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**Agenda Item 5**

**CX/NFSDU 09/31/5**

**September 2009**

## **JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

### **CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES Thirty first Session**

**Robert Shuman Hall, Museum Kunst Palast, Düsseldorf, Germany**

**2 – 6 November 2009**

### **DISCUSSION PAPER ON THE PROPOSAL FOR NEW WORK TO AMEND THE CODEX GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS (CAC/GL 9-1987)**

(Prepared by Canada based on comments from an Electronic Working Group including Australia, Argentina, the European Community, Germany, Iran, New Zealand, Sweden, United States of America, the Council for Responsible Nutrition, the International Alliance of Dietary/Food Supplement Associations and the International Dairy Federation)

#### **BACKGROUND**

1. At the 30th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) in November 2008 in Cape Town, South Africa, Canada presented a Discussion Paper and Work Proposal for new work (CX/NFSDU 08/30/8) for the Committee to Amend the *Codex General Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 09-1987). The Discussion Paper and Work Proposal can be viewed at [ftp://ftp.fao.org/codex/ccnfsdu30/nf30\\_08e.pdf](ftp://ftp.fao.org/codex/ccnfsdu30/nf30_08e.pdf)

2. In its presentation of the proposal to the 30th Session of the Committee, Canada made the following points:

- That the “Basic Principles” in the Codex General Principles for the Addition of Essential Nutrients to Foods (Principles) do not address current practices, potentially limit

consumer choice and the development of new products, and result in barriers to trade that are not justified based on safety considerations.

- That the growth in the availability of food products with added vitamins and mineral nutrients that go beyond the purposes set out in the Basic Principles appears to be the result of a growing interest on the part of consumers and the food industry in a wider selection of foods with added vitamin and mineral nutrients.

- That the CCNFSDU undertake to revise the Principles, specifically the “Basic Principles” set out therein, in order to expand their applicability to include the discretionary addition of vitamins and mineral nutrients to foods for purposes beyond the prevention or correction of demonstrated deficiencies, while preventing risks associated with indiscriminate addition.

- That the intent of this proposed revision is not to replace the “Basic Principles”, which have a public health basis, but to extend them to also set out principles for the safe discretionary addition of vitamin and mineral nutrients. This would not only acknowledge current practices but would ensure that such current practices are safe.

- That the intent is to provide for the “discretionary addition” of vitamins and mineral nutrients to foods for reasons other than those currently stated in the “Basic Principles”, while maintaining health and safety principles. Discretionary addition of vitamins and mineral nutrients to foods would generally provide consumers with a greater choice and a broader variety of foods with added vitamins and mineral nutrients at safe levels.

- That a risk-based approach be used to preserve the intent of the Principles in the prevention of the indiscriminate addition of essential nutrients to foods. This would continue to result in a decreased risk of health hazard due to nutrient excesses, deficits or imbalances.

- That a risk-based approach include, for example,

- restrictions on which foods would be allowed to have vitamins and mineral nutrients added at the discretion of the manufacturer,
- which nutrients could be added, and
- the levels to which permitted nutrients could be added.

- That the applicability of the Principles to non-traditional or indirect addition of essential nutrients should be affirmed as these methods were of growing importance. Consideration should be given to the need for any potential additional restrictions for this type of nutrient enhancement e.g., its prohibition for certain types of foods.

3. Based on discussions at the Session (ALINORM 09/32/26, paragraphs 130 to 133), the Committee agreed that an Electronic Working Group (EWG), led by Canada, would be established to revise the Discussion Paper and Proposal for New Work to Amend the Codex

General Principles for the Addition of Essential Nutrients to Foods, taking into account the comments made at the Session, for consideration by the 31st Session of the CCNFSDU.

4. Since there was little support expressed by the Committee for considering non-traditional or indirect addition of essential nutrients within the Codex General Principles for the Addition of Essential Nutrients to Foods, the discussion document and proposal would be limited at this time to addressing discretionary fortification.

