recommended intake of the nutrient(s) are present in the substitute or partially substituted food (extender) in comparable amounts. 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.]</p> <p>or</p> <p><i>Nutritional equivalence</i> 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 nutrients.</p> <p>or</p> <p><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. It can be achieved when one or more essential nutrients are</p>	<p>Summary: Four CMC and 1 CO supported option 1 while 2 CMC and 1 CO supported option 2 and another 2 CMC support option 3. One CMO and 1 CO considered that this definition was not needed. One CMC stated they preferred option 1 to minimize edits to existing definition and suggested deleting the 3rd sentence as it appears redundant with 1st sentence. One CO suggested deleting the word “normal” as it does not add any value. Another CO suggested that if option 2 is retained, a reference to protein quality be made as seen in both option 1 and 3.</p> <p>Recommendation: Retain option 1 with minor edits to the first sentence and deleting the last sentence since the concepts in that sentence are captured in the term “substitute food” in the first sentence.</p>	<p>2.4 (former 2.3) <i>Nutritional equivalence</i> means being of the addition of one or more essential nutrient to a substitute food to achieve a similar nutritive value to its normal counterpart in terms of quantity and quality of protein and in terms of kinds, quantity and bioavailability of essential nutrients. For this purpose, nutritional equivalence means that essential nutrients provided by the food being substituted, that are present in a serving or portion or 100 kcal of the food at a level of 5% or more of the recommended intake of the nutrient(s) are present in the substitute or partially substituted food (extender) in comparable amounts. [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.]]</p>

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<p><i>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>		
<p>2.5 Fortification or, which may be called enrichment, means the addition of one or more essential nutrients to a food, whether or not it is normally contained in the food for the purpose of <u>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 a population or specific population groups [with minimal risk to health].</u></p> <p>or</p> <p>Fortification means the addition of one or more essential nutrients to a food, whether or not it is normally contained present in the food, for the purpose of preventing or correcting <u>improving population health by addressing a demonstrated deficiency of one or more nutrients in the population or specific population group(s) or reducing the risk of poor nutritional status or 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] for the purpose of preventing or correcting <u>improving population health by addressing a demonstrated deficiency of one or more nutrients in the population or specific population group(s).</u></p>	<p>Summary: Half of the CMCs who responded suggested deleting this definition as it is not used in the document and half wanted to retain it. Of those who wanted to retain the definition, most preferred option 3 which changes the meaning of the term so that it means simply the addition of essential nutrients to foods. This is often the way the term is used in popular usage. One CMC suggested that if there are different interpretations of the term “fortification” internationally, a comment could be made to this effect in the introduction but not in the definition section. This CMC preferred to retain the term with its original meaning with some modification, and noted that “nutrient addition” would refer to all types of addition including restoration and nutritional equivalence, not just the previous meaning of “fortification”. CMCs who preferred to keep the third definition One CMC recommended defining “nutrient addition”.</p> <p>Recommendation: Given the diversity of views, the Committee should discuss the need for this term and the appropriate definition for it..</p>	<p>If retained, Proposed revised definition for option 3):</p> <p>2.5 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]. for the purpose of preventing or correcting improving population health by addressing a demonstrated deficiency of one or more nutrients in the population or specific population group(s).</p>
<p>2.8 Restoration means the addition to a food of</p>	<p>Summary: All EWG members except for the</p>	<p>2.8 Restoration means the addition to a food of</p>

Table 1: Comments and proposed revised <i>GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS (CAC/GL 09-1987 amended 1989, 1991)</i>		
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essential nutrient(s) which are in amounts to replace those lost during the course of good manufacturing practice, or during normal storage and handling procedures, or in order to compensate for natural variations in essential nutrients, 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.	CMO supported retaining this definition. Two CMC questioned the need for the new text added, “or in order to compensate for natural variations in essential nutrients”. One CMC suggest that it would be helpful if examples could be provided to guide a decision on its inclusion. This text was included to capture concepts in the definition of “standardization” (former 2.9) which as been proposed for deletion. Recommendation: Retain this definition but discuss possibility of deleting new text “or in order to compensate for natural variations in essential nutrients”	essential nutrient(s) which are in amounts to replace those 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.
<u>2.6 (new) Mandatory nutrient addition occurs when governments require food manufacturers to add specified essential nutrients to particular foods or categories of foods.</u> [for a specific purpose.	Summary: Most of the CMC supported retaining this definition, however, the CMO suggested moving it to section 4.1. One CO believes the definition should be deleted as the term “mandatory” is self-explanatory. Two CMC suggest to either add “within specified limits” to both definitions (mandatory and voluntary addition) or remove them from both definitions. One CMC also suggest using “food categories” rather than “categories of food” to be consistent with words used for the definition of voluntary nutrient addition. Two CMC suggest deleting “for a specific purpose” because it is unnecessary. Recommendation: Retain definition incorporating edits proposed by members of the EWG.	<u>2.6 (new) Mandatory nutrient addition is occurs when National Authorities</u> governments <u>require food manufacturers to add specified essential nutrients to particular foods or food categories.</u> of foods. [for a specific purpose.
<u>2.7 (new) Voluntary nutrient addition is when a food manufacturer may chooses to add specified nutrients to particular foods or food categories.</u> [for a specific purpose.] <u>within specified limits.</u>	Summary: Most of the CMCs supported retaining this definition while one CMO believes it is not needed. One CMC proposed edits to clarify that national authorities permit manufacturers to add essential nutrients to food. Recommendation: Retain definition incorporating edits proposed by members of the EWG.	<u>2.7 (new) Voluntary nutrient addition is when a National Authorities permit food manufacturers may chooses</u> to add specified <u>essential</u> nutrients to particular foods or food categories. [for a specific purpose.] <u>within specified limits.</u>

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<p>2.9 <i>Special purpose foods</i> are foods that have been designed to perform a specific function, such as to replace a meal, which necessitates a content of essential nutrients which cannot be achieved except by addition of one or more of these nutrients. These foods include but are not limited to foods for special dietary use, <u>and also include foods intended for infants and young children.</u></p>	<p>Summary: Most CMCs and COs agreed with retaining this definition. 3 CMCs suggested removing “also include”. One CMO, one CMC and one CO suggested to delete this definition as they thought it was already covered by other Codex standards: those for foods for special dietary uses and for infants and young children. One CMC stated that this definition is too broad and allows the inclusion of conventional foods that are not food for special dietary use. They also noted that this definition is not used in any other Codex document. They suggest replacing this definition with the definition of “foods for special dietary uses” set in the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CAC/GL146-1985).</p> <p>For reference, the description of Foods for Special Dietary Uses in CAC/GL146-1985 is as follows: “Foods for Special Dietary Uses are those foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders and which are presented as such.¹ The composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist.</p> <p>¹ This includes foods for infants and young children.”</p> <p>The definition for “special purpose foods” appears to be intended to go beyond foods for special dietary use. For example, the definition identifies products that replace a meal and could include other foods that are intended for a special purpose</p>	<p>2.9 <i>Special purpose foods</i> are foods that have been designed to perform a specific function, such as to replace a meal, which necessitates a content of essential nutrients which cannot be achieved except by addition of one or more of these nutrients. These foods include but are not limited to foods for special dietary use, <u>and also include foods intended for infants and young children</u>.</p>

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	<p>other than addressing requirements of people with a particular condition or disease or disorder.</p> <p>Note that since foods for special dietary uses includes foods for infants and young children, it is probably not necessary to state that in this definition.</p> <p>Recommendation: Retain the definition for further discussion by the Committee. Consider deleting the new text that was proposed.</p>	
2.10 <i>Nutrient density</i> means the amount of nutrients (in metric units) per stated unit of energy (MJ [KJ] or kcal).	<p>Summary: All EWG members agreed with deleting this definition or did not comment. Recommendation: Delete this definition</p>	2.10 <i>Nutrient density</i> means the amount of nutrients (in metric units) per stated unit of energy (MJ [KJ] or kcal).
2.11 <i>Standardization</i> means the addition of nutrients to a food in order to compensate for natural variations in nutrient level.	<p>Summary: All EWG members agreed with deleting this definition or did not comment. Recommendation: Delete this definition</p>	2.11 <i>Standardization</i> means the addition of nutrients to a food in order to compensate for natural variations in nutrient level.
2.11 (new) <i>Population</i> refers to a national population or specific population group(s) as appropriate.	<p>Summary: All EWG members agreed with retaining this definition. Recommendation: Retain definition with no changes.</p>	2.11 (new) <i>Population</i> refers to a national population or specific population group(s) as appropriate.

Draft Revised *GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS (CAC/GL 09-1987 amended 1989, 1991)*
(Continued)

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3. PRINCIPLES	<p>Question: Do you agree with calling Section 3 just “Principles”?</p> <p>Summary: Five CMC, 1 CMO and and 3 COs agreed with calling this section “Principles”. One CMC did not agree with calling this section “Principles.” They indicated that, given that Section 4 includes principles for specific types of nutrient addition, further clarification is needed in</p>	3. PRINCIPLES

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	<p>the Section 3 heading to distinguish between the principles in Section 3 and those in Section 4. They propose that Section 3 be entitled either “Overarching Principles” or alternatively “Core Principles”.</p> <p>Recommendation: Retain title “Principles” as most of the EWG members agreed with this heading. Note that, if this title is retained for Section 3, the same name cannot be used as a short form for the document as proposed in the proposed changes to the Introduction..</p>	
<p>3.1 (New) Fundamental {Overarching} {General} Principles</p>	<p>Question: Do you agree that there should be a separate sub-section in Section 3 called “Fundamental Principles” covering the high level principles that are overarching or of general applicability while the remaining principles of overarching or general applicability are placed in separate sub-sections?</p> <p>Summary: 7 CMC and 3 COs agreed that there should be a separate sub-section in Section 3 called “Fundamental Principles”. One CMC noted that this is consistent with the decision made at the 32nd (2010) CCNFSDU session that Section 3 include a separate section on fundamental principles. (REP 11/NFSDU, para 67). One CMC suggests using the term “General Principles”. One CMC and 1 CO believe that it is not necessary to have a sub-heading here.</p> <p>Recommendation: Retain sub-title as most of the EWG members agreed with this heading.</p>	<p>3.1 (New) Fundamental {Overarching} {General} Principles</p>
<p><u>3.1.1 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, [inadequate intakes or poor nutritional status] of one or more essential nutrients in the population or specific population groups;</u> • <u>contributing to meeting recommended nutrient intakes/ [requirements] of one or more essential</u> 	<p>Questions: Do you agree with these purposes for addition? Do you agree that these purposes for addition should be placed in Section 3, Principles? Do you agree with their placement under Fundamental principles?</p> <p>Summary: There was general agreement with these purposes for addition and with their placement in this section except for the CMO who</p>	<p><u>3.1.1 Essential nutrients may be appropriately added to foods for the purpose of:</u></p> <ul style="list-style-type: none"> • <u>contributing to correcting a demonstrated deficiency or [inadequate intakes or poor nutritional status] of one or more essential nutrients in the population or specific population groups;</u> • <u>contributing to meeting recommended</u>

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<p><u>nutrients and reducing the risk of [inadequate intakes, poor nutritional status and/or] deficiency;</u></p> <ul style="list-style-type: none"> <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>preferred them in the Introduction.. There was a misunderstanding of terminology as to what was meant by “recommended nutrient intakes” with some members considering them RNIs and other preferring different terms such as NRVs. The intent was to choose a term that enabled the broadest application and understanding of nutrient values and some members supported the use of the term “requirements“ because it was a broader and more general term. A number of members recommended the inclusion of the term “contributing to correcting” in the first dot point to be consistent with the other points.</p> <p>One CMC proposed a re-write of the paragraph as a simplification but in reading their proposal the recommendations removed the concept of “contributing to improved health” and continue to focus only on reducing the risk of inadequacy. Although some of the recommendations could be taken on board it is questionable as to whether there is any added value from this. One CMO proposed to delete reference to “poor nutritional status “ in the 1st and 2nd bullet points.</p> <p>It was recommended that reference to “overall” in the last dot point was not necessary.</p> <p>Recommendation: Retain this principle in this section with edits.</p>	<p>nutrient intakes/ [requirements] of one or more essential nutrients and reducing the risk of [inadequate intakes, poor nutritional status and/or] deficiency;</p> <ul style="list-style-type: none"> 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;
<p>3.1.2 The above <u>purposes</u> may be achieved by restoration, nutritional equivalence of substitute foods, fortification nutrient addition <u>mandated to correct inadequate intakes,</u> and ensuring the appropriate nutrient composition of a special purpose food <u>or other addition in accordance with these principles.”</u></p>	<p>Summary: Some members found this paragraph unclear and not necessary as the principles were addressed later in section 4 of the document. One CMO presented that the text may be interpreted to <i>limit the addition of nutrients to the practices mentioned.</i> A number of the other responses suggested a specific reference to “voluntary addition” and that the clause as it is written refers to mandatory addition only.</p> <p>Four CMC and 1 CO had various suggestions on how to address this. One member suggested referring to “fortification” rather than any specific</p>	<p>3.1.2 The above purposes may be achieved by restoration, nutritional equivalence of substitute foods, fortification nutrient addition mandated to correct inadequate intakes, and ensuring the appropriate nutrient composition of a special purpose food or other addition in accordance with these principles.”</p>

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	<p>sort of nutrient addition; 2 CMC and 1 CO suggested including reference to voluntary addition. One CMC recommended referring generically to “nutrient addition”. They also recommended adding a sentence to bring in the concept of standards of identity.</p> <p>Recommendation: The Committee might wish to consider deleting this principle as it does appear that there are no new concepts introduced in it. Consideration should be given as to whether there is any value added by including this clause or whether its deletion would result in removal of a key concept. If 3.1.2 is retained it does need to reflect the concepts of both voluntary and mandatory addition.</p>	
<p><u>3.1.3 (New) National authorities should determine whether [nutrient addition] fortification should be mandatory or voluntary [This decision may be based on severity and extent of public health need as demonstrated by scientific evidence. The kinds and amounts of essential nutrients to be added and 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.].</u></p> <p><u>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></p>	<p>Question: Does the text proposed here provide sufficient guidance on level of demonstration of public health need required to support mandatory versus that required for voluntary addition of essential nutrients?</p> <p>Summary: 10 CMC agreed that the text proposed provide sufficient guidance on level of demonstration of public health need required to support mandatory versus that required for voluntary addition. However, many suggested edits for consistency and one CMC supported only the first two sentences stating that the 3rd sentence should be moved to section 4 which addresses this topic. The 4 COs also had suggested edits. The CMO suggested that this principle be deleted as they consider that it is not necessary to specify the conditions to take into account when choosing the type of nutrient addition. They further state that the choice of mandatory addition of essential nutrients to foods in order to address a specific public health concern is the responsibility of national authorities.</p> <p>Recommendation: Retain principle incorporating some of the suggested edits by EWG members.</p>	<p><u>3.1.3 (New) National authorities should determine whether [nutrient addition] fortification should be mandatory or voluntary [This decision may be based on severity and extent of public health need as demonstrated by scientific evidence. The kinds and amounts of essential nutrients to be added and the and food vehicle chosen to be fortified will depend upon the particular nutritional problems to be corrected or prevented, the characteristics of the target populations, and their food consumption patterns. of the area.].</u></p>

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	<p>Discuss possibility of moving the 3rd sentence (starting “the kinds and amounts of essential nutrients...”) to Section 4.</p>	
<p>3.1.4 (Former 3.11 with modifications) <u>The mandatory and voluntary addition of essential nutrients to foods should be in accordance with food law and other policies established by national authorities.</u> When provision is made in national food standards, regulations or guidelines for the addition of essential nutrients to foods, specific provisions should be included identifying <u>the target appropriate foods.</u> the essential nutrients to be considered or to be required or permitted to be added and <u>the minimum and where appropriate, maximum</u> levels at which they should be present.</p>	<p>Question: Is it appropriate to add the proposed text relating to food law into this sub-section or should it be retained with revised former 6.1?</p> <p>Summary: Nine CMC and 4 COs agreed with this revised principle with minor edits. Many suggested removing “mandatory and voluntary” in the first sentence as in the introduction it is stated that the <i>principles</i> are applicable, as appropriate, to both mandatory and voluntary addition of essential nutrients unless otherwise indicated. Some also recommended deleting the word “appropriate” in the 2nd sentence as it is not defined. One CMO and 2 COs suggested deleting reference to the target/appropriate foods as they consider that the requirement to include specific provisions identifying the appropriate foods introduces a new element to the paragraph and goes beyond what should (i.e. an obligation) be included in national food standards, regulations or guidelines. Another CMC suggested significant changes to this principle.</p> <p>Recommendation: Retain this principle with minor edits.</p>	<p>3.1.4 The mandatory and voluntary <u>addition of essential nutrients to foods should be in accordance with food law and other policies established by national authorities.</u> When provision is made in national food standards, regulations or guidelines for the addition of essential nutrients to foods, specific provisions should be included identifying <u>the target appropriate foods.</u> the essential nutrients to be considered or to be required or permitted to be added and <u>where appropriate the minimum and where appropriate, maximum</u> levels at which they should be present.</p>
<p>3.1.5 (Former 3.8 with additions) Addition of essential nutrients to foods should not be used to mislead or deceive the consumer, <u>including by presentation or labelling practices,</u> as to the nutritional merit <u>[or the health benefit]/[and possible additional health benefit]</u> of the food.</p>	<p>Question: Are the changes in square brackets acceptable? Which are preferred? Do any additional principles need to be included to provide sufficient guidance for National Authorities to ensure that consumers will not be misled?</p> <p>Summary: There was general agreement with this principle although slight changes to wording were proposed by a few CMC. Of the CMC who</p>	<p>3.1.5 (Former 3.8 with additions) Addition of essential nutrients to foods should not be used to mislead or deceive the consumer, including by presentation or labelling practices, as to the nutritional merit [or the health benefit]/[and possible additional health benefit] of the food.</p>