#### **ELECTRONIC WORKING GROUP**

5. In March 2009 Canada invited all members of CCNFSDU interested in participating in the EWG to provide contact information by April 3, 2009. Expressions of interest in participating in the EWG were received from Argentina, Australia, Belgium, Brazil, the European Community, Germany, Greece, Iran, Japan, Malaysia, New Zealand, Republic of Korea, South Africa, Thailand, United States of America, CIAA (Confederation of the Food and Drink Industries of the EU), CRN (Council for Responsible Nutrition), EuSalt (European Salt Producers' Association), IADSA (International Alliance of Dietary/Food Supplement Associations), IDF (International Dairy Federation), ISDI (International Special Dietary Foods Industries, and WHO (World Health Organization) .

6. EWG participants were invited to provide comments on both the Discussion Paper and the Project Document, "Proposal for New Work to Amend the Codex General Principles for the Addition of Essential Nutrients to Foods" by July 31, 2009.

7. Participants were particularly asked to provide comments on sections 1 to 3 of the Project Document, "Purpose and Scope of the Proposed New Work", "Its Relevance and Timeliness" and "The Main Aspects to be Covered" .

#### **First Round of Comments**

8. Comments were received from Australia, Argentina, the European Community, Germany, Iran, New Zealand, Sweden, United States of America, IADSA and IDF. The ten members and observers who provided comments were generally in favour of proceeding with the development of the proposal for new work to amend the General Principles for discussion by the 31st Session of CCNFSDU. A number of suggestions were submitted proposing revisions to the Discussion Paper and the Proposal for New Work (Project Document) to provide additional clarity as to the proposed intent as well as to bring into consideration additional factors. In particular the following comments were made:

- Need to clarify whether the intent of the proposal is to affirm that the current Principles apply to both mandatory and voluntary addition of essential nutrients to foods.
- Need to clarify the differences and similarities in principles for mandatory versus voluntary fortification and possibly include reference to this in the Principles.

- Consider revision of definition of “fortification” such that its purpose is not limited to preventing or correcting a demonstrated deficiency of an essential nutrient but to also encompass other public health benefits as demonstrated by relevant scientific data.
- Need to clarify whether the intent of the proposal is to develop additional general principles to guide voluntary/discretionary addition of essential nutrients or to set out specific guidelines intended to be applied internationally with regard to permitted nutrients, foods and levels.
- The Principles should include the concept of “science-based approach” to incorporate, in addition to health risk, the potential health benefits of discretionary/voluntary fortification.
- Consider harmonizing terminology with that used in the WHO/FAO Guidelines on Food Fortification with Micronutrients, especially “voluntary fortification in which the impetus comes from consumers and industry”.
- Retain the current focus of the Principles on essential nutrients in general, rather than only vitamins and mineral nutrients specifically.
- Re-affirm that the Principles apply to all foods including those for infants and young children.
- The Committee may wish to discuss under this agenda item whether it would be desirable to request FAO/WHO to develop internationally agreed upon upper levels of nutrient intake [to be based on A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances, WHO/FAO 2006].

9. Canada used the above comments, as well as other suggestions made by EWG participants regarding language and clarity, in revising the Discussion Paper and the Project Document, “Proposal for New Work to Amend the Codex General Principles for the Addition of Essential Nutrients to Foods”. These were circulated to all EWG participants on August 24, 2009, with a request for a second round of comments by September 11, 2009.

### **Second Round of Comments**

10. Comments on the Draft Revised Discussion Paper and Project Document were received from Argentina, Australia, the European Community, United States of America, IDF and CRN.

11. In addition to very helpful editorial comments as well as suggestions for further clarity, the comments included the following:

- Support for maintaining the current focus of the *Principles* on essential nutrients in general, rather than on vitamins and minerals specifically.
- A review of the *Principles* is timely to guide the voluntary addition of essential nutrients to foods.

- Criteria governing mandatory fortification should remain the responsibility of national authorities, therefore question the need to provide an extension of the basic principles, such as a detailed differentiation between the principles for mandatory and voluntary fortification.
- The selection of appropriate foods to fortify and the selection of nutrients to be added, will depend on the local, national or regional situation, therefore question the need to provide specific details on criteria and principles for voluntary fortification.
- The review of the basic principles may lead to a reflection on whether there is a need to maintain the definitions and reasons for the addition of vitamins and minerals to foods.
- With reference to the setting of maximum and minimum levels of addition, the *Principles* should guide national authorities when considering whether certain practices could be potentially misleading to the consumer, and in carrying out their own risk assessment which might include establishing maximum levels.
- The list of models that apply a risk-based approach should include: Richardson, D.P. Risk management of vitamins and minerals: a risk categorisation model for the setting of maximum levels in food supplements and fortified foods. Food Science and Technology Bulletin: Functional Foods 4 (6) 51–66, 2007.
- The proposed new work should include a request for the FAO/WHO to establish internationally recognized UL and HOI values. The absence of a UL for some nutrients is widely misinterpreted as indicating that there is insufficient data to evaluate risk. For several vitamins and bioactives ingredients, this conclusion was valid only prior to the publication of the FAO/WHO nutrient risk assessment document that defines the HOI.
- Need to clarify whether the *Principles* apply to Vitamin and mineral Food Supplements.

**Revised Discussion Paper and Proposal for New Work to Amend the Codex General Principles for the Addition of Essential Nutrients to Foods**

12. Based on the additional comments received during round 2, Canada is pleased to provide the revised versions of the Discussion Paper and Proposal for New Work to Amend the Codex General Principles for the Addition of Essential Nutrients to Foods, for discussion at the 31st Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses.

## Annex 1

## DISCUSSION PAPER

**Revised Proposal for New Work to Amend the Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987)****Introduction**

1. The Codex *General Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 09-1987) (*Principles*) provide guidance for the maintenance or improvement of the overall nutritional quality of foods through the addition of essential nutrients for the purpose of fortification (as currently defined in the *Principles*), restoration and nutritional equivalence. The *Principles* also address the addition of essential nutrients to special purpose foods to ensure an adequate and appropriate nutrient content. The *Principles* further aim to prevent the indiscriminate addition of essential nutrients to foods, thereby decreasing the risk of health hazard due to nutrient excesses, deficits or imbalances. These *Principles* also state that they are intended to apply to all foods to which essential nutrients are added. Thus, any proposed new principles should take into consideration foods for infants and young children.

2. Since the introduction of the *Principles* in 1987, and their subsequent amendments in 1989 and 1991, there has been a growing understanding of the role of nutrients in foods in health and disease risk reduction. Changes in lifestyle and dietary habits have also prompted a growing interest by the food industry to provide consumers with a wider selection of fortified foods.

3. Some jurisdictions, (for example, including the European Community and Argentina), allow the addition of essential nutrients to foods for reasons other than those listed in the *Principles*, for example, voluntary (discretionary) additions to provide consumers with a greater variety of foods with added vitamins and mineral nutrients. Some of these jurisdictions indicate that restrictions for voluntary fortification should only be justified on the basis of safety and on the possibility to mislead consumers. The *Principles* thus no longer address all situations where essential nutrients are added to foods. A review of the *Principles* may thus be timely, including the extension of the basic principles to guide the voluntary addition of essential nutrients to foods.

4. An apparent gap in the *Principles* is that “mandatory” versus “voluntary” fortification by manufacturers is not explicitly addressed. Voluntary fortification occurs when a manufacturer freely chooses to fortify a food or foods. In some cases, the impetus for voluntary fortification comes from government, but more commonly the voluntary fortification appears to be the result of a growing interest on the part of consumers and the food industry for a wider selection of foods with added vitamin and mineral nutrients with plausible health benefits.<sup>1</sup>

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<sup>1</sup> *Guidelines on Food Fortification with Micronutrients*. Edited by Lindsay Allen et al.

## Types of Fortification

5. Currently, the Principles define “fortification or enrichment” to mean “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 a demonstrated deficiency of one or more nutrients in the population or specific population groups.” By comparison, the definition of “fortification” in the 2006 WHO/FAO publication on “Guidelines on Food Fortification with Micronutrients” extends the definition to include other public health benefits. Thus, it may be appropriate to consider in any new work whether there is a need to revise the definition of these terms.

6. In addition, Section 6 of the Principles currently states that “Fortification should be the responsibility of national authorities” and does not appear to provide a comprehensive set of principles intended for both mandatory and voluntary addition of essential nutrients to foods.