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	<p>proposed revised wording, the suggested changes consisted mostly of shortening to simplify the sentence, with one CMC suggesting deleting everything after “the consumer”. 6 CMC and 2 CO preferred the term “or the health benefit” while 3 CMC preferred “possible additional health benefit”.</p> <p>No EWG member proposed any additional principles and the CMO stated that no additional principle needed to be included to provide guidance for National Authorities to ensure that consumers will not be misled.</p> <p>Recommendation: Use simplified wording proposed by one CMC, which makes the principle more concise.</p>	
<p>3.2 (New) Selection of Nutrients and Determination of amounts</p>	<p>Question: Do you agree with combining “Selection of Nutrients” and “Determination of amounts”?</p> <p>Summary: All CMCs agreed with this. One CO indicated that they thought all the points under these two were principles and preferred that they be numbered under 3.1, i.e. as 3.1.6 and 3.1.7, with relevant bullets included below those. Another CO indicated that these principles only apply to enrichment which they defined elsewhere as equivalent to the existing meaning of fortification. Possibly they are saying that they don’t apply to restoration, nutritional equivalence and special purpose foods.</p> <p>Recommendation: Retain the revised title but the Committee may wish to verify whether all parts of this section are applicable to all types of addition.</p>	<p>3.2 (New) Selection of Nutrients and Determination of amounts</p>
<p>3.2.1 Former 3.2 with modifications (also considered to cover 6.2.5): The <u>addition of an essential nutrient should be [scientifically and nutritionally justified in line with one or more of the purposes stated in 3.1.1 and be</u> present at a level which will not result in either</p>	<p>Question: Considering that there appears to be general agreement about the purposes set out in 3.1, is it necessary to retain a statement that addition should be nutritionally justified?</p> <p>Summary: There was very varied response to this</p>	<p>3.2.1 Former 3.2 with modifications (also considered to cover former 6.2.5): The [amount of an added] or [addition of an] essential nutrient should be <u>[scientifically and nutritionally justified]</u> [in line with one or more of the purposes</p>

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<p>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: <u>3.2.1 (new) 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 and as well as intake from food supplements, other relevant sources, upper levels of intake and identification of special sub populations at risk.</u></p>	<p>question and the options presented. Two CMCs and the CMO felt that we did not need to retain a statement that addition should be nutritionally justified as they felt this point was already addressed in 3.1.1. In two of these cases, the second option was supported with modifications. One CMC preferred the second option with edits, noting that the concept of “risk-based” has been implicitly covered above. This CMC also suggested other changes to distinguish between effects on intake in the target versus the national population. Another CMC simply indicated a preference for Option 2. Four CMCs preferred option 1, three of these with edits. Two COs preferred option 1.</p> <p>Once CMC suggested that the question may better have been whether <i>amounts</i> of added essential nutrients should be both rational and safe, or only safe. In their view, 3.2.1 should be worded to indicate that the amounts should be both. By changing the wording to “amounts” it would not be redundant with 3.1.1. Some CMCs felt that the last sentence of option 1 was not needed as it was already addressed elsewhere or it should be left in brackets for further consideration or it should be moved to 3.2.2. One CMC prefers option 1 as they believe that if we only say that the addition should be risk-based (as in option 2), it leaves out the important concept that the addition should not only be safe but also rational. One CO suggested that specific mention of section 3.1.1 makes the mention “nutritionally justified” redundant and thus suggests removing it, others preferred to keep both references.</p> <p>Other changes were also suggested to improve the meaning.</p> <p>Recommendation: An alternative is proposed that blends options 1 and 2 and includes the</p>	<p>stated in 3.1.1] and be present at a level which will not result in either an excessive intake or, for the target population, an insignificant intake of [the added] essential nutrient[s], considering [total intakes] amounts from all [relevant] other sources [including food supplements], [Upper Levels of intake and identification of special subpopulations at risk] in the diet. [Upper levels of intake based on scientific risk assessment may be used to identify the need for any restrictions on the types of foods to be fortified.]</p>

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	various alternative wordings for consideration by the Committee.	
<p>3.2.2 (new) The Upper Level of Intake should be used to assess potential exposure to excessive intakes and to estimate safe limits of addition for essential nutrients, including considerations of populations at risk of excessive intake.</p>	<p>Question: Regarding 3.2.2, 3.2.3 and 3.2.4, should Codex guidelines include this guidance on dietary modelling and use of the UL to assess the safety of proposed nutrient addition? Please explain.</p> <p>Summary: 2 CMCs indicated agreement with the proposed text and there were a few suggested edits. Because the question posed was inserted next to 3.2.3 in the consultation document, most of the comments were given under 3.2.3 or 3.2.4 and in some cases they would lead to further changes to 3.2.2, these are all discussed below.</p>	<p>3.2.2 (new) The Upper Level of Intake should be used to assess potential exposure to excessive intakes of essential nutrients and to estimate safe limits of addition for essential nutrients, <u>[including considerations of populations at risk of excessive intake]</u>. <u>[This exposure assessment should also help to identify the need for any restrictions on the types of foods to which nutrients should be added.]</u></p>
<p>3.2.3 (new) Potential change to population intakes should be estimated as part of the decision making about nutrient addition. Such Assessment of potential exposure 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 daily intake reference values for adequacy and for safety (e.g. the Upper Level of Intake).”</p> <p>OR:</p> <p><i>National authorities may establish maximum limits for the addition of essential nutrients to foods to reduce any potential risks for adverse effects on health. Maximum limits for the addition of essential nutrients to foods should be based on the following criteria:</i></p> <p><i>(i) Upper Level of Intake (UL) of essential nutrients established by scientific risk assessment based on generally accepted scientific data, taking into consideration, as appropriate, the varying degrees of sensitivity of different consumer groups;</i></p>	<p>Summary: All respondents except the CMO agreed with having guidance on this here, some indicating that it was useful for National Authorities in assessing safety of nutrient addition. There may have been some confusion regarding the question since a second question was posed, “Do you agree with this approach to guiding addition of essential nutrients to foods?” that was meant to refer to some italicized text (originally provided by the EU) that was shown in Appendix II but not Appendix III (see column at left). Therefore, it appears that most took the second question as also referring to 3.2.2 to 3.2.4 and, unfortunately, few commented on the italicized text.</p> <p>Two CMCs proposed changes to 3.2.3. Another CMC said that 3.2.3 could be deleted because it was too detailed but they also proposed changes to 3.2.2 that would capture some of the concepts in 3.2.3.</p> <p>The CMO indicated that the new italicized text proposed should be used instead of 3.2.2-3.2.3.</p>	<p>3.2.3 (new) Potential change to population intakes should be estimated as part of the decision making about nutrient addition <u>[to evaluate safety and adequacy]</u>. Such Assessment of potential exposure 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 daily intake reference values for adequacy and for safety (e.g. the Upper Level of Intake).”</p> <p><i>Alternative for 3.2.2 and 3.2.3: National authorities may establish maximum limits for the addition of essential nutrients to foods to reduce any potential risks for adverse effects on health. Maximum limits for the addition of essential nutrients to foods should be based on the following criteria:</i></p> <p><i>(i) Upper Level of Intake (UL) of essential nutrients established by scientific risk assessment based on generally accepted scientific data, taking into consideration, as appropriate, the varying</i></p>

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<p><i>(ii) the daily intake of essential nutrients from other dietary sources.</i> <i>When the maximum levels are set, due account may be taken of the reference intake values of essential nutrients for the population.</i> <i>When maximum amounts are close to the Upper Level of Intake (UL) restrictions of foods to which nutrients may be added should take account of the contribution of individual foods to the overall diet of the population in general or of sub-groups of the population."</i></p>	<p>This text does not elaborate on dietary modeling and the use of the UL in it but rather follows the approach taken in the Codex Guidelines on Vitamin and Mineral Food Supplements.</p> <p>The COs were split with two of those commenting tending to see the text in these subsections as too much detail and more like guidance than principles. Two CMCs recommended deleting "including considerations of populations at risk of excessive intake" but others did not express objection and therefore it is placed in square brackets to indicate that this, in particular, might need further discussion.</p> <p>Recommendation: Overall, regarding 3.2.2 and 3.2.3, as a first option, the text is retained with some edits. The Committee should also consider the alternative shown in italics which did not get full consideration by the eWG..</p>	<p><i>degrees of sensitivity of different consumer groups;</i> <i>(ii) the daily intake of essential nutrients from other dietary sources.</i> <i>When the maximum levels are set, due account may be taken of the reference intake values of essential nutrients for the population.</i> <i>When maximum amounts are close to the Upper Level of Intake (UL) restrictions of foods to which nutrients may be added should take account of the contribution of individual foods to the overall diet of the population in general or of sub-groups of the population.</i></p>
<p>3.2.4 (new) <u>Where an Upper Level of Intake is not available, the scientific evidence to support the safe addition of an essential nutrient should include:</u> <u>a) use of other values such as a Highest Observed Intake; demonstration of an upper level or a range of intake that is unlikely to result in adverse health effects, and</u> <u>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.]</u></p>	<p>Summary: There was general agreement with having a principle to this effect in the document. There were proposed changes from 3 member states/organizations. More than one recommended including a definition of Highest Observed Intake (HOI) or a reference to a definition. The CMO preferred to retain the alternative of demonstrating an upper level or a range of intake along with "other values such as a Highest Observed Intake".</p> <p>Discussion: The definition of HOI cited 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" is: "Highest observed intake⁴⁰ – the highest level of intake observed or administered as reported within a stud(ies) of acceptable quality. It is derived only when no adverse health effects have been identified."</p>	<p>3.2.4 (new) <u>Where an Upper Level of Intake is not available, [National authorities may consider] the scientific evidence to support the safe addition of an essential nutrient [should be considered], including [demonstration of an upper level or a range of intake that is unlikely to result in adverse health effects] [or the potential relevance of Highest Observed Intake¹; demonstration of an upper level or a range of intake that is unlikely to result in adverse health effects, and</u> <u>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.]</u></p> <p>footnote 1: Highest observed intake – the highest level of intake observed or administered as reported within a stud(ies) of acceptable quality. It is derived only when no adverse health effects</p>

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	<p>Footnote 40: A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances. Report of a joint FAO/WHO technical workshop 2005, WHO, 2006.</p> <p>Recommendation: Revise text taking the approach of including HOI in the text and providing the definition in a footnote rather than incorporating it into the text, to ensure that it is captured in its complete form. If “demonstration of an upper level or a range of intake that is unlikely to result in adverse health effects” is included, it may be useful to indicate that this would be done by the National Authority.</p>	<p>have been identified. (appropriate source to be cited.)</p>
<p>3.2.5 (new) <u>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.</u></p>	<p>Question: Should severity of adverse effects be taken into account and not just the UL?</p> <p>Summary: One CMC and one CMO did not believe this principle is necessary. One did not comment. In another case, the position was not clear. All the others supported retaining it with 2 CMCs proposing changes. The three COs who commented did not support retaining this. The main comment made by those who objected was that it was not necessary to take severity into effect but rather it is sufficient to consider the UL and the total dietary intake of the nutrient. One CMC indicated that the reason for considering it is that it would possibly allow for more flexibility in some cases. For the changes proposed, one CMC indicated that the principle should apply to both mandatory and voluntary addition. The other suggested it was not necessary to refer to “National Authorities” and made other editorial changes.</p> <p>Recommendation: The paragraph should be retained for further discussion regarding the necessity of taking severity into account. The two sets of changes proposed are both considered in</p>	<p>[3.2.5 (new) <u>The severity of the adverse effect on which the Upper Level of Intake Level (UL) is based should be reviewed by national authorities and should to inform restrictions on the addition of essential nutrients permitted to be added to foods on a voluntary basis.]</u></p>

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	<p>the following revised draft which accepts the notion that consideration of the severity of effect should apply to both mandatory and voluntary addition and retains the reference to national authorities in square brackets but struck out.</p>	
<p>3.2.6 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.</p>	<p>Question: No specific question was asked and so people were asked to indicate concurrence with the text proposed or provide changes they felt were necessary.</p> <p>Summary: Seven CMCs indicated agreement to retain this with one saying the reason being that interaction between nutrients may not be addressed by ULs. Another CMC and the CMO said to delete it, one indicating that it is covered by 3.2.1. One had no comments and 1 suggested to change it to refer to the amount. The principle was supported by three COs one of which suggested changing it to refer to the amount. Also, one of these suggested that it continue as part of the fundamental principles.</p> <p>Discussion: Those who preferred that the principle refer to the amount of the added nutrient did not indicate the reason for this. There was also no explanation given for deleting the principle although in previous consultations, the need for it was questioned if principles relating more generally to avoiding adverse effects are included.</p> <p>Recommendation: The two alternatives are retained for further discussion in the Committee.</p>	<p>3.2.6 Former 3.3 The [amount of an essential nutrient added] / [addition of an essential nutrient] to a food should not result in an adverse effect on the metabolism of any other nutrient.</p>
<p>3.2.7 (new) "National authorities may establish <u>minimum limits for the addition of essential nutrient to foods to ensure that consumers are not misled and that the foods to which the nutrients are added meet the purpose of the addition of nutrients to foods as described in the Introduction of the [General Principles][Guidelines].</u> Minimum amounts for the addition of essential nutrients to foods should take into account the conditions of use for a source of</p>	<p>Summary: Five CMCs preferred the first option provided, 2 preferred the second option, another preferred retaining only part of the first option, i.e. the second sentence, and one suggested text that combined the two. Three COs preferred the first option and one indicated that, for restoration, there shouldn't be a requirement to meet the minimum for a source claim.</p> <p>Discussion: The new ideas in this principle are</p>	<p>3.2.7 (new) National authorities may establish <u>minimum limits for the addition of essential nutrient to foods to ensure that consumers are not misled and that the foods to which the nutrients are added meet the purpose of the addition of nutrients to foods as described in the Introduction of the [General Principles][Guidelines].</u> [Minimum amounts for the addition of essential nutrients to foods should take into account the</p>

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<p><u>claim in the Guidelines for use of nutrition and health claims (CAC/GL 23-1997) ".</u></p> <p>Or: <u>(new) The minimum amount of addition of an essential nutrient should take into account the intended purpose, and all other sources of the essential nutrient in the diet, including food supplements.</u></p>	<p>that minimum levels may be set and what the basis should be. One of the CMC that preferred the second option indicated that it was “not adequate to establish a linkage between the minimum amount of addition and the conditions of the use of nutrition claims.” The exact meaning of this statement needs to be clarified by the member but seems to be saying that the minimum for a source claim should not be the only basis for the minimum amounts for addition. While this may be implied by the wording of the first option, it does say “should take into account the conditions of use for a source of claim...” which does not necessarily mean that this should always be the basis.</p> <p>An alternative wording was suggested that removed text in the first version that is already stated elsewhere as well as the reference to the conditions of use for a “source of” claim and includes wording from the second option.</p> <p>Recommendation: The question of whether or how to refer to the conditions of use for “source of” claims or another basis described should be further discussed by the committee. Edits are proposed to the first option, and two options for the basis of setting the minimum amounts.</p>	<p><u>conditions of use for a source of claim in the Guidelines for use of nutrition and health claims (CAC/GL 23-1997)].</u> <u>[The minimum amount of addition of an essential nutrient should take into account the intended purpose, and all other sources of the essential nutrient in the diet, including food supplements.]</u></p>
<p>3.3 (New) Selection of Foods</p>	<p>Summary: No comments were provided by CMCs or the CMO concerning this title. However, one CO suggested to revise the title to: “considerations on foods that could have added nutrients” to avoid discrimination and another CO suggested to delete this title.</p> <p>Recommendation: Retain this title given general consensus among CMCs and CMO.</p>	<p>3.3 (New) Selection of Foods</p>
<p>3.3.1 (new) <u>Certain foods may have to should be excluded from voluntary fortification nutrient addition because of their ubiquity in the food supply</u></p>	<p>Summary: Five CMCs support this principle while 1 CMC and 1 CO suggested deleting it. One CMC believes these restrictions should not apply in the case of nutrient addition for the purpose of</p>	<p>3.3.1 (new) <u>[Certain foods may have to should be excluded from voluntary fortification nutrient addition because of their ubiquity in the food supply and thus the potential for exposure</u></p>

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<p><u>and thus the potential for exposure to high intakes associated with a risk of adverse health effects in non-target populations.</u></p>	<p>correcting or preventing inadequate intakes. Three COs do not support excluding foods because of their ubiquity in the food supply.</p> <p>The CMO considers that the selection of foods to which essential nutrients may be added so as to avoid any risks to health should take into account the specific dietary habits and socioeconomic situations at local level and proposes to replace paragraph 3.3.1 with: <i>"The selection of appropriate foods to which essential nutrients may be added is best determined at national/regional/local level taking into account dietary habits, socioeconomic situations and the need to avoid any risks to health."</i></p> <p>One CMC believes this section should first address selection of foods for adding essential nutrients to achieve appropriate purposes before addressing any restrictions and propose an alternative. They do not consider it appropriate to propose a universal principle that appears to suggest that staple foods are never an appropriate vehicle for voluntary nutrient addition to meet a public health need.</p> <p>Recommendation: The paragraph with should be retained for further consideration by the Committee along with alternative options proposed.</p>	<p><u>to high intakes associated with a risk of adverse health effects in non-target populations.]</u></p> <p>Or</p> <p>[The selection of appropriate foods to which essential nutrients may be added is best determined at national/regional/local level taking into account dietary habits, socioeconomic situations and the need to avoid any risks to health.]</p> <p>Or</p> <p>[The selection of food(s) to which to add an essential nutrient(s) should primarily be based on achieving appropriate purposes of nutrient addition as identified in 3.1.1.]</p>
<p>-(new) [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>Summary: All members agreed or had no comments concerning the deletion of this principle except for 1 CMC who suggested retaining it with significant edits: Consideration should be given to the nutrient profile content of risk-increasing nutrients in potential target foods to assess whether an increased consumption resulting from nutrient addition would pose other health risks. of the</p>	<p>(new) [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>

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	<p>food before [fortification] nutrient addition to ensure that nutritionally appropriate foods are selected. for [fortification] [nutrient addition].</p> <p>Recommendation: Given the consensus among most eWG members and the fact that 3.3.2 includes reference to taking into account the nutritional value of the foods selected as vehicles for addition of essential nutrients, it is recommended to delete this principle.</p>	
<p>3.3.2 (new) <u>The selection of appropriate foods to which essential nutrients may be added should take into account the nutritional value of the foods and is best determined by National Authorities.</u></p> <p>Or</p> <p><u>Foods or categories of foods to which particular groups of essential nutrients may not be added may be determined by national authorities taking into account their nutritional value.</u></p>	<p>Question: Which of these two options is preferred? Please indicate the reason for your choice. If neither, please explain.</p> <p>Summary: Seven CMCs preferred option 1, 2 CMCs and 1 CMO preferred option 2 with edits while another CMC does not support either option. Four COs suggest deleting this principle as they consider that the selection of food should not be based on the nutritional value of a food but on the added-value of the food as a vehicle to reach the target population. One CMC prefers option 1 but suggests deleting “appropriate” and adding a 2nd sentence “Nutrient addition to energy-dense and nutrient-poor foods should be avoided.” One CMC proposes that the provisions in new proposed 3.3.4 and 3.3.5 be added to 3.3.2:</p> <p><u>Foods or categories of foods to which particular groups of essential nutrients may not be added may be determined by national authorities taking into account their nutritional value. In addition, essential nutrients should not be added to alcoholic beverages and unprocessed foods, including, but not limited to, fruit, vegetables, meat, poultry and fish.</u></p> <p>Recommendation: Propose retaining option 1 with options for wording and consider the proposal to combine proposed 3.3.4 and 3.3.5 with new 3.3.2.</p>	<p>3.3.2 (new) <u>The selection of appropriate foods [or categories of foods] to which essential nutrients [may] / [may not] be added should take into account the nutritional value of the foods and is best determined by National Authorities.</u></p> <p><u>[In addition, essential nutrients should not be added to alcoholic beverages and unprocessed foods, including, but not limited to, fruit, vegetables, meat, poultry and fish.] (Note: with this option, new 3.3.4 and 3.3.5 would be deleted.)</u></p> <p>Or</p> <p><u>Foods or categories of foods to which particular groups of essential nutrients may not be added may be determined by national authorities taking into account their nutritional value.</u></p>
<p>3.3.4 (new) <u>Essential nutrients should not be added to unprocessed foods, including, but not limited to, fruit,</u></p>	<p>Summary: All CMC and 2 COs agreed with this principle. One CMC and 1 CMO believed it</p>	<p>3.3.4 (new) <u>Essential nutrients should not be added to unprocessed foods, including, but not</u></p>

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<u>vegetables, meat, poultry and fish.</u>	should be deleted. The CMO believes that this principle is not relevant to international guidelines. Recommendation: Retain as is and further discuss in committee if it should be deleted or combined with 3.3.2..	<u>limited to, fruit, vegetables, meat, poultry and fish.</u>
3.3.5 (new) <u>Essential nutrients should not be added to alcoholic beverages. containing more than 1.2% by volume of alcohol</u>	Summary: There was general agreement with this principle except for one CMC and 1 CMO. The CMO thought it should be deleted as they believe it is not relevant within the context of international guidelines. The CMC suggested combining 3.3.4 and 3.3.5 with a revised 3.3.2. Recommendation: Retain as is and further discuss in committee if it should be deleted or combined with 3.3.2.	3.3.5 (new) <u>Essential nutrients should not be added to alcoholic beverages. containing more than 1.2% by volume of alcohol</u>
<u>3.4 (new) Technological aspects</u>		<u>3.4 (new) Technological aspects</u>
3.4.1 (new) The sources of the <u>added</u> 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 <u>in the following order</u> : 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, or national legislation. may be used.	Summary: The CMO proposed to delete the section on technological aspects as many of the issues covered (3.4.2., 3.4.3 and 3.4.4) are not principles and their intended purpose may be met by 3.2.7.. They also recommended that section 3.4.1 be moved to section 3.2 (selection of nutrients and determination of amounts). One CMC also suggested moving 3.4.1 to section 3.2. Another CMC supported keeping 3.4.1 but has no preference for the need for 3.4.2 – 3.4.4 The CMO suggests purity criteria should not be prioritised but just listed. Recommendation: Retain with the text as proposed as there are no real objections to the content of 3.4.1, except the recommendation to delete “in the following order”. The committee may wish to discuss the possibility of moving this principle to section 3.2 and all others support it staying in this section.	3.4.1 (new) The sources of the <u>added</u> 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 <u>[in the following order]</u> : 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, or national legislation. may be used.
3.4.2 <i>Former 3.4 with modifications</i> The <u>added</u> essential nutrient should be sufficiently stable in the	Summary: All members except the CMO were either ok with this principle or did not provide	3.4.2 <i>Former 3.4 with modifications</i> The <u>added</u> essential nutrient should be sufficiently stable in

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<p>food under customary conditions of <u>processing</u>, packaging, storage, distribution and use.</p>	<p>comments. As noted above, the CMO suggested deleting the principle. Recommendation: Retain with the text as proposed</p>	<p>the food under customary conditions of <u>processing</u>, packaging, storage, distribution and use.</p>
<p>3.4.3 <i>Former 3.6</i> The added 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>Summary: One CMC suggests wording change to convey that changes to the original food characteristics should be “minimal”. Although as proposed it reads that the nutrient added should have minimal impact – there may be a desire for a positive impact from the nutrient. The original wording seems to adequately cover negative impacts. Recommendation: Retain with the text as proposed as most of members agreed with retaining this principle as written but consider change suggested by one member..</p>	<p>3.4.3 <i>Former 3.6</i> The <u>added</u> essential nutrient should [have minimal impact on the original food characteristics] / [not impart undesirable characteristics to the food] (e.g. colour, taste, flavour, texture, cooking properties) and should not unduly shorten shelf-life.</p>
<p>3.4.4 <i>Former 3.7</i> Technology and processing facilities should be available to permit the [standardized] addition of the essential nutrient to a food in a [satisfactory manner] <u>[manner to ensure nutrient availability, consistency, distribution and stability]</u>.</p>	<p>Summary: Most agree to keep (except one CMO and 1 CO). One CMC suggests deleting “standardized” and replace availability with “bioavailability”. Others have not made specific comments on the text in square brackets. Recommendation: Keep text as proposed with the replacement of availability with bioavailability and discuss whether reference to standardised is required given the second text in square brackets.</p>	<p>3.4.4 <i>Former 3.7</i> Technology and processing facilities should be available to permit the [standardized] addition of the essential nutrient to a food in a [satisfactory manner] <u>[manner to ensure nutrient [bio]availability, consistency, distribution and stability]</u>.</p>
<p>Former 3.5 The essential nutrient should be biologically available from the food.</p>	<p>Summary: All members agreed to delete this principle or had no comments. Three members stated that they agreed with the deletion if 3.4.1 and 3.4.4 were kept. Recommendation: Delete this principle.</p>	<p>Former 3.5 The essential nutrient should be biologically available from the food.</p>
<p>3.5 Monitoring</p>	<p>There was general agreement to have a section on monitoring.</p>	<p>3.5 Monitoring</p>
<p><i>Former 3.10</i> Methods of measuring, controlling and/or enforcing the levels of added essential nutrients in foods should be available to monitoring bodies to facilitate efficient monitoring of those products -</p>	<p>It was proposed to delete this principle. Summary: 3 CMCs and the CMO agreed, and 7 had no comments. 3 COs agreed.</p>	<p><i>Former 3.10</i> Methods of measuring, controlling and/or enforcing the levels of added essential nutrients in foods should be available to monitoring bodies to facilitate efficient monitoring of those products -</p>

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	<p>Recommendation: Delete the principle since it expresses a basic expectation underlying Codex standards and does not need to be repeated here.</p>	
<p>3.5.1 (new) National authorities should monitor population total intakes, <u>from all sources</u>, of the nutrients essential added to foods from all dietary and supplement sources and <u>in order to</u> assess the extent to which the public health need [or other purpose for addition] is addressed and to ensure that any risk of excessive intakes is minimised.</p>	<p>Summary 6 CMCs agreed, and 2 had no comment. 3 COs agreed, and one recommended that it be deleted as not necessary.</p> <p>2 CMCs and the CMO generally supported this section, but proposed re-wording. Two CMCs recommended similar changes for re-wording so that what would be monitored are “intakes from all sources including the essential nutrients added to foods.” The CMO’s suggested rewording is based on the fact that they consider the monitoring of total intakes by national authorities as important, rather than an obligation.</p> <p>Recommendation: Consider the changes proposed and discuss whether the change regarding what would be monitored is changing the meaning to surveillance of all nutrient intake rather than monitoring of the impact of the nutrients added. Also, it should be discussed whether this principle should be expressed as an obligation or something important to do.</p>	<p>3.5.1 (new) <u>[It is important that National authorities] / [National authorities should]</u> monitor population total intakes, <u>from all sources, including</u> of the essential nutrients essential added to foods from all dietary and supplement sources and <u>in order</u> to assess the extent to which [the <u>selected</u> public health need for other purpose for addition] <u>or [the purposes identified in 3.1.1]</u> is addressed and to ensure that any risk of excessive intakes is minimised.</p>
<p>3.5.2 (new) <u>Monitoring of total nutrient intakes should use the same [method]/[approach] as used in deciding the nutrient addition.</u></p>	<p>Summary 3 CMCs and the CMO preferred the term “approach”, and 5 had no preference or made no comment. One CO preferred “approach”, 2 had no preference, and one suggested deletion. One agreed with the paragraph, but questions whether a reference should be provided that links to the approach for deciding the nutrient addition.</p> <p>2 CMCs did not generally support this principle. One stated that the main purpose of monitoring is to measure changes after an intervention, and this</p>	<p>3.5.2 (new) <u>Monitoring of total nutrient intakes should use the same method/approach as used in deciding the nutrient addition.</u></p>

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	<p>could be done using other measures such as blood or urinary data. The US similarly stated that approaches used to decide on levels of foods for nutrient addition are not the same as those used for monitoring total intakes after implementation.</p> <p>Recommendation: Retain the principle for further discussion in Committee regarding the validity of needing to use the same approach for both assessment and monitoring.</p>	
<p>4.0 Specific Type of Nutrient Addition</p>	<p>Summary: Only 4 CMCs and one CO commented on this title. Two CMCs suggested adding the words “Principles for” at the beginning. Another suggested deleting “specific”. The other agreed with it as is.</p> <p>Recommendation: Retain title with proposed changes for consideration by the Committee.</p>	<p>4.0 [Principles for] [Specific] Types of Nutrient Addition</p>
<p>4.1 (new) Nutrient Addition <u>Mandated</u> For Purposes of fortification <u>[Correcting]/[Reducing] Inadequate Intakes</u></p>	<p>Question general to 4.1: Do you agree with the title of this section and the justification that there are some principles unique to mandated addition? You may wish to make specific comments under each of the proposed principles.</p> <p>Summary Response to this title was mixed and showed certain fundamental differences in understanding. The CMO indicated that they believe that there are some principles that apply to mandatory addition only but that the title should not specify the purposes, since “it is the responsibility of National Authorities to decide the public health reason that is the basis for the mandatory addition.” They would like the title to read, “Mandatory addition of essential nutrients”. They consider that the principles that apply to mandatory addition only are the ones in 4.1.1 through 4.1.5, with some limited changes. They</p>	<p>4.1 (new) Nutrient <u>Addition of Essential Nutrients [to Address a Demonstrated Public Health Need] [and Mandatory Addition] <u>Mandated</u> For Purposes of fortification <u>[Correcting]/[Reducing] Inadequate Intakes</u></u></p>

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	<p>considered that any voluntary addition is covered under Section 3. On the other hand, two of the CMCs clearly did not believe that the principles in 4.1 only apply to mandatory addition but could apply to voluntary addition that is intended to address a public health need, such as deficiencies or inadequate intakes or potentially inadequate intakes, etc. of essential nutrients. Further, the CMO believes that mandatory addition should not be tied to one specific purpose, whereas the 2 CMCs believe that addressing a public health need should not be tied only to mandatory addition and consider that the principles in 4.1 are about addressing a public health need. They also consider that other types of addition, e.g. restoration, can be mandatory and this is another reason not to put “mandatory” or “mandated” in the title of this section.</p> <p>Among the other CMCs who commented, three were okay with the proposed title, two were okay with the first part of the title but suggested changes to the wording after “Purposes of”, and two others preferred “mandatory” to “mandated”.</p> <p>Among the COs, 2 preferred the words “Mandatory” to “mandated” and one other was okay with the proposed title.</p> <p>Recommendation: Since there is a desire from different parties to keep these principles but for different reasons leading to different views on the title, the Committee may wish to consider putting both concepts in the title and seek to make further distinctions regarding the intent in the text within the section.</p>	

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<p>4.1.1 <i>Former 6.2.1</i> There should be a demonstrated <u>public health</u> need for increasing the intake of an essential nutrient in one or more populations groups through <u>mandated addition</u>. [through fortification]. This may be in the form of need may be demonstrated by actual clinical or subclinical evidence of deficiency, estimates indicating low <u>inadequate</u> or <u>potentially inadequate</u> levels of intake of nutrients or <u>by estimates of</u> possible deficiencies likely to develop because of changes taking place in food habits. <u>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></p>	<p>Summary: 3 CMCs agreed with the wording proposed, the CMO agreed but preferred the word “mandatory” to “mandated”. 3 did not comment and the others proposed changes. Similarly, one CO agreed, and 2 COs suggested changes. One CMC preferred retaining the definition of fortification similar to its current meaning and thus suggested using the term here. This CMC and one other, as above, feel that either voluntary or mandatory addition can be used to address a demonstrated public health need. One proposed adding wording to clarify this point. Other comments were related to what should be included as to how a need might be demonstrated. Among these were suggestions to either delete different parts of the second sentence or make changes to deal with what appeared to be a weak basis for demonstrated need. One CO agreed with the paragraph as amended but commented that the obligation to demonstrate a public health need should apply to both mandatory and voluntary addition of essential nutrients and that the point should therefore be stated as part of the fundamental principles.</p> <p>Recommendation: Retain the principle here with consideration of changes proposed by various members. An effort was made to retain all the various possible ways suggested to express how a need might be demonstrated in a way by which the Committee can review them one by one. Most recent new ones are in square brackets.</p>	<p>4.1.1 <i>Former 6.2.1</i> There should be a demonstrated <u>public health</u> need for increasing the intake of an essential nutrient in one or more populations groups <u>[through mandated addition]</u> <u>[which may be accomplished by mandatory addition of essential nutrients. A demonstrated public health need, however, may also be addressed through voluntary addition.]</u> [through fortification]. This may be in the form of need may be demonstrated by actual clinical or subclinical evidence of deficiency, <u>subclinical evidence of deficiency, [suboptimal nutritional status], [evidence from valid biochemical indicators]</u>, estimates indicating low <u>inadequate</u> or potentially inadequate intake of nutrients, estimates indicating <u>potentially inadequate intakes of nutrients, and/or by estimates of</u> 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>4.1.2 <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 <u>of inadequate intake</u>.</p>	<p>Summary 3 CMC and the CMO agreed with this principle as stated, and 3 CMC had no comment. 3 of the COs also agreed; one recommended that this be included under “fundamental principles”.</p>	<p>4.1.2 <i>Former 6.2.2</i> The food(s) selected as a vehicle for the <u>added</u> essential nutrient(s) should be consumed by the population at risk <u>[of inadequate intake]</u>.</p>

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	<p>Four other CMCs generally supported this section, but proposed re-wording or re-organizing. One believes this could be part of the General Principles. One proposed retaining the original text, and deleting “of inadequate intake“. Another stated that they consider that more than one food may be selected as a vehicle, and thus suggest referring to “food(s)” in this provision and in 4.1.3 and 4.1.4. And another provided revisions:</p> <p style="padding-left: 40px;">4.1.2 The selected target food as a vehicle for addition of the essential nutrient(s) should be consumed in habitual amounts by the population at risk of inadequate intake.</p> <p>Recommendation: It is recommended to keep the principle in this section with minor edits as shown. The text, “of inadequate intake” is placed in square brackets for further discussion.</p>	
<p>4.1.3 <i>Former 6.2.4</i> The amount of the essential nutrient added to the food should be sufficient to [reduce inadequate intakes] [correct or prevent the deficiency] when the food is consumed in [normal] [habitual] amounts by the population at risk.</p>	<p>Summary 3 CMC agreed, and 3 CMC had no comment. One CO agreed. Three other COs also agreed, but suggested re-wording or re-organizing.</p> <p>4 CMC and the CMO generally supported this section, but proposed re-wording or re-organizing.</p> <p>Recommendation: Further changes are proposed based on suggestions by several participants, including removing the end of the sentence since the points are covered in 4.1.2 or 4.1.4. Also, it was felt that using “public health need” may be broad enough to cover all intended purposes under this section although the CMO indicated that both inadequate intake and correct or prevent deficiency should be retained.</p>	<p>4.1.3. The amount of the essential nutrient added to the food should aim to be sufficient to reduce inadequate intakes] [correct or prevent the deficiency] meet the public health need when the food is consumed in habitual amounts by the population at risk.</p>
<p>4.1.4. <i>Former 6.2.3</i> The intake of the food selected as a vehicle should be stable and uniform and the [lower and upper levels of intake] [amount of the food consumed by the lower and upper percentiles of the</p>	<p>Summary 4 CMC and the CMO agreed with the text as proposed, and 4 CMC had no comment. 2 CO agreed with it and 2 others also agreed, but</p>	<p>[Switch order with 4.1.3]: 4.1.4. <i>Former 6.2.3</i> The intake of the food selected as a vehicle should be stable and uniform and the [lower and upper levels of intake] [amount of the</p>

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<p>population] should be known.</p>	<p>suggested re-wording or re-organizing.</p> <p>2 CMC generally supported this section, but proposed re-wording or re-organizing. One suggested keeping only the latter part of the sentence so that it would start “The amount...” Another suggested minor rewording, and also proposed that the section be moved right after 4.1.2 as it is about the food vehicle and this would keep principles about the food vehicle together.</p> <p>Recommendation: Retain the text as proposed and suggest switching the order with 4.1.3 to follow 4.1.2.</p>	<p><u>food consumed by the lower and upper percentiles of the population]</u> should be known.</p>
<p>6.2.5 The amount of the essential nutrient added should not result in excessive intakes by individuals with a high intake of a fortified food.</p>	<p>Question: Can this be considered to be covered in 3.2.1?</p> <p>6.2.5 The amount of the essential nutrient added should not result in excessive intakes by individuals with a high intake of a fortified food.</p> <p>Recommendation: There was agreement to remove this principle since it is already covered.</p>	<p>6.2.5 The amount of the essential nutrient added should not result in excessive intakes by individuals with a high intake of a fortified food.</p>
<p>3.9 The additional cost [of mandatory addition of essential nutrients to foods] should be reasonable for the intended consumer.}}</p> <p><u>4.1.5 Former 3.9 revised</u> The cost effectiveness of the addition of essential nutrients to foods for the intended consumer should be considered.</p>	<p>Questions: Do you agree with the changes to this principle? Do you agree with the suggestion to move this principle to section 3?</p> <p>Summary: 3 CMC and one CO stated they “agreed”, but did not specify what question they were answering.</p> <p><u>Regarding changes to this principle:</u> Only 4 CMC responded directly to this question, and indicated support. No CMC indicated they did not support the changes. 2 COs agreed. 2 others also agreed, but suggested re-wording or re-organizing.</p> <p>One CMC stated that cost-effectiveness is not</p>	<p><u>4.1.5 Former 3.9 revised</u> The cost effectiveness of the addition of essential nutrients to foods for the intended consumer should be considered.</p>