7. In considering whether the heading and certain text in Section 6 of the Principles should be revised and other provisions added, it may be important to recognize different types of mandatory and voluntary fortification. For example, the types of fortification described in the 2006 WHO/FAO publication include:

- Mandatory fortification of an entire commodity (e.g., requiring iodine fortification of all food grade salt for human consumption);
- Mandatory fortification applied only to a food identified and labeled in a certain way (e.g., requiring fortification of grain products identified and labeled as “enriched” to be fortified with folic acid and certain other micronutrients);
- Voluntary fortification in which the impetus comes from government (e.g., voluntary fortification of certain fat-soluble vitamins to margarine); and
- Voluntary fortification in which the impetus comes from consumers and industry (e.g. voluntary addition of calcium to orange juice).

8. An initial step in any new work proposal might be 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.

9. As noted above, one objective of the review of the Principles would be to re-affirm that the Principles encompass voluntary fortification. Another 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 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.”

10. Voluntary fortification can provide consumers with a greater choice and a broader variety of foods with added essential nutrients (e.g., vitamin and mineral nutrients). Whether or not this benefits their health would depend on a number of factors. Socio-economic situations, life styles, and dietary habits may put some population segments at higher risk of not achieving recommended intakes for some essential nutrients. Moreover, health benefits may extend beyond simply the prevention or correction of a vitamin or mineral deficiency.

### **Limits and Levels of Fortification**

11. To preserve the intent of the Principles, potential new work would consider scientific advances in nutrient risk assessment as they may relate to updating the principles. In this regard, it may be noted that the Codex Guidelines for Vitamin and Mineral Food Supplements also provide principles for establishing maximum levels based on scientific risk assessment. A risk-based approach should be encouraged to identify the parameters that would have to be considered and introduced for voluntary fortification to reduce the risk of health hazard due to excess or imbalance of nutrients in the diet, or due to a change in dietary patterns resulting in excess, inadequacy or imbalance in the diet, that could result from the indiscriminate addition of essential nutrients. Such an approach would include consideration of criteria or principles related to:

- a) selection of appropriate foods to fortify,
- b) selection of nutrients to be added, and
- c) determination of levels to which permitted nutrients could be added.

12. Several models of applying a risk-based approach exist in this regard [Flynn et al., 2003; Health Canada, 2005; European Commission, 2006; Rasmussen et al., 2006; Kloosterman et al., 2007; Richardson, 2007].

13. Similarly, to preserve the intent of the Principles with regard to helping to prevent practices that may mislead or deceive the consumer, the need for an evidence-based approach to determining the validity of a health rationale for voluntary addition could be cited in the General Principles. On the other hand, some countries may not always have sufficient data to conduct scientific risk assessments. Thus, the Committee will need to consider the implications of insufficient data as they relate to these fortification principles.

### ***Foods subject to voluntary fortification***

14. Consideration could also be given to the question of whether there is a need for principles regarding the prohibition of voluntary fortification of certain types of foods and if so, which ones (e.g., beverages exceeding certain alcoholic content; foods considered to have negligible nutritional value; foods exceeding a certain level of risk-increasing nutrients/components, such as sodium, saturated and trans fat, sugar, etc.). Consideration could also be given as to whether there are circumstances when staple foods may need to be excluded because of their ubiquity in the food supply and the potential that their voluntary fortification could lead to exposure to high

intakes associated with risk of adverse health effects. The preceding would have to be balanced with the risk of eliminating potential opportunities for reaching specific target groups, for example a food commonly used by members of a sub-population group, that could benefit from a fortification of a food that is more acceptable to them.

***Essential nutrients permitted for voluntary fortification: setting maximum and minimum levels of addition***

15. A risk-based approach would take into consideration all sources of exposure, including intakes from supplements, and Upper Levels of Intake (ULs), where these have been established. Such an approach may inform guidance regarding the need to set maximum levels of addition.

16. In setting maximum levels of addition for voluntary fortification, consideration would also have to be given to the factors that would need to be taken into account where there is not yet a scientifically established value for ULs for a nutrient, and whether there is a need to set maximum levels for nutrients where the risk of adverse effects, even at high levels of intakes, appears to be extremely low or non-existent according to available data.

17. The proposed work would also consider whether there is a need to revise or add principles for the establishment of minimum levels of nutrient addition. For example, Section 3.2 currently states that “The essential nutrient should be present at a level which will not result in either an excessive or insignificant intake of the added essential nutrient considering amounts from other sources in the diet.”