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	<p>only related to the intended consumer, and as a result suggested removing that part of the sentence.</p> <p>Another CMC agreed that this wording was preferable to the original wording in 3.9; however, they were uncertain about the appropriateness of addressing cost considerations in a Codex text.</p> <p><u>Question regarding moving this principle to section 3:</u></p> <p>3 CMC agreed with moving to Section 3; 3 CMC and the CMO, and 2 COs did not agree with moving the text; and 2 CMC and one CO did not comment on this question.</p> <p>Of these, one of the CMC suggested that since this principle is relevant to all forms of addition, it should be moved to Section 3. Others thought that it applied better to mandatory addition of nutrients (or to correct inadequate intakes), and therefore was best retained in this section.</p> <p>Recommendation: Retain the principle as revised. The committee may wish to discuss where to place the text, in Section 4.2 or Section 3.1.</p>	
<p>4.2 Nutrient Addition for Purposes of Restoration</p>	<p>Question: Do you consider that this section should be deleted? Please explain why there is or is not the need to retain these principles.</p> <p>Summary: 8 CMC, and 3 CO believed this principle should be retained. Reasons for retaining this section included that this is a type of addition practiced in many countries. One CMC stated that it should be retained given that it identifies specific principles relevant to one or more purposes in 3.1.1.</p> <p>The CMO and one CO believed it should be deleted. The CMO considered that this section</p>	<p>4.2 Nutrient Addition for Purposes of Restoration</p>

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	<p>should be deleted, as the purposes of addition of essential nutrients to foods and the principles applicable to all types of addition, are laid down in the Introduction section and in section 3 of the document. They indicated that they would welcome a discussion about the relevance of including principles or guidance for the different types of nutrient addition in international guidelines.</p> <p>1 CMC had no comment. The comment of one CMC was not clear.</p> <p>Recommendation: This section should be retained and discussed further at the Committee. A discussion could seek greater understanding of the rationale for keeping or not keeping these sections in the General Principles in order to make a decision.</p>	
<p>4.2.1 <i>Former 4.1</i> Where the food has been identified as a significant contributor to intake source of energy and/or essential nutrients in the food-supply population group(s), and particularly where there is demonstrated evidence of public health need, restoration of the essential nutrients of concern lost during processing, storage or handling, should be [strongly recommended]/[carefully considered].</p>	<p>Summary <u>Preference of “Strongly recommended” vs “carefully considered”</u> Only 1 CMC and 2 CO preferred the “carefully considered” wording; however, 2 of these believed the word “carefully” was unnecessary.</p> <p>5 CMC and 1 CO preferred “strongly recommended” or simply “recommended”. 3 of these 5 CMC stated they preferred the term “recommended”. 3 CMC and the CMO had no comments.</p> <p><u>Other comments</u> 2 CMC and 1 CO suggested deleting the word “energy”. In contrast, one CMC suggested retaining the word “energy”. One CMC also suggested deleting the word “demonstrated”. One CO supported use of “contributor to intake”</p> <p>Recommendation:</p>	<p>4.2.1 <i>Former 4.1</i> Where the food has been identified as a significant [source] [contributor to intake] of [energy and/or] essential nutrients in the food-supply population group(s), and particularly where there is [a] demonstrated evidence of public health need, restoration of the essential nutrients of concern lost during processing, storage or handling, should be [strongly recommended]/[carefully considered].</p>

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	<p>Retain the principle with changes. There appears to be a slight preference for retaining “recommended” as opposed to “strongly recommended” and for using either of those as opposed to “carefully considered”. Also, it is suggested that it may not be necessary for a food to be considered for restoration if it is only a significant source of energy and not of any essential nutrient and therefore the word “energy” could be proposed for deletion.</p>	
<p>4.2.2 <i>Former 4.2</i> A food should be considered a significant contributor to intake source of an essential nutrient if the edible portion of the food prior to processing, storage or handling contains the essential nutrient in amounts equal to or greater than 10% of the [recommended nutrient intake]/ [NRV]/ [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]/[INL 98], 10% of the average daily intake of the nutrient).</p>	<p>Question: On which type of reference value should the 10% calculation be based?</p> <p>Summary 3 CMC and 3 CO supported using the NRV as a first option, and reasons included “because they are more general and this ensures their ease of use”. 3 CMC suggested that “recommended nutrient intake” be used which may be interpreted broadly, or alternatively basing the calculation on NRV for the general population as it is a single reference value. One CMC recommended using INL98. Another recommended using the Daily Intake Reference Value. 2 CMC had no comment.</p> <p>Other comments One CMC recommended changing the term <i>intake</i> to <i>consumption</i> to distinguish nutrient intake from food consumption. Another CMC suggested using the word « may » instead of « should », and “habitual daily intake” instead of “reasonable daily intake”. One CO also suggested this.</p> <p>Discussion A value of 10% is an arbitrary value and the choice of 10% of either NRV or INL 98 would provide different values. The intent of the two principles in this section is to ensure that nutrient</p>	<p>4.2.2 <i>Former 4.2</i> A food should be considered a significant contributor to intake source of an essential nutrient if the edible portion of the food prior to processing, storage or handling contains the essential nutrient in amounts equal to or greater than 10% of the [daily intake reference value]/ [recommended nutrient intake]/ [NRV]/ [INL 98] in a reasonable daily [intake] / [consumption] of the food (or in the case of an essential nutrient for which there is no [daily intake reference value]/ [recommended intake]/ [NRV]/[INL 98], 10% of the average daily intake of the nutrient).</p> <p>[Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this nutrient need not be restored.]</p>

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	<p>intakes are not adversely affected by food processing and that countries make an effort to address the nutrient losses where they are significant to the population.</p> <p>An option proposed by one of the CMC was to refer to the generic term “daily intake reference value”, which has been adopted in the Codex General Principles for Establishing Nutrient Reference Values (NRVs).¹</p> <p>However, there would still be a requirement to select an individual reference value upon which the 10% would be calculated, as with INL98 or recommended nutrient intake. This may be acceptable because it leaves National Authorities the responsibility to determine which reference value is appropriate. For instance, in Canada, Weighted Recommended Nutrient Intakes or WRNI were established for this purpose by determining the population weighted average of the RNIs, which were the recommended intake values for Canadians in existence at that time.</p> <p>Recommendation: Retain the principle with alternatives proposed for further consideration. The Committee may wish to discuss the degree of precision that is in this principle as well as the choice of the basis for the calculation. Alternatively, the Committee may wish to consider deleting this principle and leave the decision as to what “significant contributor” means to National Authorities.</p> <p>Also, as proposed by one CMC under 4.3.3, the</p>	

¹ Daily intake reference value is defined as:

“Daily Intake Reference Values as used in these principles refer to reference nutrient intake values provided by FAO/WHO or other recognized authoritative scientific bodies that may be considered in establishing an NRV. These values may be expressed in different ways (e.g. as a single value or a range), and are applicable to the total population or to a segment of the population (e.g. , recommendations for a specified age range). For macronutrients, they are generally expressed as a percentage of energy intake.”

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	<p>Committee may wish to consider the value of adding a statement similar to the following one that appears in 4.3.2 (and 4.3.3). “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.” The word “equivalent” could be replaced with “restored”.</p>	
<p>4.3 Nutrient Addition for Purposes of Nutritional Equivalence</p>	<p>Question: Do you consider that this section should be deleted? Please explain why there is or is not the need to retain these principles.</p> <p>Summary 7 CMC and 3 CO supported retaining this section, and reasons included that many countries apply this principle, and that this section clarifies when this type of addition should be done. One CMC and the CMO supported deleting this. The CMC provided no rationale and the CMO referred to comments made in 4.2. Another CMC had no comments. The comments of one CMC were not clear.</p> <p>Recommendation: This section should be retained and discussed further at the Committee. A discussion could seek greater understanding of the rationale for keeping or not keeping these sections in the General Principles in order to make a decision.</p>	<p>4.3 Nutrient Addition for Purposes of Nutritional Equivalence</p>
<p>4.3.1 <i>Former 5.1</i> Where a substitute food is intended to replace a food which has been identified as a significant source <u>[contributor to intake]</u> of energy and/or essential nutrients in the food supply <u>[population group(s)]</u>, 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.</p>	<p>Summary 6 CMC and 3 CO agreed to retaining the principle. 4 CMC and one CMO had no comments.</p> <p>Of those agreeing to retain, some CMC and 2 CO suggested either deleting “energy”, or putting it into brackets. One CMC and one CO suggested deleting “strongly”.</p> <p>One CMC suggested deleting « contributor to</p>	<p>4.3.1 <i>Former 5.1</i> Where a substitute food is intended to replace a food which has been identified as a significant <u>[source]</u> / <u>[contributor to intake]</u> of <u>[energy and/or]</u> essential nutrients in the food supply <u>[population group(s)]</u>, and particularly where there is <u>[a]</u> demonstrated evidence of public health need, nutritional equivalence in terms of the essential nutrients of concern should be <u>[strongly]</u> <u>[recommended]</u>/ <u>[considered]</u>.</p>

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	<p>intake » and using « source ».</p> <p>In the case of this principle, unlike 4.2.1, alternative wording to “strongly recommended” was not proposed. In 4.2.1, there appeared to be a slight preference for retaining “recommended” as opposed to “strongly recommended”. Here, there were only three comments related to this part of the principle and in 2 cases, it was again suggested to remove “strongly”. The third comment was to use “considered”. Also, similar to 4.2.1, it is suggested that it may not be necessary to retain the word “energy” and this could be proposed for deletion.</p> <p>Recommendation: Retain the principle with changes similar to 4.2.1.</p>	
<p>4.3.2 <i>Former 5.2</i> A food being substituted or partially substituted should be considered a significant source<u>contributor to intake</u> of an essential nutrient if a serving or portion or 100 kcal of the food contains the essential nutrient in amounts equal to or greater than 5% of the [recommended nutrient intake]/[NRV]/ [INL 98].</p> <p>Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this nutrient need not be equivalent.</p>	<p>Summary 2 CMC and 1 CO supported using NRV. 1 CMC supported using INL98. 3 CMC and one CMO had no comments.</p> <p>3 CMC had other recommendations/comments:</p> <p>One suggested including the kJ equivalent for 100 kcal and using daily intake reference value as the basis for the 5% calculation.</p> <p>Another questioned why the definition for “significant contributor to intake” is not the same in the case of restoration and nutritional equivalence. They considered that it might be worthwhile to re-look at how these particular benchmarks for restoration and nutritional equivalence were derived and determine if they should be revised. They also suggested removing the second sentence as it is covered as a separate principle in 4.3.3.</p>	<p>4.3.2 <i>Former 5.2</i> A food being substituted or partially substituted should be considered a significant source<u>contributor to intake</u> of an essential nutrient if a serving or portion or 100 kcal of the food contains the essential nutrient in amounts equal to or greater than 5% of the [recommended nutrient intake]/[NRV]/ [INL 98]. [Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this need not be equivalent.]</p>

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	<p>Another commented they were uncertain about the intent of the provision in the first sentence with either the original wording or proposed edits but supported retaining the second principle (former 5.3).</p> <p>One CO commented that this proposal is only relevant for foods that provide calories; others such as seasonings, bouillons, waters etc. with zero or very low calorie content would need another approach.</p> <p>Recommendation: Similar to 4.2.2, retain the principle with alternatives proposed for further consideration. The Committee may wish to discuss the degree of precision that is in this principle as well as the choice of the basis for the calculation. Alternatively, the Committee may wish to consider deleting this principle and leave the decision as to what “significant contributor” means to National Authorities.</p>	
<p>4.3.3 <i>Former 5.3</i> Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this nutrient need not be equivalent.</p>	<p>Summary 5 CMC supported this section. 5 CMC and the CMO had no comment One CMC suggested deleting “for their intended use”. Another wondered whether a similar statement is needed for restoration. One CO considers the objective of this sentence is not clear.</p> <p>Recommendation: Retain the principle for further consideration by the Committee, including consideration of its placement in the document.</p>	<p>4.3.3 <i>Former 5.3</i> Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this nutrient need not be equivalent.</p>
<p>4.4 Nutrient addition to Special Purpose Foods</p>	<p>Summary 6 CMC supported retaining this section. 3 CMC and 3 CO recommended deleting this section. 1 CMC had no comment. The comments</p>	<p>4.4 Nutrient addition to Special Purpose Foods</p>

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	<p>of one CMC were not clear.</p> <p>The CMO considers that there is no need for a section that covers "special purpose foods" as these foods are covered by other relevant Codex standards and guidelines, such as those for foods intended for infants and young children and for use in Very Low Energy Diets. They note that these Codex standards have been adopted or amended <u>after</u> the last revision of the General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987) in 1991. Therefore, they considers that the revision of the General Principles document provides an opportunity to bring it in line with these more recently updated Codex standards for foods that are designed to perform a specific function. In addition, deletion of this section would remove any confusion resulting from the inclusion of principles related to "special purpose foods" in the General Principles for the addition of essential nutrients to foods. Therefore, the CMO would prefer deletion of this section and the definition of "special purpose foods" in section 2.</p> <p>Comment from the chair: It may be worth considering whether having this principle here serves as the Codex General Principle that provides for the existence of the other standards for foods with added essential nutrients. Also, please refer to notes above associated with 2.9, Definition of Special Purpose Food.</p> <p>Recommendation: Retain for further discussion by the Committee.</p>	
<p>4.4.1 Former 7.1 [Essential] nutrients may be added to special purpose foods, including foods for special dietary uses, to ensure an appropriate and adequate nutrient content [for their intended use] [based on the principles in this guidance wherever applicable]. Where appropriate, such addition should be made with due regard to the nutrient [composition] [density] of</p>	<p>Question: Is this (i.e. deletion of "nutrient density" and replacing it with "nutrient composition") an acceptable change? If not, please explain.</p> <p>Summary 5 CMC agreed with the change referred to in the question. 2 suggested deleting the square brackets</p>	<p>4.4.1 Former 7.1 [Essential] nutrients may be added to special purpose foods, including foods for special dietary uses, to ensure an appropriate and adequate nutrient content [for their intended use] [based on the principles in this guidance wherever applicable]. Where appropriate, such addition should be made with due regard to the</p>

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<p>such foods. <u>[Consideration should be given to the target population and their nutrient requirements based on general reference intakes such as RNIs.]</u></p>	<p>throughout the principle. 3 CMC and the CMO had no comments.1 CO agreed with the deletion of “density”.</p> <p>2 CMC suggested further changes similar to each other. Because of the definition of special purpose food, the text could be simplified. Also the second and third sentences were suggested for deletion because they are not needed or not clear as to their meaning. For the last sentence, one of the CMCs suggested some further edits, consistent with changes proposed above in 4.2 and 4.3. This version is shown as “alternative” in the right hand column.</p> <p>Recommendation: Retain the principle and consider changes proposed by 2 CMCs.</p>	<p>nutrient [composition] {density} of such foods. <u>[Consideration should be given to the target population and their nutrient requirements based on general reference intakes such as RNIs.]</u></p> <p><i>Alternative:</i> [Essential] nutrients may be added to special purpose foods [,-including foods for special dietary uses,-] to ensure an appropriate and adequate nutrient content [for their intended use][based on the principles in this guidancee 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 nutrient requirements [of the target population] based on [general] [relevant] [daily intake reference values] [such as RNIs].</p>

Table 2: Proposed Revised Text showing changes

Table 2: Proposed Revised Text showing changes (from Column 3 of Table 1)
<p>INTRODUCTION</p> <p>(Revised) The [General Principles] [Guidelines] for the Addition of Essential Nutrients to Foods (the Principles) provide a framework for the addition of essential nutrients to food and are intended to provide guidance to [National Authorities] [these] responsible for developing guidelines and legal texts pertaining to the addition of essential nutrients to foods to establish a uniform through the establishment of a set of principles that serve as a basis for the rational and safe pertaining to the addition of essential nutrients to foods.</p> <ul style="list-style-type: none"> • To maintain and improve the overall nutritional quality of foods. • 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. • To facilitate acceptance in international trade of foods which contain added essential nutrients. <p>(new) The [General Principles] [Guidelines] for the Addition of Essential Nutrients to Foods take into consideration provisions in are consistent and used in conjunction with the Codex Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses (CAC Procedural Manual), where applicable.</p> <p>(new) The [General Principles] for the Addition of Essential Nutrients to Food are applicable, as appropriate, to both mandatory and voluntary addition of essential nutrients unless otherwise indicated.</p> <p>(new) National authorities should may also consult the FAO/WHO publications <i>Guidelines on food fortification with micronutrients (WHO, 2006)</i> for further guidance on nutrient addition. information.</p>
<p>1. SCOPE</p> <p>These [Principles] [Guidelines] are intended to apply to the addition of all foods to which essential nutrients to foods are added, <u>not including vitamin and mineral food supplements¹</u>.</p> <p>¹See the Codex <i>Guidelines for Vitamin and Mineral Food Supplements</i> (CAC/GL-55-2005)</p>
<p>2. [DEFINITIONS] [DESCRIPTION]</p> <p>For the purpose of these [Principles] [Guidelines]:</p> <p>[2.1 Nutrient means any substance normally consumed as a constituent of food:</p> <p>(a) which provides energy; or</p> <p>(b) which is needed for growth and development and maintenance of healthy life; or</p> <p>(c) a deficit of which will cause characteristic bio-chemical or physiological changes to occur.]</p>
<p>2.2 Essential nutrient means any substance normally consumed as a constituent of food which is needed for growth and development and the maintenance of healthy life and which cannot be synthesized in adequate amounts by the body.</p>

Table 2: Proposed Revised Text showing changes (from Column 3 of Table 1)
<p>2.3 (former 2.4) <i>Substitute food</i> is a food which is designed to resemble a common food in appearance and texture, [flavour and odour], and is intended to be used as a complete or partial replacement for the food it resembles, [e.g., plant protein-based beverages as a replacement for milk.]</p>
<p>2.4 (former 2.3) <i>Nutritional equivalence</i> means being of the addition of one or more essential nutrient to a substitute food to achieve a similar nutritive value to its normal counterpart in terms of quantity and quality of protein and in terms of kinds, quantity and bioavailability of essential nutrients. For this purpose, nutritional equivalence means that essential nutrients provided by the food being substituted, that are present in a serving or portion or 100 kcal of the food at a level of 5% or more of the recommended intake of the nutrient(s) are present in the substitute or partially substituted food (extender) in comparable amounts. [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.]]</p>
<p>If retained, Proposed revised definition for option 3):</p>
<p>2.5 <i>Fortification</i> 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]. for the purpose of preventing or correcting improving population health by addressing a demonstrated deficiency of one or more nutrients in the population or specific population group(s).</p>
<p>2.8 <i>Restoration</i> means the addition to a food of essential nutrient(s) which are in amounts to replace those lost during the course of good manufacturing practice, or during normal storage and handling procedures, [or in order to compensate for natural variations in essential nutrients.] 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>2.6 (new) Mandatory nutrient addition is occurs when National Authorities governments require food manufacturers to add specified essential nutrients to particular foods or food categories. of foods. [for a specific purpose.</p>
<p>2.7 (new) Voluntary nutrient addition is when a National Authorities permit food manufacturers may chooses to add specified essential nutrients to particular foods or food categories. [for a specific purpose.] within specified limits.</p>
<p>2.9 <i>Special purpose foods</i> are foods that have been designed to perform a specific function, such as to replace a meal, which necessitates a content of essential nutrients which cannot be achieved except by addition of one or more of these nutrients. These foods include but are not limited to foods for special dietary use, [and also include foods intended for infants and young children].</p>
<p>2.10 <i>Nutrient density</i> means the amount of nutrients (in metric units) per stated unit of energy (MJ [KJ] or kcal).</p>
<p>2.11 <i>Standardization</i> means the addition of nutrients to a food in order to compensate for natural variations in nutrient level.</p>
<p>2.11 (new) <i>Population</i> refers to a national population or specific population group(s) as appropriate.</p>
<p>3. PRINCIPLES</p>

Table 2: Proposed Revised Text showing changes (from Column 3 of Table 1)
<p>3.1 (New) Fundamental {Overarching} {General} Principles</p>
<p>3.1.1 Essential nutrients may be appropriately added to foods for the purpose of:</p> <ul style="list-style-type: none"> • contributing to correcting a demonstrated deficiency or [inadequate intakes or poor nutritional status] of one or more essential nutrients in the population or specific population groups; • contributing to meeting [recommended nutrient intakes]/ [requirements] of one or more essential nutrients and reducing the risk of [inadequate intakes, poor nutritional status and/or] deficiency; • contributing to the maintenance or improvement of health and/or nutritional status of the population or specific population groups and/or • maintaining or improving the overall nutritional quality of foods;
<p>3.1.2 The above purposes may be achieved by restoration, nutritional equivalence of substitute foods, fortification nutrient addition mandated to correct inadequate intakes, and ensuring the appropriate nutrient composition of a special purpose food or other addition in accordance with these principles.”</p>
<p>3.1.3 (New) National authorities should determine whether [nutrient addition] fortification should be mandatory or voluntary [This decision may be based on severity and extent of public health need as demonstrated by scientific evidence. The kinds and amounts of essential nutrients to be added and the and food vehicle chosen to be fortified will depend upon the particular nutritional problems to be corrected or prevented, the characteristics of the target populations, and their food consumption patterns. of the area.].</p>
<p>3.1.4 The mandatory and voluntary addition of essential nutrients to foods should be in accordance with food law and other policies established by national authorities. When provision is made in national food standards, regulations or guidelines for the addition of essential nutrients to foods, specific provisions should be included identifying the target appropriate foods, the essential nutrients to be considered or to be required or permitted to be added and where appropriate the minimum and where appropriate, maximum levels at which they should be present.</p>
<p>3.1.5 (Former 3.8 with additions) Addition of essential nutrients to foods should not be used to mislead or deceive the consumer, including by presentation or labelling practices, as to the nutritional merit [or the health benefit]/[and possible additional health benefit] of the food.</p>
<p>3.2 (New) Selection of Nutrients and Determination of amounts</p>
<p>3.2.1 Former 3.2 with modifications (also considered to cover former 6.2.5): The [amount of an added] or [addition of an] essential nutrient should be [scientifically and nutritionally justified] [in line with one or more of the purposes stated in 3.1.1] and be present at a level which will not result in either an excessive intake or, for the target population, an insignificant intake of [the added] essential nutrient[s], considering [total intakes] amounts from all [relevant] other sources [including food supplements], [Upper Levels of intake and identification of special subpopulations at risk] in the diet. [Upper levels of intake based on scientific risk assessment may be used to identify the need for any restrictions on the types of foods to be fortified.]</p>
<p>3.2.2 (new) The Upper Level of Intake should be used to assess potential exposure to excessive intakes of essential nutrients and to estimate safe limits of addition for essential nutrients, [including considerations of populations at risk of excessive intake]. [This exposure assessment should also help to identify the need for any restrictions on the types of foods to which nutrients should be added.]</p>
<p>3.2.3 (new) Potential change to population intakes should be estimated as part of the decision making about nutrient addition [to evaluate safety and adequacy]. Such Assessment of potential exposure 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 daily intake reference values for adequacy and for safety (e.g. the Upper Level of Intake).”</p>

Table 2: Proposed Revised Text showing changes (from Column 3 of Table 1)

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

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

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

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

3.2.4 (new) ~~Where an Upper Level of Intake is not available, [National authorities may consider] the scientific evidence to support the safe addition of an essential nutrient [should be considered], including [demonstration of an upper level or a range of intake that is unlikely to result in adverse health effects] [or the potential relevance of Highest Observed Intake¹; 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.]

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

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

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

3.2.7 (new) ~~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 to which the nutrients are added meet the purpose of the addition of nutrients to foods as described in the Introduction of the [General Principles][Guidelines]. [Minimum amounts for the addition of essential nutrients to foods should take into account the conditions of use for a source of claim in the Guidelines for use of nutrition and health claims (CAC/GL 23-1997)]. [The minimum amount of addition of an essential nutrient should take into account the intended purpose, and all other sources of the essential nutrient in the diet, including food supplements.]~~

3.3 (New) Selection of Foods

3.3.1 (new) ~~[Certain foods {may have to} [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 in non-target populations.]~~

Or

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

Table 2: Proposed Revised Text showing changes (from Column 3 of Table 1)
<p>Or</p> <p>[The selection of food(s) to which to add an essential nutrient(s) should primarily be based on achieving appropriate purposes of nutrient addition as identified in 3.1.1.]</p>
<p>(new) [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>3.3.2 (new) <u>The selection of appropriate foods [or categories of foods] to which essential nutrients [may] / [may not] be added should take into account the nutritional value of the foods and is best determined by National Authorities.</u></p> <p>[In addition, essential nutrients should not be added to alcoholic beverages and unprocessed foods, including, but not limited to, fruit, vegetables, meat, poultry and fish.] (Note: With this option, new 3.3.4 and 3.3.5 would be deleted.)</p> <p>Or</p> <p>Foods or categories of foods to which particular groups of essential nutrients may not be added may be determined by national authorities taking into account their nutritional value.</p>
<p>[3.3.4 (new) <u>Essential nutrients should not be added to unprocessed foods, including, but not limited to, fruit, vegetables, meat, poultry and fish.]</u></p>
<p>[3.3.5 (new) <u>Essential nutrients should not be added to alcoholic beverages, containing more than 1.2% by volume of alcohol]</u></p>
<p><u>3.4 (new) Technological aspects</u></p>
<p>3.4.1 (new) The sources of the <u>added</u> 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 <u>[in the following order]</u>: <u>FAO/WHO standards, or if FAO/WHO standards are not available, international Pharmacopoeias or recognized international standards.</u> In the absence of criteria from these sources, or national legislation, may be used.</p>
<p>3.4.2 <i>Former 3.4 with modifications</i> The <u>added</u> essential nutrient should be sufficiently stable in the food under customary conditions of <u>processing</u>, packaging, storage, distribution and use.</p>
<p>3.4.3 <i>Former 3.6</i> The <u>added</u> essential nutrient should <u>[have minimal impact on the original food characteristics] / [not impart undesirable characteristics to the food]</u> (e.g. colour, taste, flavour, texture, cooking properties) and should not unduly shorten shelf-life.</p>
<p>3.4.4 <i>Former 3.7</i> Technology and processing facilities should be available to permit the [standardized] addition of the essential nutrient to a food in a <u>[satisfactory manner] [manner to ensure nutrient [bio]availability, consistency, distribution and stability].</u></p>

Table 2: Proposed Revised Text showing changes (from Column 3 of Table 1)
Former 3.5 The essential nutrient should be biologically available from the food.
3.5 Monitoring
<i>Former 3.10</i> Methods of measuring, controlling and/or enforcing the levels of added essential nutrients in foods should be available to monitoring bodies to facilitate efficient monitoring of those products.
3.5.1 (new) It is important that National authorities] / [National authorities should] monitor population total intakes, from all sources, including of the essential nutrients essential added to foods from all dietary and supplement sources and in order to assess the extent to which [the selected public health need for other purpose for addition] or [the purposes identified in 3.1.1] is addressed and to ensure that any risk of excessive intakes is minimised.
3.5.2 (new) Monitoring of total nutrient intakes should use the same method /approach as used in deciding the nutrient addition.
4.0 [Principles for] [Specific] Types of Nutrient Addition
4.1 (new) Nutrient Addition of Essential Nutrients [to Address a Demonstrated Public Health Need] [and Mandatory Addition] Mandated For Purposes of fortification [Correcting]/[Reducing] Inadequate Intakes
4.1.1 <i>Former 6.2.1</i> There should be a demonstrated public health need for increasing the intake of an essential nutrient in one or more populations groups [through mandated addition] [which may be accomplished by mandatory addition of essential nutrients . A demonstrated public health need, however, may also be addressed through voluntary addition.] [through fortification] . This may be in the form of need may be demonstrated by actual clinical or subclinical evidence of deficiency, subclinical evidence of deficiency , [suboptimal nutritional status], [evidence from valid biochemical indicators], estimates indicating low inadequate or potentially inadequate intake of nutrients, estimates indicating potentially inadequate intakes of nutrients , and/or by estimates of 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
4.1.2 <i>Former 6.2.2</i> The food(s) selected as a vehicle for the added essential nutrient(s) should be consumed by the population at risk [of inadequate intake] .
4.1.3. The amount of the essential nutrient added to the food should aim to be sufficient to [reduce inadequate intakes] [correct or prevent the deficiency] meet the public health need. when the food is consumed in habitual amounts by the population at risk.
[Switch order with 4.1.3]: 4.1.4. <i>Former 6.2.3</i> The intake of the food selected as a vehicle should be stable and uniform and the [lower and upper levels of intake] [amount of the food consumed by the lower and upper percentiles of the population] should be known.

Table 2: Proposed Revised Text showing changes (from Column 3 of Table 1)
6.2.5 The amount of the essential nutrient added should not result in excessive intakes by individuals with a high intake of a fortified food.
4.1.5 <i>Former 3.9 revised</i> The cost effectiveness of the addition of essential nutrients to foods for the intended consumer should be considered.
4.2 Nutrient Addition for Purposes of Restoration
4.2.1 <i>Former 4.1</i> Where the food has been identified as a significant <u>[source] / [contributor to intake]</u> of [energy and/or] essential nutrients in the food supply <u>population group(s)</u> , and particularly where there is <u>[a]</u> demonstrated evidence of public health need, restoration of the essential nutrients of concern lost during processing, storage or handling, should be <u>[strongly recommended]</u> / [carefully considered] .
4.2.2 <i>Former 4.2</i> A food should be considered a significant <u>contributor to intake</u> source of an essential nutrient if the edible portion of the food prior to processing, storage or handling contains the essential nutrient in amounts equal to or greater than 10% of the <u>[daily intake reference value]/ [recommended nutrient intake]/ [NRV]/ [INL 98]</u> in a reasonable daily <u>[intake]/ [consumption]</u> of the food (or in the case of an essential nutrient for which there is no <u>[daily intake reference value]/ [recommended intake]/ [NRV]/[INL 98]</u> , 10% of the average daily intake <u>of the nutrient</u>). <u>[Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this nutrient need not be restored.]</u>
4.3 Nutrient Addition for Purposes of Nutritional Equivalence
4.3.1 <i>Former 5.1</i> Where a substitute food is intended to replace a food which has been identified as a significant <u>[source] / [contributor to intake]</u> of [energy and/or] essential nutrients in the food supply <u>population group(s)</u> , and particularly where there is <u>[a]</u> demonstrated evidence of public health need, nutritional equivalence in terms of the essential nutrients of concern should be <u>[strongly] [recommended]</u> / [considered] .
4.3.2 <i>Former 5.2</i> A food being substituted or partially substituted should be considered a significant source <u>contributor to intake</u> of an essential nutrient if a serving or portion or 100 kcal of the food contains the essential nutrient in amounts equal to or greater than 5% of the <u>[recommended nutrient intake]/[NRV]/ [INL 98]</u> . Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this need not be equivalent.
4.3.3 <i>Former 5.3</i> Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this nutrient need not be equivalent.
4.4 Nutrient addition to Special Purpose Foods
4.4.1 <i>Former 7.1</i> <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] [based on the principles in this guidance wherever applicable]</u> . Where appropriate, such addition should be made with due regard to the nutrient <u>[composition] [density]</u> of such foods. <u>[Consideration should be given to the target population and their nutrient requirements based on general reference intakes such as RNIs.]</u>
<i>Alternative:</i> <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

Table 2: Proposed Revised Text showing changes (from Column 3 of Table 1)

~~regard to the nutrient [composition] [density] of such foods.~~ Consideration should be given to the nutrient requirements [of the target population] based on [general] [relevant] [daily intake reference values] [such as RNIs].

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

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

(new) The Principles take into consideration provisions in the Codex Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses (CAC Procedural Manual), where applicable.

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

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

1. SCOPE

These Principles apply to the addition of essential nutrients to foods, not including vitamin and mineral food supplements¹.

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

2. DEFINITIONS

For the purpose of these Principles:

2.2 *Essential nutrient* means any substance normally consumed as a constituent of food which is needed for growth and development and the maintenance of life and which cannot be synthesized in adequate amounts by the body.

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

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

Table 3: Proposed Revised Text from Table 2 – Clean Version
nutrients.
If retained, Proposed revised definition for option 3):
2.5 Fortification means the addition of one or more essential nutrients to a food [whether or not it is normally contained in the food].
2.8 Restoration means the addition to a food of essential nutrient(s) in amounts to replace those lost during the course of good manufacturing practice, or during normal storage and handling procedures, [or in order to compensate for natural variations in essential nutrients.]
2.6 (new) Mandatory nutrient addition is when National Authorities require food manufacturers to add specified essential nutrients to particular foods or food categories.
2.7 (new) Voluntary nutrient addition is when National Authorities permit food manufacturers to add specified essential nutrients to particular foods or food categories
2.9 Special purpose foods are foods that have been designed to perform a specific function, such as to replace a meal, which necessitates a content of essential nutrients which cannot be achieved except by addition of one or more of these nutrients. These foods include but are not limited to foods for special dietary use, [and also include foods intended for infants and young children].
2.11 (new) Population refers to a national population or specific population group(s) as appropriate.
3.0 PRINCIPLES
3.1 (New) Fundamental Principles
3.1.1 Essential nutrients may be appropriately added to foods for the purpose of: <ul style="list-style-type: none"> • contributing to correcting a demonstrated deficiency or [inadequate intakes] of one or more essential nutrients in the population; • contributing to meeting [requirements] of one or more essential nutrients and reducing the risk of [inadequate intakes and/or] deficiency; • contributing to the maintenance or improvement of health and/or nutritional status of the population and/or • maintaining or improving the nutritional quality of foods;
3.1.3 (New) National authorities should determine whether [nutrient addition] should be mandatory or voluntary [This decision may be based on severity and extent of public health need as demonstrated by scientific evidence. The kinds and amounts of essential nutrients to be added and the food vehicle chosen will depend upon the particular nutritional problems to be corrected or prevented, the characteristics of the target populations, and their food consumption patterns.
3.1.4 The addition of essential nutrients to foods should be in accordance with food law and other policies established by national authorities. When provision is made in national food standards, regulations or guidelines for the addition of essential nutrients to foods, specific provisions should be included identifying the foods, the essential nutrients required or permitted to be added and where appropriate

Table 3: Proposed Revised Text from Table 2 – Clean Version
the minimum and maximum levels at which they should be present.
3.1.5 (<i>Former 3.8 with additions</i>) Addition of essential nutrients to foods should not be used to mislead or deceive the consumer
3.2 (New) Selection of Nutrients and Determination of amounts
3.2.1 <i>Former 3.2 with modifications (also considered to cover former 6.2.5):</i> The [amount of an added] <i>or</i> [addition of an] essential nutrient should be [scientifically and nutritionally justified] [in line with one or more of the purposes stated in 3.1.1] and not result in either an excessive intake or, for the target population, an insignificant intake of [the added] essential nutrient[s], considering [total intakes] from all [relevant] sources [including food supplements], [Upper Levels of intake and identification of special subpopulations at risk] [Upper levels of intake based on scientific risk assessment may be used to identify the need for any restrictions on the types of foods to be fortified.]
3.2.2 (new) The Upper Level of Intake should be used to assess potential exposure to excessive intakes of essential nutrients and to estimate safe limits of addition, [including considerations of populations at risk of excessive intake]. [This exposure assessment should also help to identify the need for any restrictions on the types of foods to which nutrients should be added.]
3.2.3 (new) Potential change to population intakes should be estimated as part of the decision making about nutrient addition [to evaluate safety and adequacy]. Assessment of potential exposure could be made through a dietary modelling approach of scenarios using data on population intakes, proposed amounts of an essential nutrient in a target food and daily intake reference values for adequacy and for safety.”
<i>Alternative for 3.2.2 and 3.2.3: [National authorities may establish maximum limits for the addition of essential nutrients to foods to reduce any potential risks for adverse effects on health. Maximum limits for the addition of essential nutrients to foods should be based on the following criteria:</i>
<i>(i) Upper Level of Intake (UL) of essential nutrients established by scientific risk assessment based on generally accepted scientific data, taking into consideration, as appropriate, the varying degrees of sensitivity of different consumer groups;</i>
<i>(ii) the daily intake of essential nutrients from other dietary sources.</i>
<i>When the maximum levels are set, due account may be taken of the reference intake values of essential nutrients for the population. When maximum amounts are close to the Upper Level of Intake (UL) restrictions of foods to which nutrients may be added should take account of the contribution of individual foods to the overall diet of the population in general or of sub-groups of the population.]</i>
3.2.4 (new) Where an Upper Level of Intake is not available, [National authorities may consider] the scientific evidence to support the safe addition of an essential nutrient [should be considered], including [demonstration of an upper level or a range of intake that is unlikely to result in adverse health effects] [or the potential relevance of Highest Observed Intake ¹ .
footnote 1: Highest observed intake – the highest level of intake observed or administered as reported within a stud(ies) of acceptable quality. It is derived only when no adverse health effects have been identified. (appropriate source to be cited.)
[3.2.5 (new) The severity of the adverse effect on which the Upper Level of Intake (UL) is based should be reviewed to inform restrictions