18. 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. For example, should the minimum level be the same as the amount required to be present for a claim and/or declaration of the nutrient in nutrition labelling? What other criteria might be considered?

**Scientific Advice**

19. The Committee may wish to discuss under this agenda item whether it would be desirable to request FAO/WHO to establish international Upper Levels of Intake, which could build on the report of the 2005 Joint FAO/WHO Technical Workshop on Nutrient Risk Assessment.

**Summary**

20. This Discussion Paper identifies the rationales for a review of the Codex Principles for the Addition of Essential Nutrients to Foods and presents several issues and questions to be considered in amending and/or clarifying the Principles. In reviewing the Principles, several objectives would be considered. While recognizing the desire of some consumers for a broader choice of foods with added essential nutrients, and industry’s interest in not having unjustifiable barriers to trade, it is equally important, to prevent the indiscriminate addition of essential nutrients to foods for health protection, and to ensure that consumers are not misled regarding the nutritional quality of foods to which essential nutrients are added.

## References

European Commission. Health & Consumer Protection Directorate E. (2006). *Discussion Paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs*.

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Kloosterman J, Fransen HP, de Stoppelaar J, Verhagen H, Rompelberg C. (2007). Safe addition of vitamins and minerals to foods: Setting maximum levels for fortification in the Netherlands. *Eur J Nutr* 46:220-229.

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Richardson DP, Risk management of vitamins and minerals: a risk categorisation model for the setting of maximum levels in food supplements and fortified foods. *Food Science and Technology Bulletin: Functional Foods* 4 (6) 51–66, 2007.

World Health Organization/Food and Agriculture Organization of the United Nations, *Guidelines on Food Fortification with Micronutrients*. Edited by Lindsay Allen, Bruno de Benoist, Omar Dary and Richard Hurrell. 2006.

## PROJECT DOCUMENT

### REVISED PROPOSAL FOR NEW WORK TO AMEND THE CODEX GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS (CAC/GL 09-1987)

#### 1. PURPOSE AND THE SCOPE OF THE PROPOSED NEW WORK

The *Codex General Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 09-1987) (*Principles*) provide guidance for the maintenance or improvement of the overall nutritional quality of foods through the addition of essential nutrients for the purpose of fortification (as defined in the *Principles*), restoration, and nutritional equivalence. The *Principles* also address the addition of essential nutrients to special purpose foods to ensure an adequate and appropriate nutrient content. The *Principles* aim 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. The principles are intended to apply to all foods to which essential nutrients are added. Thus, any proposed new principles should take into account foods for infants and young children.

Some jurisdictions, (for example, the European Community and Argentina), allow the addition of essential nutrients to foods for reasons other than those listed in the *Principles*, for example, voluntary (discretionary) additions to provide consumers with a greater variety of foods with added vitamins and mineral nutrients. Some of these jurisdictions indicate that restrictions for voluntary fortification should only be justified on the basis of safety and on the possibility to mislead consumers. The *Principles* thus no longer address all situations where essential nutrients are added to foods. A review of the *Principles* may be timely, including the extension of the basic principles to guide the voluntary addition of essential nutrients to foods.

An apparent gap in the *Principles* is that mandatory versus voluntary fortification by manufacturers is not explicitly addressed. Voluntary fortification occurs when a manufacturer freely chooses to fortify a food or foods. In some cases, the impetus for voluntary fortification comes from government, but more commonly the voluntary fortification appears to be the result of a growing interest on the part of consumers and the food industry for a wider selection of foods with added vitamin and mineral nutrients with plausible health benefits.<sup>1</sup>

Since the introduction of the *Principles* in 1987, and their subsequent amendments in 1989 and 1991, there have been a number of changes in the availability of fortified foods in countries and in approaches to controlling the addition of essential nutrients to foods.

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<sup>1</sup>*Guidelines on Food Fortification with Micronutrients*. Edited by Lindsay Allen et al. WHO/FAO. 2006. pg 250.

In addition, the *Principles* do not take into consideration scientific advances in nutrient risk assessment, including related standards recently established by authoritative scientific bodies for Upper Levels of Intake. In this regard, the Committee also supports further consideration of the desirability and feasibility of the establishment of international Upper Levels of Intake through scientific advice provided by WHO and FAO.