Table 3: Proposed Revised Text from Table 2 – Clean Version
on the addition of essential nutrients to foods.]
3.2.6 <i>Former 3.3</i> The [amount of an essential nutrient added] / [addition of an essential nutrient] to a food should not result in an adverse effect on the metabolism of any other nutrient.
3.2.7 (new) National authorities may establish minimum limits for the addition of essential nutrient to foods. [Minimum amounts for the addition of essential nutrients to foods should take into account the conditions of use for a source of claim in the Guidelines for use of nutrition and health claims (CAC/GL 23-1997)]. [The minimum amount of addition of an essential nutrient should take into account the intended purpose, and all other sources of the essential nutrient in the diet, including food supplements.]
3.3 (New) Selection of Foods
3.3.1 (new) [Certain foods may have to be excluded from voluntary nutrient addition because of their ubiquity in the food supply and thus the potential for exposure to high intakes associated with a risk of adverse health effects in non-target populations.] Or [The selection of appropriate foods to which essential nutrients may be added is best determined at national/regional/local level taking into account dietary habits, socioeconomic situations and the need to avoid any risks to health.] Or [The selection of food(s) to which to add an essential nutrient(s) should primarily be based on achieving appropriate purposes of nutrient addition as identified in 3.1.1.]
3.3.2 (new) The selection of appropriate foods [or categories of foods] to which essential nutrients [may] / [may not] be added should take into account the nutritional value of the foods and is best determined by National Authorities. [In addition, essential nutrients should not be added to alcoholic beverages and unprocessed foods, including, but not limited to, fruit, vegetables, meat, poultry and fish.] (Note: With this option, new 3.3.4 and 3.3.5 would be deleted.)
3.3.4 (new) Essential nutrients should not be added to unprocessed foods, including, but not limited to, fruit, vegetables, meat, poultry and fish.]
3.3.5 (new) Essential nutrients should not be added to alcoholic beverages.]
3.4 (new) Technological aspects
3.4.1 (new) The sources of the added essential nutrient may be either natural or synthetic and their selection should be based on considerations such as safety and bioavailability. In addition, purity criteria should take into account [in the following order]: FAO/WHO

Table 3: Proposed Revised Text from Table 2 – Clean Version
standards, international Pharmacopoeias or recognized international standards, or national legislation.
3.4.2 <i>Former 3.4 with modifications</i> The added essential nutrient should be sufficiently stable in the food under customary conditions of processing, packaging, storage, distribution and use.
3.4.3 <i>Former 3.6</i> The added essential nutrient should [have minimal impact on the original food characteristics] / [not impart undesirable characteristics to the food] (e.g. colour, taste, flavour, texture, cooking properties) and should not unduly shorten shelf-life.
3.4.4 <i>Former 3.7</i> Technology and processing facilities should be available to permit the [standardized] addition of the essential nutrient to a food in a manner to ensure nutrient [bio]availability, consistency, distribution and stability.
3.5 Monitoring
3.5.1 (new) [It is important that National authorities] / [National authorities should] monitor population intakes from all sources including the essential nutrients added to foods to assess the extent to which [the selected public health need or other purpose for addition] <i>or</i> [the purposes identified in 3.1.1] is addressed and to ensure that any risk of excessive intakes is minimized.
3.5.2 (new) Monitoring of total nutrient intakes should use the same approach as used in deciding the nutrient addition.
4.0 [Principles for] Types of Nutrient Addition
4.1 (new) Addition of Essential Nutrients [to Address a Demonstrated Public Health Need] [and Mandatory Addition]
4.1.1 <i>Former 6.2.1</i> There should be a demonstrated public health need for increasing the intake of an essential nutrient in one or more populations [which may be accomplished by mandatory addition of essential nutrients. A demonstrated public health need, however, may also be addressed through voluntary addition.] This need may be demonstrated by clinical evidence of deficiency, subclinical evidence of deficiency, [suboptimal nutritional status], [evidence from valid biochemical indicators], estimates indicating inadequate intake of nutrients, estimates indicating potentially inadequate intakes of nutrients, and/or by estimates of possible deficiencies because of changes in food habits.
4.1.2 <i>Former 6.2.2</i> The food(s) selected as a vehicle for the added essential nutrient(s) should be consumed by the population at risk [of inadequate intake].
4.1.3. The amount of the essential nutrient added to the food should aim to be sufficient to meet the public health need.
[Switch order with 4.1.3]:
4.1.4. <i>Former 6.2.3</i> The intake of the food selected as a vehicle should be stable and uniform and the [amount of the food consumed by the lower and upper percentiles of the population] should be known.
4.1.5 <i>Former 3.9 revised</i> The cost effectiveness of the addition of essential nutrients to foods for the intended consumer should be considered.
4.2 Nutrient Addition for Purposes of Restoration

Table 3: Proposed Revised Text from Table 2 – Clean Version
<p>4.2.1 <i>Former 4.1</i> Where the food has been identified as a significant [source] / [contributor to intake] of essential nutrients in the population, and particularly where there is [a] demonstrated public health need, restoration of the essential nutrients of concern lost during processing, storage or handling, should be [recommended].</p>
<p>4.2.2 <i>Former 4.2</i> A food should be considered a significant contributor to intake of an essential nutrient if the edible portion of the food prior to processing, storage or handling contains the essential nutrient in amounts equal to or greater than 10% of the [daily intake reference value]/ [recommended nutrient intake]/ [NRV]/ [INL 98] in a reasonable daily [intake] / [consumption] of the food (or in the case of an essential nutrient for which there is no [daily intake reference value]/ [recommended nutrient intake]/ [NRV]/ [INL 98] 10% of the average daily intake of the nutrient). [Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this nutrient need not be restored.]</p>
<p>4.3 Nutrient Addition for Purposes of Nutritional Equivalence</p>
<p>4.3.1 <i>Former 5.1</i> Where a substitute food is intended to replace a food which has been identified as a significant [source] / [contributor to intake] of essential nutrients in the [population], and particularly where there is [a] demonstrated public health need, nutritional equivalence in terms of the essential nutrients of concern should be [recommended].</p>
<p>4.3.2 <i>Former 5.2</i> A food being substituted or partially substituted should be considered a significant contributor to intake of an essential nutrient if a serving or portion or 100 kcal of the food contains the essential nutrient in amounts equal to or greater than 5% of the [recommended nutrient intake]/[NRV]/ [INL 98]. Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this need not be equivalent.</p>
<p>4.3.3 <i>Former 5.3</i> Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this nutrient need not be equivalent.</p>
<p>4.4 Nutrient addition to Special Purpose Foods</p>
<p>4.4.1 <i>Former 7.1</i> [Essential] nutrients may be added to special purpose foods, including foods for special dietary uses, to ensure an appropriate and adequate nutrient content [for their intended use] [based on the principles in this guidance wherever applicable]. Where appropriate, such addition should be made with due regard to the nutrient [composition] of such foods. [Consideration should be given to the target population and their nutrient requirements based on general reference intakes such as RNIs.]</p> <p><i>Alternative:</i> [Essential] nutrients may be added to special purpose foods to ensure an appropriate and adequate nutrient content [for their intended use] Consideration should be given to the nutrient requirements [of the target population] based on [relevant] [daily intake reference values].</p>

APPENDIX B

Electronic Working Group on the Review of the “General Principles for the Addition of Essential Nutrients to Foods” CAC/GL 09-1987, amended 1989, 1991**Second Discussion Paper
June 14, 2012**

Dear Working Group members

Thank you for comments submitted on our first discussion paper. We hope the following will provide the background necessary, along with a draft revised text with explanatory notes, to support a further round of robust discussion.

Background:

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

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

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

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

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

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

Another objective of the review would be to consider the need to expand the definition of fortification to encompass the purpose of meeting recommended nutrient intakes and reducing the risk of inadequate intake as demonstrated by relevant scientific data, as well as the current purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups.

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

- selection of appropriate foods to fortify (e.g., establishment of qualifying and /or disqualifying criteria),
- selection of nutrients to be added, and

- determination of levels to which permitted nutrients could be added according to scientific relevant data.

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

There was considerable discussion at the 32nd and at the eWG and pWG that took place prior to 33rd sessions of the CCNFSDU.

The 33rd session established an eWG to be chaired by Canada and co-chaired by New Zealand to address in particular:

- the structure (format) of the General Principles considering both headings and subheadings where these are required;
- sections 3 to 7 of the General Principles (CAC/GL 9-1987) to obtain agreement on which principles are overarching or of general applicability, which principles are additional for specific types of additions, which principles could be considered guidance factors rather than principles, which principles are to be retained and which may not be needed;
- whether the purposes of addition should be stated in the “Introduction” with principles for these included in the “Overarching” or “General principles” section;
- which definitions are required;
- the level of demonstration of public health need required to support mandatory versus that required for voluntary addition of essential nutrients.

The terms of reference for the 2012 eWG agreed upon by the Committee at its 33rd session include obtaining agreement on the structure or format of the General Principles document, considering headings as well as subheadings where these are required.

It was suggested that getting agreement on this first item might be desirable before proceeding to other outstanding issues. A decision on structure is nevertheless closely tied to an understanding of what is intended to be the content of each section and so, besides the proposed revised format below, a table was attached showing the proposed revised format and, in a separate column, brief descriptions of what different principles/guidance factors the chair and co-chair considered would fall into each section or subsection.

First Round of Consultation:

For this working group, a first consultation document was circulated for comment in February, 2012. This consultation focussed on the structure of the document.

Responses to the first consultation of 2012 were received from 10 Member States and 5 Member Organisations.

As an overall summary, there continues to be a diversity of views regarding the overall structure of the document and the status of Principles versus Guidance/Guidelines. Some members suggested significant changes to the structure of the document with others wanting minimal change. There is a need to take a pragmatic approach to the General Principles, recognising that a significant compromise is required to meet the needs of all members.

The issue of Principles versus Guidelines is deflecting the ability of the working group to focus on the main purpose of the review, which is the content of the document. To this end the chairs of the eWG propose that the title of the document remain **General Principles** as in the original text of the “General Principles for the Addition of Essential Nutrients to Foods” CAC/GL 09-1987. As noted in the first round discussion document, this would be consistent with existing Codex documents with respect to the level of detail and specificity and length of the document.

The chairs of the eWG endeavoured to ascertain whether the status of Principles or Guidance, and indeed the structure, impacted on the substance that the General Principles should capture. All respondents to the

discussion paper agreed that most if not all the points were principles. Where there was disagreement was with the points related to the specific types of addition, i.e. restoration and nutritional equivalence. Thus, there appears to be significant agreement on many of the key aspects that should be captured in the Principles but varying views as to **where** the various aspects should be captured in the document. At the same time, some respondents noted that not every proposed new principle, or modification or deletion of existing principles has been agreed to and this will need to be addressed. This was intended to be dealt with when the principles themselves are discussed in the second round. There has been much discussion as to whether the terms “fundamental, basic or overarching” principles describe the highest order principles. Difference in opinion may be due to interpretation or language differences but members appear to have strong but conflicting preferences. The chairs of the eWG propose that consideration be given to calling section 3 “Principles” of which the first sub-section 3.1 is “Fundamental Principles” and the following sub-sections (3.2 – 3.5) refer to principles related to particular aspects of nutrient addition under sub-headings such as “selection of food” and “monitoring”.

There also remains a diversity of views as to whether there should be a separate section on the principles related to mandatory fortification, although general agreement that the decision to mandate addition of essential nutrients to foods should be made at the national level based on public health need.

Under the section titled “**specific types of nutrient addition**” the chairs have proposed a section “**nutrient addition mandated to correct inadequate intakes**”. We think this may pick up the key concerns of members and is a proposed compromise of the different positions.

Given the continued challenges in reaching a consensus on a revised structure, the chairs of the eWG are proposing that where there is no agreement, the eWG consider an approach that takes the original structure of the “General Principles for the Addition of Essential Nutrients to Foods” CAC/GL 09-1987 and attempts to make just the limited changes required to capture the original intent of the new work to extend the scope. This is forming the basis of the second round of consultation and will enable the eWG to focus on the content of the General Principles. This proposed revised structure is shown in Appendix I.

Second Round of Consultation 2012:

The focus of the second round of consultation is on the content of the revised General Principles, within the terms of reference for this eWG. There has been some consideration of text to date and where there has been no agreement we have reverted to the original text of the “General Principles for the Addition of Essential Nutrients to Foods” CAC/GL 09-1987 showing some of the proposed changes that have been made to that text, where applicable.

The full text of course is open to review but we do ask Members to consider carefully recommendations that in the past have not been able to be resolved and focus on the elements that they believe are inaccurate, inappropriate or misleading. There are some areas of the text that may not be necessary but in actual fact are not wrong and retaining them on the basis of request by some Members may be acceptable.

Presenting the text in a way that members can follow has been a challenge. We have presented the proposed revised structure in Appendix I, and text with full identification of what is text from the “original” document (CAC/GL 09-1987 (amended 1989, 1991), what is new text, proposed deletions and proposed movement of position in Appendix II. We have also provided, as much as possible, the reasoning for the addition, deletion or modification and an indication of the degree of agreement and a sense of other comments that have been made.

You will see that the **Definitions** section has minimal proposed changes from what has been offered in the past. This reflects that this section has not been the focus of our consultations to date. There is an issue with reference to the term “fortification” with some members wishing to retain the term and others wanting to replace it with “nutrient addition”. In this second round, we expect the focus to be on whether a particular definition is needed or not. We do however welcome comment on the definitions keeping in mind our approach to minimise change from the original document where there is no agreement.

You will also find in Appendix III a clean copy of the proposed text with specific questions in the right hand column. Where there is no question, please indicate your concurrence with the text as worded or indicate what change(s) would be necessary. For ease of response, we ask that you respond to the questions in the right hand column and make any specific comments on the clean text in Appendix III, using track changes, providing your reasoning in the comments column, as well.

The chairs of the working group have gone back to previous submissions to ensure that all comments have been considered in preparing this revised text and format for the consideration of the working group. While we have addressed many, we have not addressed all comments or recommendations made at Step 3 in response to the report of the eWG (CX/NFSDU 11/33/7). We invite you to resubmit previous comments and recommendations, as appropriate, in light of this single revised version and the proposed text contained in it.

Please return your comments by July 31, 2012 (see revised schedule below). Reply all to the email from which this document is received to share your comments with all members of the eWG.

Many thanks and regards,

Nora Lee and Jenny Reid,

The Chairs of the Electronic Working Group

Revised Schedule for Electronic Working Group

February 6, 2012

1st round of eWG discussion: request for comments sent to eWG on the format of the *General Principles for the Addition of Essential Nutrients to Foods*

March 15, 2012

Deadline for submission of eWG participants' comments at 1st round

~~May~~ June 14, 2012

2nd round of eWG discussion: summary of 1st round and request for comments on additional issues as per charge to eWG by Committee

July 2- 31, 2012: Deadline for submission of eWG participants' comments at 2nd round

September 17, 2012

Revised draft General Principles for the Addition of Essential Nutrients to Foods based on eWG input submitted to Codex Secretariat for distribution for comment at Step 3.

October 29, 2012: Deadline for comments at Step 3

Appendix I. Proposed Revised Format Following Round One

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

Appendix III. Response form for eWG comments on Draft Revised *General Principles for the Addition of Essential Nutrients to Foods*

Appendix IV. eWG distribution list

APPENDIX C

Appendix II

Draft Revised General Principles for the Addition of Essential Nutrients to Foods, version of June 12, 2012 for consideration by the Electronic Working Group (eWG)

Explanatory note: Draft revised text is shown in the left column. Notes and questions are in the right hand column. We are showing proposed changes with respect to the original text throughout. Text underlined is new compared to the existing General Principles document, i.e. CAC/GL 09-1987, amended 1989, 1991. Text highlighted in yellow is new text suggested by the co-chairs of the eWG. The co-chairs have, in some cases, proposed a choice of the alternatives, showing this by ~~strikeout~~. The existing General Principles document is referred to as the “original” document and the numbering from that document is identified as “former” when new numbering is being proposed. Square brackets are only used where there is a choice of two options or where additional changes were made to new text. All text underlined or struck out can be considered to be under discussion until agreed to by the Committee since very few decisions have been made, although we have attempted to reflect in the Notes and Questions column the level of agreement based on comments from previous eWGs, at Step 3 or during discussion at the Committee.