In view of the expanded nutrient addition now occurring in many countries, the *Principles* need to be expanded to include principles for the voluntary addition of essential nutrients that do not meet the current criteria of fortification, restoration, nutritional equivalence or a special purpose food. The intent of the Principles, “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”, would be equally applicable in this regard, but different means would be required to address it, such as, for example, application of Upper Levels of Intake.

The purpose of this proposed new work is not to replace the “Basic Principles”, which have a public health basis, but to extend them 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.

## **2. ITS RELEVANCE AND TIMELINESS**

The work is in line with the Terms of Reference for the CCNFSDU including

- (a) to study specific nutritional problems assigned to it by the Commission and advise the Commission on general nutrition issues; and
- (b) to draft general provisions, as appropriate, concerning the nutritional aspects of all foods.

The work is timely because of the increase in the voluntary addition of essential nutrients for purposes other than those stated in the *Principles* (namely, for the purpose of fortification (as currently defined), restoration, nutritional equivalence or special purpose).

It is essential that consumers be protected from risk to health due to nutrient excesses or imbalances. The addition of an essential nutrient to a food for any purpose must take into consideration all related health risks.

## **3. THE MAIN ASPECTS TO BE COVERED**

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.

As noted in the Discussion Document, 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 deficiency, 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.

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).

#### **4. AN ASSESSMENT AGAINST THE CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES**

The proposed new work would assist governments in formulating policies with regard to both mandatory and voluntary addition of essential nutrients to foods.

The new work would also lessen impediments to international trade by providing clear guidance on considerations that need to be addressed with regard to the above.

#### **5. RELEVANCE TO THE CODEX STRATEGIC OBJECTIVES**

The proposed new work on the *Principles* is consistent with the strategic vision and goals outlined in the Codex Alimentarius Commission, Strategic Plan (2008-2013). It would contribute to: Goal 1 - Promoting sound regulatory frameworks and Goal 2 - Promoting widest and consistent application of scientific principles and risk analysis.

## **6. INFORMATION ON THE RELATION BETWEEN THE PROPOSAL AND OTHER EXISTING CODEX DOCUMENTS**

The *Codex General Principles for the Addition of Essential Nutrients to Foods* may be considered by this Committee and other Codex Committees in the development or revision of Codex guidelines and standards. In addition, the revision of these principles may take into account related Codex texts such as the *Guidelines for Vitamin and Mineral Food Supplements*, and the *Guidelines on Formulated Supplementary Foods for Older Infants and Children*.

## **7. IDENTIFICATION OF THE RELATION BETWEEN THE PROPOSAL AND OTHER EXISTING CODEX DOCUMENTS**

None foreseen.

## **8. IDENTIFICATION OF ANY NEED FOR TECHNICAL INPUT TO THE STANDARD FROM EXTERNAL BODIES SO THAT THIS CAN BE PLANNED FOR**

The Committee supports further consideration of the desirability and feasibility of the establishment of international Upper Levels of Intake through scientific advice provided by WHO and FAO.

## **9. THE PROPOSED TIME-LINE FOR COMPLETION OF THE NEW WORK, INCLUDING THE START DATE, THE PROPOSED DATE FOR STEP 5 AND THE PROPOSED DATE FOR ADOPTION BY THE COMMISSION**

Subject to approval by this (the 31st) Session of the Committee, the new work could commence following the 33rd Session of the Codex Alimentarius Commission meeting (2010). Proposed amendments to the *General Principles for the Addition of Essential Nutrients to Foods* could be circulated for government comments at Step 3 in 2011 following the 32nd Session of the CCNFSDU (2010). It is anticipated that the 33rd or 34th Sessions of the CCNFSDU (2012; 2013) could advance the document to Step 5 and the 35<sup>th</sup> or 36<sup>th</sup> Sessions of the CCNFSDU (2014; 2015) could advance the document to Step 8. Therefore, the work could be completed in four to five years.

### **Proposed timelines:**

**Start Date:** 2010

**Proposed Date for Adoption at Step 5:** 2012-2013

**Proposed Date for Adoption by the Commission:** 2014-2015