Draft Revised <i>GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS (CAC/GL 09-1987 amended 1989, 1991)</i>	Notes and Questions
<p>INTRODUCTION</p> <p>The [General Principles] [Guidelines] for the Addition of Essential Nutrients to Foods (<u>the Principles</u>) [provide a framework for the addition of essential nutrients to food and] are intended to provide guidance to [National Authorities] <u>[those]</u> responsible for developing guidelines and legal texts pertaining to the addition of essential nutrients to foods to establish a uniform through the establishment of a set of principles that serve as a basis for the rational and safe pertaining to the addition of essential nutrients to foods.</p> <ul style="list-style-type: none"> • To maintain and improve the overall nutritional quality of foods. • 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. • To facilitate acceptance in international trade of foods which contain added essential nutrients. 	<p>This first paragraph was revised from the original introduction to strengthen the idea that this paragraph should address the purpose of the document as opposed to the purposes of addition. It combines together the first 2 bullet points in the original document with edits to clarify that the responsible parties are National Authorities, that the principles serve as the basis for rational <i>and</i> safe addition, and to delete the last bullet point of the original document, “facilitate acceptance in international trade...”. In the case of this last change, this was done as there appears to be consensus that repeating the trade related purpose is unnecessary here given that it is a purpose of all Codex standards and guidance documents.</p> <p>The third bullet point of the original Introduction has been confirmed through the work of previous working groups and the Committee as being one of the purposes for addition of essential nutrients to foods. Elaboration of the appropriate purposes for addition is proposed to be placed in Section 3, and therefore the third bullet point is moved to that section. Please see that section for explanatory notes.</p> <p>The text of the original 4th bullet point concerning prevention of indiscriminate addition and prevention of practices that may mislead or deceive is proposed to be deleted since it is felt that</p>

<p>Draft Revised <i>GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS (CAC/GL 09-1987 amended 1989, 1991)</i></p>	<p>Notes and Questions</p>
	<p>the addition of the words “and safe” introduces the high level principle related to the first part of that bullet, and “rational” introduces that in relation to the second part. Rational could be said to encompass addition according to appropriate nutritional purposes and done in a way that is not misleading or deceptive. There are then subsections in the document that provide guidance to achieve both these objectives.</p> <p>Question: Does this revised paragraph provide a sufficient introduction describing the purpose of the document, keeping in mind that the purposes for addition of essential nutrients to foods are proposed to be moved to Section 3? If not, please explain your concerns and indicate what you would prefer to have retained in this first part of the introduction.</p> <p>Do you agree with the deletions and relocations of text? If not, please explain and provide alternative text.</p>
<p>(new) <u>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 on Nutrition and Foods for Special Dietary Uses (CAC Procedural Manual), where applicable.</u></p>	<p>This paragraph is identified here as “new” since it is not part of the original document. Nevertheless, there appears to be general agreement with its inclusion. At the 32nd session of the Committee, the paragraph was discussed and it was clarified that the <i>Nutritional Risk Analysis Principles</i> apply in the framework of Codex while the <i>Principles for the Addition of Essential Nutrients to Foods</i> are intended for governments and so the proposed text was revised to clarify that the relevant provisions would be “taken into consideration” “where applicable”..</p>
<p>(new) <u>The <i>General Principles for the Addition of Essential Nutrients to Food</i> are applicable, as appropriate, to both mandatory and voluntary addition of essential nutrients unless otherwise indicated.</u></p>	<p>While there continues to be interest in a separate section to address mandatory fortification, it is also generally agreed that most of the principles apply in both voluntary and mandatory addition and that any type of addition may be made mandatory or voluntary. Since this appears to be less a principle than an instruction on the use of the principles, the co-chairs suggest placing this overall statement in the introduction.</p> <p>Question: Do you agree with this statement? Is it in the right place? If not, where would you suggest it to be placed?</p>

Draft Revised <i>GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS (CAC/GL 09-1987 amended 1989, 1991)</i>	Notes and Questions
<p>(new) National authorities should also consult the <i>FAO/WHO Guidelines on food fortification with micronutrients</i> (WHO, 2006) for further information.</p>	<p>Some members suggest referring to the WHO/FAO 2006 Guidelines on Food Fortification with Micronutrients or to general FAO/WHO texts in the Introduction.</p> <p>Question: Do you agree that there should be reference to guidance on food fortification in other WHO/FAO texts? If so, is the text proposed acceptable?</p>
<p>1. SCOPE These [principles] [Guidelines] are intended to apply to all foods to which essential nutrients are added, not including vitamin and mineral food supplements¹.</p> <p>¹See the <i>Codex Guidelines for Vitamin and Mineral Food Supplements</i> (CAC/GL-55-2005)</p>	<p>There was general agreement with the content of the SCOPE including the reference to NOT include vitamin and mineral supplements. There was one suggestion that this could be referenced in a footnote rather than in the text. Also, it has been recommended to have a footnote with a reference to the <i>Codex Guidelines for Vitamin and Mineral Food Supplements</i> (CAC/GL-55-2005).</p> <p>One member suggested deleting “are intended to” which would further simplify the text.</p>
<p>2. DEFINITIONS DESCRIPTION For the purpose of these [Principles] [Guidelines]:</p>	<p>Most comments have supported changing the name of this section to Definitions.</p> <p>While there has been some focus so far on the definitions, from the early discussions there is and will continue to be a difference of views, especially on the breadth of definitions to cover. The last eWG had decided to revisit the definitions once there was general agreement on the structure and content of the text as this would direct the extent of the definition section. In the terms of reference for this eWG, the work with regard to definitions was to address determining which were required. Therefore, we have not tried to reach a resolution on the details of the definitions.</p> <p>There were some delegations that wanted the definitions section limited to the definition of nutrient and essential nutrient only.</p> <p>Decisions about reference to mandatory /voluntary and fortification will influence this section.</p> <p>Question: After reviewing all the other parts of the document, please indicate for each of the definitions below if you consider it is still needed. For those that you would</p>

Draft Revised <i>GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS (CAC/GL 09-1987 amended 1989, 1991)</i>	Notes and Questions
	retain, please indicate preferred text and any additional changes you would recommend, including changes you may have previously recommended.
<p>2.1 Nutrient means any substance normally consumed as a constituent of food:</p> <p>(a) which provides energy; or</p> <p>(b) which is needed for growth and development and maintenance of healthy life; or</p> <p>(c) a deficit of which will cause characteristic bio-chemical or physiological changes to occur.</p>	There is general agreement to retain this definition unchanged with the exception of one observer noting that this definition is the same as that found in the Codex <i>Guidelines on Nutrition Labelling</i> , except for the word “healthy” which they recommend deleting.
<p>2.2 Essential nutrient means any substance normally consumed as a constituent of food which is needed for growth and development and the maintenance of healthy life and which cannot be synthesized in adequate amounts by the body.</p> <p>or</p> <p>2.2 Essential nutrient means any substance normally consumed as a constituent of food which <u>cannot be synthesized in adequate amounts by the body and</u></p> <p>(a) which is needed for growth and development and the maintenance of healthy life and cannot be synthesized in adequate amounts by the body; or</p> <p>(b) a deficit of which will cause characteristic bio-chemical or physiological changes to occur.</p>	<p>There is agreement to retain this definition but also there are recommendations to rearrange the text and introduce text from the definition of Nutrient to emphasize the defining characteristics of “essential nutrients” in a parallel structure with the definition of “Nutrient”. This is now captured by the second option text.</p> <p>The word “healthy” would need to be deleted here if it were deleted in the definition of “Nutrient.”</p>
<p>2.3 (former 2.4) Substitute food is a food which is designed to resemble a common food in appearance and texture, flavour and odour, and is intended to be used as a complete or partial replacement for the food it resembles, e.g., plant protein-based beverages as a replacement for milk.</p>	There appears to be considerable agreement <u>that reference to flavour and odour</u> be removed with some delegations seeing <u>no need for this definition at all.</u>
<p>2.4 (former 2.3) Nutritional equivalence means being of the addition of one or more essential nutrient to a substitute food to achieve a similar nutritive value <u>to its normal counterpart</u> in terms of quantity and quality of protein and in terms of kinds, quantity and bioavailability of essential nutrients. For this purpose, nutritional equivalence means that essential nutrients provided by the food being substituted, that are present in a serving or portion or 100 kcal of the food at a level of 5% or more of the recommended intake of the nutrient(s) are present in the substitute or partially substituted food (extender) in comparable amounts. 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.]</p> <p>or</p> <p>Nutritional equivalence is achieved when an essential nutrient is added to a substitute food in amounts</p>	<p>Similar to above, it was recommended to delete the reference to flavour and odour as this is considered not necessary and may be difficult to achieve.</p> <p>The second version of the definition at left brings in part of the WHO definition (2010). It has also been identified that the definition should just define nutritional equivalence,– not state how to achieve it; that is the role of the principles.</p> <p>There was a recommendation to include an example. An example of a substitute food is included with the draft revised definition of substitute food, 2.3.</p> <p>Some members did not support a need to use or define nutritional equivalence. Where a reason was given, this was stated as being because it was not considered necessary to</p>

<p>Draft Revised GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS (CAC/GL 09-1987 amended 1989, 1991)</p>	<p>Notes and Questions</p>
<p><u>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 nutrients.</u></p> <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. <u>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.</u></i></p>	<p>include guidance about this in this document.</p> <p>One member wanted to include in the definition a reference to a food being a significant contributor and where there is evidence of public health need that nutritional equivalence should be recommended, all text that is derived from the principles on nutritional equivalence.</p>
<p>2.5 Fortification or, which may be called enrichment, means the addition of one or more essential nutrients to a food, whether or not it is normally contained in the food for the purpose of <u>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 a population or specific population groups [with minimal risk to health].</u></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 contained <u>present</u> in the food, for the purpose of preventing or correcting <u>improving population health by addressing a demonstrated deficiency of one or more nutrients in the population or specific population group(s) or reducing the risk of poor nutritional status or inadequate nutrient intake.</u></p> <p>or</p> <p><i>Fortification</i> 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] for the purpose of preventing or correcting <u>improving population health by addressing a demonstrated deficiency of one or more nutrients in the population or specific population group(s).</u></p>	<p>There remains divergence of views on the need to define fortification. Some members do not want to refer to fortification and suggest referring to nutrient addition only. The purpose of nutrient addition captured in the original definition is now proposed to be included in new text in Section 3, below and principles related to it remain in the document. Others support the simplified definition of fortification and there are others that want to define mandatory fortification and voluntary fortification.</p> <p>Question: Is a definition for fortification useful even if the term is not used in the document? Note that “nutrient addition” has been used in place of “fortification” throughout the current draft of the text. Do you prefer to retain the term “fortification” but have it mean, generally, addition of essential nutrients to foods? Do you prefer to retain the term “fortification” with its original meaning?</p>
<p>2.8 Restoration means the addition to a food of essential nutrient(s) which are in amounts to replace those lost during the course of good manufacturing practice, or during normal storage and handling procedures, or in order to compensate for natural variations in essential nutrients, 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>There was agreement from some members to retain the definition of restoration as it was a form of nutrient addition that was used however others recommended that the principles that underpinned the nutrient addition were not different from other forms of nutrient addition and so principles on it did not need to be separated out and a definition was not needed.</p> <p>In the version here, modifications are suggested to simplify the</p>

Draft Revised <i>GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS (CAC/GL 09-1987 amended 1989, 1991)</i>	Notes and Questions
	definition. The underlined text “in order to compensate...” is from the definition of Standardization which has been recommended for deletion.
2.6 (new) 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.	The definitions of voluntary and mandatory addition/fortification were not in the original General Principles and are relevant to the intent of the review of the General Principles, ie to ensure voluntary addition is understood to be covered by these principles. These definitions were captured under section 3 in earlier draft revised versions. It was later recognised that they were definitions and should be in the definitions section. There are some members that do not support retaining definitions for these terms. Where the term addition of essential nutrient is used rather than fortification , defining the terms mandatory or voluntary was seen by some as unnecessary.
2.7 (new) Voluntary nutrient addition is when a food manufacturer may chooses to add specified nutrients to particular foods or food categories. for a specific purpose. within specified limits.	See 2.6 above
2.9 <i>Special purpose foods</i> are foods that have been designed to perform a specific function, such as to replace a meal which necessitates a content of essential nutrients which cannot be achieved except by addition of one or more of these nutrients. These foods include but are not limited to foods for special dietary use, <u>and also include foods intended for infants and young children.</u>	There is some support for a definition of special purpose foods including the extension to refer to the inclusion of foods for infants and young children. There are some members that want a very minimal definitions section and would exclude defining special purpose foods as the permissions for addition are retained in other Codex standards and guidelines.
2.10 <i>Nutrient density</i> means the amount of nutrients (in metric units) per stated unit of energy (MJ [KJ] or kcal).	This would be removed if the term is no longer used in the document based on proposed changes to the principles related to Special Purpose Foods.
2.11 <i>Standardization</i> means the addition of nutrients to a food in order to compensate for natural variations in nutrient level.	In previous comments, this has been placed in square brackets. We have proposed deleting the definition but including the concept within the definition of restoration (see 2.8 above).
2.11 (new) <i>Population</i> refers to a national population or specific population group(s) as appropriate.	This definition was proposed during a previous eWG to clarify that the term, population, when used in the document could refer to the total population or a special population group.
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3. PRINCIPLES	
3.1 (New) Fundamental [Overarching] [General] Principles	<p>In the original text, there are no sub-headings in Section 3. The whole of section 3 is entitled “Basic Principles”. In the course of the work on the revisions of the General Principles, it has been suggested to add sub-headings to help organize the existing and new principles. In the first round consultation document of this eWG, the title, Fundamental Principles, was proposed for a separate section and, besides a proposed section on Mandatory addition, all the remaining titles were identified as sub-headings under “Additional Principles”. Following the review of comments received from the first round, a different structure is proposed, as discussed in the main part of the Second Round Discussion Document. A section called either “Fundamental or Overarching or General or Basic or High Level Principles,” is still proposed but it would be a sub-section of Section 3, i.e. 3.1. This sub-section contains principles of the type proposed in the first consultation document for the section by the same title and considered to be higher level types of principles. Given the proposal to call this sub-section “Fundamental Principles, to avoid confusion, it is suggested then to call Section 3 simply “Principles”.</p> <p>Several comments were received that the principles related to nutrient restoration, nutritional equivalence and special purpose food were not at the same level as the other “additional principles”. Here they, as well as principles related to addressing inadequate intakes in a population, are placed in a separate Section under individual sub-sections. A difficulty remains that principles related to addressing inadequate intakes in a population are seen as more important than the other three and yet they are treated similarly. Otherwise, the “additional principles” are retained in Section 3.</p> <p>Question: Do you agree with calling Section 3 just “Principles”? Do you agree that there should be a separate sub-section in Section 3 called “Fundamental Principles” covering the high level principles that are overarching or of general applicability while the remaining principles of overarching or general applicability are placed in separate sub-sections?</p>

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<p>3.1.3 (New) National authorities should determine whether [nutrient addition] fortification should be mandatory or voluntary [This decision may be based on severity and extent of public health need as demonstrated by scientific evidence. The kinds and amounts of essential nutrients to be added and 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> <p>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.]</p>	<p>Text to introduce into the principles clarity regarding the application of the principles to voluntary and mandatory addition was needed to address one of the main aspects of the work as set out in the Project Document. Several alternative wordings have been proposed over the course of the previous two intersession eWGs. While it appears to be generally agreed that the basis on which National Authorities would decide to make addition of essential nutrients mandatory is related to the degree of public health need, concern was raised that this decision should be left to National Authorities and that the Codex text should not specify the differences between mandatory and voluntary addition, such as which conditions would determine whether the addition should be mandatory.</p> <p>Question: Does the text proposed here provide sufficient guidance on level of demonstration of public health need required to support mandatory versus that required for voluntary addition of essential nutrients?</p>
<p>3.1.4 (Former 3.11 with modifications) <u>The mandatory and voluntary addition of essential nutrients to foods should be in accordance with food law and other policies established by national authorities.</u> When provision is made in national food standards, regulations or guidelines for the addition of essential nutrients to foods, specific provisions should be included identifying <u>the target appropriate foods,</u> the essential nutrients to be considered or to be required or permitted to be added and <u>the minimum and where appropriate, maximum</u> levels at which they should be present.</p>	<p>Text stating that “addition should be in accordance with food law and other policies established by national authorities” was introduced by the eWG working between the 31st and 32nd sessions. It was originally introduced to be part of a modified 6.1 which talks about fortification being the responsibility of national authorities. However, since it is referring to basically all types of mandatory or voluntary nutrient addition, here we propose that it be added to a slightly modified version of the original 3.11.</p> <p>Question: Is it appropriate to add the proposed text relating to food law into this sub-section or should it be retained with revised former 6.1?</p>
<p>3.1.5 (Former 3.8 with additions) Addition of essential nutrients to foods should not be used to mislead or deceive the consumer, <u>including by presentation or labelling practices,</u> as to the nutritional merit <u>[or the health benefit]/[and possible additional health benefit]</u> of the food.</p>	<p>This is a revision of former 3.8 with the changes introduced by the eWG working between the 31st and 32nd sessions and not modified since.</p> <p>Question: Are the changes in square brackets acceptable? Which are preferred? Do any additional principles need to be included to provide sufficient guidance for National Authorities to ensure that consumers will not be misled?</p>

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<p>3.1.1 Essential nutrients may be appropriately added to foods for the purpose of:</p> <ul style="list-style-type: none"> • <u>correcting a demonstrated deficiency, [inadequate intakes or poor nutritional status] of one or more essential nutrients in the population or specific population groups;</u> • <u>contributing to meeting [recommended nutrient intakes]/ [requirements] of one or more essential nutrients and reducing the risk of [inadequate intakes, poor nutritional status and/or] deficiency;</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>In keeping with one of the purposes for the work, the first electronic working group, working between the 31st and 32nd sessions, proposed the addition of text that elaborated the purposes for addition. This text drew from the definition of “fortification”, from bullet 3 of the existing introduction, and from the Project Document, and is intended to address the need 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. The term, <u>or specific population groups</u>, can be deleted if the definition of “population” is accepted. Also, to align the new text better with the Project Document, it is proposed to consider the words “recommended nutrient intakes” as an alternative to “requirements”.</p> <p>Originally, this text was proposed for inclusion in the introduction section but at the 32nd session of the committee, it was proposed to be moved to within the principles themselves, section 3. There was subsequent discussion about the placement of these purposes in the eWG working between the 32nd and 33rd sessions as well as in the physical working group prior to the 33rd session, which led to a tentative decision to place them within the principles. However, a final position has not been taken. The purposes can be seen as principles, particularly with the inclusion of the word “appropriately” in the initial part of the text. This text sets out the appropriate purposes for addition and provides guidance for “rational” addition, as stated in the Introduction.</p> <p>Questions: Do you agree with these purposes for addition? Do you agree that these purposes for addition should be placed in Section 3, Principles? Do you agree with their placement under Fundamental principles?</p>
<p>3.1.2 The above <u>purposes</u> may be achieved by restoration, nutritional equivalence of substitute foods, fortification nutrient addition <u>mandated to correct inadequate intakes</u>, and ensuring the appropriate nutrient composition of a special purpose food <u>or other addition in accordance with these principles.</u>”</p>	<p>The original General Principles identify the purposes of addition as being restoration, nutritional equivalence of substitute foods, fortification and ensuring the appropriate nutrient composition of a special purpose food. Identifying the purposes of addition in terms of their nutritional rationale, as in 3.1.1 above, requires differentiating them from the original “purposes”. There appears to be a consensus emerging that these original “purposes” can be understood as specific types of addition that act as means to achieve</p>

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	<p>the nutritional purposes. Therefore, modified text was introduced in the course of the eWG working between the 32nd and 33rd sessions to make this clearer. Here, the word “principles” is changed to “purposes” since it aligns better with the way they are described above.</p> <p>The word “fortification” is proposed to be deleted and wording that describes what fortification means in the original text is used instead. Conceptually, this was proposed by the US (with slightly different wording than shown here).</p> <p>The co-chairs noted that it is not by application only of these specific types of nutrient addition that the purposes may be achieved and so we have proposed additional text to ensure that this is clear.</p> <p>Question: Do you agree with these changes?</p>
<p>3.2 (New) Selection of Nutrients and Determination of amounts</p>	<p>New sub-heading: Here, two previously suggested sub-headings, “Selection of nutrients” and “Determination of amounts”, have been combined. When the co-chairs were working to place individual principles, there appeared to be only one principle under “Selection of nutrients” which said that the addition should be “scientifically and nutritionally justified” but otherwise talks about levels of nutrients to be added.</p> <p>Some Members support including technological aspects in this section, however, for now, we have retained a separate section for technological aspects.</p> <p>Question: Do you agree with combining Selection of nutrients and Determination of amounts?</p>
<p>3.2.1 Former 3.2 with modifications (also considered to cover 6.2.5): The <u>addition of an essential nutrient should be scientifically and nutritionally justified in line with one or more of the purposes stated in 3.1.1 and be</u> 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: 3.2.1 (new) <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</u></p>	<p>Modifications to this principle were initiated in the first eWG between the 31st and 32nd sessions, First “scientifically justified” was added and in the next round, “nutritionally justified” was added. One member more recently suggested adding text speaking to “nutritional justification” to the paragraph numbered 3.1.3 above and deleting both “scientifically justified” and “nutritionally justified”, here. (The text added to 3.1.3 would read: “National authorities should determine when addition of essential nutrients to food is justified and whether addition should be mandatory or voluntary.”) It is not clear what is meant by “scientifically</p>

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<p>adverse health effects being addressed, total dietary intake of the added nutrients from foods and as well as intake from food supplements, other relevant sources, upper levels of intake and identification of special sub populations at risk.</p>	<p>justified” if the term “nutritionally justified” is included, here. One suggested alternative edit would state: “...considering amounts from all dietary and supplement sources ...”</p> <p>If the second version of this text is selected, it would appear that the statement is lost that there is a need for a nutritional justification for addition of essential nutrients.</p> <p>Question: Considering that there appears to be general agreement about the purposes set out in 3.1, is it necessary to retain a statement that addition should be nutritionally justified?</p>
<p>3.2.2 (new) <u>The Upper Level of Intake should be used to assess potential exposure to excessive intakes and to estimate safe limits of addition for essential nutrients, including considerations of populations at risk of excessive intake.</u></p>	<p>See discussion in 3.2.3 below.</p>
<p>3.2.3 (new) <u>Potential change to population intakes should be estimated as part of the decision making about nutrient addition. Such Assessment of potential exposure 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 daily intake reference values for adequacy and for safety (e.g. the Upper Level of Intake).”</u></p>	<p>This proposed principle was formerly proposed to fall under Monitoring but is moved from there as the text refers to the assessment needed to inform the decision for nutrient addition. Some members have commented that Codex guidelines do not need to elaborate on dietary modelling and use of the UL.</p> <p>“Reference daily intake values” is changed to “daily intake reference values” to align with the term used in the draft Codex <i>General Principles for Establishment of Nutrient Reference Values for Nutrients Associated with Non-communicable Diseases</i>.</p> <p>Question: Regarding 3.2.2, 3.2.3 and 3.2.4, should Codex guidelines include this guidance on dietary modelling and use of the UL to assess the safety of proposed nutrient addition? Please explain.</p> <p>There has also been a suggestion to use the type of guidance found in the Codex <i>Guidelines on vitamin and mineral food supplements</i></p>

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<p><i>National authorities may establish maximum limits for the addition of essential nutrients to foods to reduce any potential risks for adverse effects on health. Maximum limits for the addition of essential nutrients to foods should be based on the following criteria:</i></p> <p><i>(i) Upper Level of Intake (UL) of essential nutrients established by scientific risk assessment based on generally accepted scientific data, taking into consideration, as appropriate, the varying degrees of sensitivity of different consumer groups;</i></p> <p><i>(ii) the daily intake of essential nutrients from other dietary sources.</i></p> <p><i>When the maximum levels are set, due account may be taken of the reference intake values of essential nutrients for the population.</i></p> <p><i>When maximum amounts are close to the Upper Level of Intake (UL) restrictions of foods to which nutrients may be added should take account of the contribution of individual foods to the overall diet of the population in general or of sub-groups of the population."</i></p>	<p>to guide the setting of minimum and maximum amounts. The option proposed is shown at left in italics.</p> <p>Question: Would you agree with this approach to guiding addition of essential nutrients to foods?</p>
<p>3.2.4 (new) <u>Where an Upper Level of Intake is not available, the scientific evidence to support the safe addition of an essential nutrient should include:</u></p> <p><u>a) use of other values such as a Highest Observed Intake, demonstration of an upper level or a range of intake that is unlikely to result in adverse health effects, and</u></p> <p><u>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.]</u></p>	<p>Different alternatives have been proposed for this text. In one case, it was suggested to change it to: "When a UL is not available, the scientific evidence to support the safe addition of an essential nutrient should be considered, including the rationale for why a UL was not established." Another alternative was to indicate in 3.2.3 (and presumably in 3.2.2) that the UL is one example of a reference value for safety and to delete clause b) since this is already covered there.</p> <p>Another alternative is to amend clause a) to provide another example of a value that could be used to assess intakes, as shown.</p> <p>Question: What is the best guidance to national authorities to assess the safety of potential intakes when there is no UL?</p>
<p>3.2.5 (new) <u>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.</u></p>	<p>It has been suggested to remove this principle. At the Nov 2011 PWG, it was stated that any adverse effect was unacceptable and that referring to severity was unnecessary. Others believed that the potential for a severe adverse effect if the UL for a given nutrient is exceeded would require a more precautionary approach to the</p>

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	<p>selection of nutrients for addition.</p> <p>Question: Should severity of adverse effects be taken into account and not just the UL?</p>
<p>3.2.6 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.</p>	<p>Some have questioned the meaning of this statement and whether it is needed if principles related more generally to avoiding adverse effects are included. Alternatively, the sentence could be ended after the word “effect”. Others support its inclusion as is.</p> <p>One member suggested changing the beginning of this sentence to “The <u>amount of an added</u> essential nutrient should not result...”</p>
<p>3.2.7 (new) <u>"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 to which the nutrients are added meet the purpose of the addition of nutrients to foods as described in the Introduction of the [General Principles][Guidelines]. Minimum amounts for the addition of essential nutrients to foods should take into account the conditions of use for a source of claim in the Guidelines for use of nutrition and health claims (CAC/GL 23-1997) "</u>.</p> <p>Or:</p> <p><u>(new) The minimum amount of addition of an essential nutrient should take into account the intended purpose, and all other sources of the essential nutrient in the diet, including food supplements.</u></p>	<p>A member has suggested providing guidance on setting a minimum level, as shown in italics at left. Another member suggests there should be guidance</p>
<p><u>3.3 (New) Selection of Foods</u></p>	<p>This is a new sub-heading compared to the first round consultation document but is similar to one previously proposed.</p>
<p>3.3.1 (new) <u>Certain foods may have to 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 in non-target populations.</u></p>	<p>The new wording here allows more flexibility as there may be cases where a country may decide to permit addition of nutrients to a staple food on a voluntary basis to help ensure reaching the target population.</p>
<p>-(new) [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>There was a lack of support from many countries for using the concept of nutrient profiling in the document as there are no agreed upon criteria. Instead the co-chairs propose a new principle in 3.3.2 taking into account comments received.</p>
<p>3.3.2 (new) <u>The selection of appropriate foods to which essential nutrients may be added should take into account the nutritional value of the foods and is best determined by National Authorities.</u></p> <p>Or</p>	<p>As noted above, the first option at the left is modified text suggested by some members removing the words “nutrient profile” but still acknowledging that the nutritional value of the food should be one</p>

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<u>Foods or categories of foods to which particular groups of essential nutrients may not be added may be determined by national authorities taking into account their nutritional value.</u>	consideration in choosing it. It is believed that the selection of foods to which a nutrient may be added is best determined at the local level and should take into account regional/national context. A second wording has been proposed by a member. Question: Which of these two options is preferred? Please indicate the reason for your choice. If neither, please explain.
3.3.4 (new) <u>Essential nutrients should not be added to unprocessed foods, including, but not limited to, fruit, vegetables, meat, poultry and fish.</u>	This is new text suggested during the eWG between the 31 st and 32 nd sessions. Some members have indicated it is not needed while others support keeping it.
3.3.5 (new) <u>Essential nutrients should not be added to alcoholic beverages, containing more than 1.2% by volume of alcohol</u>	This is new text suggested during the eWG between the 31 st and 32 nd sessions. While there appears to be general agreement about the prohibition against addition of essential nutrients to alcoholic beverages, it is suggested to remove the indication of the specific alcoholic content as the definition of alcoholic beverages may vary across jurisdictions.
<u>3.4 (new) Technological aspects</u>	This sub-heading was proposed during the eWG between the 32 nd and 33 rd sessions.
3.4.1 (new) The sources of the <u>added</u> 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 <u>in the following order</u> : 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, or national legislation, may be used.	This is a new principle proposed in a previous eWG and there is general agreement with its inclusion. This text includes newer edits proposed by a member to streamline the text. This new principle also addresses bioavailability of the added nutrient and therefore it is considered that Former 3.5 (below) could be deleted.
3.4.2 <i>Former 3.4 with modifications</i> The <u>added</u> essential nutrient should be sufficiently stable in the food under customary conditions of <u>processing</u> , packaging, storage, distribution and use.	The edits to this text are from a previous eWG. Some members have indicated it is not needed while others support keeping it.
3.4.3 <i>Former 3.6</i> 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.	Some members have indicated it is not needed while others support keeping it.
3.4.4 <i>Former 3.7</i> Technology and processing facilities should be available to permit the [standardized] addition of the essential nutrient to a food in a satisfactory manner <u>[manner to ensure nutrient availability, consistency, distribution and stability]</u> .	Some members suggests 3.4.2, 3.4.3 and 3.4.4 should be deleted as they believe they are not relevant within the context of international guidelines, while others support their retention. Question: Please comment on whether these principles should

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	be retained.
Former 3.5 The essential nutrient should be biologically available from the food.	This could be deleted if 3.4.1 (new) is accepted. On the other hand, bioavailability of the added nutrient may be affected by the food matrix to which it is added and this may not be addressed by 3.4.1.
3.5 Monitoring	This sub-heading was proposed during the eWG between the 32 nd and 33 rd sessions. It has also been proposed as “Assessment and Monitoring”. We have placed text related to assessment in Section 3.2.
<i>Former 3.10</i> Methods of measuring, controlling and/or enforcing the levels of added essential nutrients in foods should be available to monitoring bodies to facilitate efficient monitoring of those products.	Some members had indicated that this statement expresses a basic expectation underpinning Codex standard development and therefore not required to be stated in these General Principles. Others have supported retaining it.
3.5.1 (new) <u>National authorities should monitor population total intakes, from all sources, of the nutrients essential added to foods from all dietary and supplement sources and in order to assess the extent to which the public health need [or other purpose for addition] is addressed and to ensure that any risk of excessive intakes is minimised.</u>	This is a new principle which was proposed in an eWG and more than one variation proposed and subsequently further changed, all with the same intent. Here, the co-chairs have selected one of the alternatives and made additional changes to clarify the text.
3.5.2 (new) <u>Monitoring of total nutrient intakes should use the same [method]/[approach] as used in deciding the nutrient addition.</u>	This was formerly part of 3.5.1 above and is here suggested as a separate principle.
4.0 Specific Type of Nutrient Addition	In the first round, all the principles below except for those in 4.1 were listed as Additional Principles. The following approach follows the revised structure proposed. The subsection titles could be shortened by deleting “Nutrient addition for the purpose of”.
4.1 Nutrient Addition Mandated For Purposes of fortification [Correcting]/[Reducing] Inadequate Intakes	It has been suggested to not use the term, fortification, because it may have different meanings in different countries and these don’t necessarily align with that in the original document. It was suggested to use instead “nutrient addition” and to refer to inadequate intakes. The term, inadequate intakes, is viewed as an overarching term (referred to in the Codex nutritional risk principles and guidelines) that encompasses nutrient deficiency and inadequacy.

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	<p>Many of the respondents agreed that there should be a separate section on mandatory addition because it addresses more serious concerns and consequently requires distinct considerations compared to voluntary. However, it was also pointed out by a member that the principles in original Section 6 are about increasing the intake of an essential nutrient based on a demonstrated need in one or more population(s) identified to be at risk and that mandatory addition is just one way to address a demonstrated need. In that country, standards of identity for several enriched cereal grains are required to contain folic acid at specific levels based on a demonstrated need for women of childbearing age but food manufacturers can voluntarily choose to use enriched or unenriched versions of these grains.</p> <p>In order to meet the needs of both points of view, the co-chairs suggest using the term “mandated”, which we believe could apply to both scenarios, i.e. where it is fully mandatory to add nutrients to specified foods or where specific products are mandated to have nutrient addition according to specific criteria. Thus, the principles in this section would guide decisions to address a demonstrated public health need that justifies government intervention, whether through a mandatory or voluntary approach.</p> <p>Question: Do you agree with the title of this section and the justification that there are some principles unique to mandated addition? You may wish to make specific comment under each of the proposed principles.</p>
<p>4.1.1 <i>Former 6.2.1</i> There should be a demonstrated <u>public health</u> need for increasing the intake of an essential nutrient in one or more populations groups through <u>mandated addition</u>. [through fortification]. This may be in the form of <u>need may be demonstrated by</u> actual clinical or subclinical evidence of deficiency, estimates indicating low <u>inadequate or potentially inadequate</u> levels of intake of nutrients or <u>by estimates of</u> possible deficiencies likely to develop because of changes taking place in food habits. <u>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></p>	<p>Discussion concerning the last sentence is addressed in 3.1.1. There is general support for this principle with details of the wording still to be decided.</p>

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4.1.2 <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 of inadequate intake .	There is general support for this principle with details of the wording still to be decided.
4.1.3 <i>Former 6.2.4</i> The amount of the essential nutrient added to the food should be sufficient to [reduce inadequate intakes] [correct or prevent the deficiency] when the food is consumed in [normal] [habitual] amounts by the population at risk.	There is general support for this principle with details of the wording still to be decided.
4.1.4. <i>Former 6.2.3</i> The intake of the food selected as a vehicle should be stable and uniform and the [lower and upper levels of intake] [amount of the food consumed by the lower and upper percentiles of the population] should be known.	There have been comments made that it is difficult to determine the lower and upper percentiles of intake of a food and also that the requirement for “uniform” intake may be too restrictive. A narrow range of intake would be more appropriate.
6.2.5 The amount of the essential nutrient added should not result in excessive intakes by individuals with a high intake of a fortified food.	Question: Can this be considered to be covered in 3.2.1?
3.9 The additional cost [of mandatory addition of essential nutrients to foods] should be reasonable for the intended consumer.}} 4.1.5 <i>Former 3.9 revised</i> <u>The cost effectiveness of the addition of essential nutrients to foods for the intended consumer should be considered.</u>	The revised wording is proposed on the basis that that the cost effectiveness of nutrient addition should be considered rather than just the additional cost. One member has indicated that this principle applies to all types of addition and so should be moved to section 3. Question: Do you agree with the changes to this principle? Do you agree with the suggestion to move this principle to section 3?
4.2 Nutrient Addition for Purposes of Restoration	There are some members that do not support the need for a section on restoration on the basis that the principles should be the same as those for general addition of essential nutrients. Question: Do you consider that this section should be deleted? Please explain why there is or is not the need to retain these principles.
4.2.1 <i>Former 4.1</i> Where the food has been identified as a significant <u>contributor to intake source</u> of energy and/or essential nutrients in the food supply <u>population group(s)</u> , and particularly where there is demonstrated evidence of public health need, restoration of the essential nutrients of concern lost during processing, storage or handling, should be [strongly recommended]/[carefully considered].	Some changes are suggested that reflect previous comments made. The question has been raised for discussion as to whether “energy” should be deleted.
4.2.2 <i>Former 4.2</i> A food should be considered a significant <u>contributor to intake source</u> 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]/ [INL 98] in a reasonable daily intake <u>of the food</u> (or in the case of an essential	Some changes are suggested that reflect previous comments made. One member suggested to delete the proposal to refer to NRV since these are labelling nutrient reference values not suited to this application. However, another member indicated that NRVs are

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nutrient for which there is no [recommended intake]/ [NRV]/[INL 98], 10% of the average daily intake <u>of the nutrient</u>).	appropriate since they don't vary by age and sex group and that CCNFSDU is currently revising and expanding the NRVs. Question: On which type of reference value should the 10% calculation be based?
4.3 Nutrient Addition for Purposes of Nutritional Equivalence	There are some members that do not support the need for a section on nutritional equivalence on the basis that the principles should be the same as those for general addition of essential nutrients. Question: Do you consider that this section should be deleted? Please explain why there is or is not the need to retain these principles.
4.3.1 <i>Former 5.1</i> Where a substitute food is intended to replace a food which has been identified as a significant source [contributor to intake] of energy and/or essential nutrients in the food supply [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.	Some changes are suggested that reflect previous comments made.
4.3.2 <i>Former 5.2</i> A food being substituted or partially substituted should be considered a significant source contributor to intake of an essential nutrient if a serving or portion or 100 kcal of the food contains the essential nutrient in amounts equal to or greater than 5% of the [recommended nutrient intake]/[NRV]/ [INL 98]. Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this nutrient need not be equivalent.	Some changes are suggested that reflect previous comments made.
4.3.3 <i>Former 5.3</i> Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this nutrient need not be equivalent.	There is support for retaining as is.
4.4 Nutrient addition to Special Purpose Foods	There are some members that do not support the need for a section on special purpose foods as the specific provisions for these foods are covered by other Codex standards and guidelines. Question: Do you consider that this section should be deleted? Please explain why there is or is not the need to retain these principles.
4.4.1 <i>Former 7.1</i> [Essential] nutrients may be added to special purpose foods, including foods for special dietary uses, to ensure an appropriate and adequate nutrient content [for their intended use] [based on the principles in this guidance wherever applicable]. Where appropriate, such addition should be made with due regard to the nutrient [composition] {density} of such foods. [Consideration should be given to the target population and their nutrient requirements based on general reference intakes such as RNIs.]	It has been suggested to delete “nutrient density” and replace it with “nutrient composition.” Question: Is this an acceptable change? If not, please explain.

APPENDIX D

Distribution List for Electronic Working Group on Addition of Essential Nutrients to Foods –
2012 CCNFSDU

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