codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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

Prepared by Canada

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, 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 nutrient excesses, deficits or imbalances.

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. In addition, there have been a number of changes in technologies for achieving addition or enhancement of essential nutrient levels in foods.

Of importance is the fact that a number of jurisdictions have now sanctioned the addition of essential nutrients for reasons other than those listed in the *Principles*, for example, “discretionary” fortification of foods to provide consumers with a greater variety of foods with added vitamins and mineral nutrients. Some of these jurisdictions indicate that restrictions for discretionary 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, and the above changes suggest that a review of the *Principles* may be timely, particularly with respect to the reconsideration of the basic principles guiding the addition of essential nutrients to foods.

In reviewing the *Principles*, it will also be important to ensure that they apply equally to the augmentation or enhancement of essential nutrients in foods through non-traditional means (indirect methods) as well as through traditional means (direct addition), as similar considerations are appropriate regardless of the means used to increase the essential nutrient content of a food.

Discretionary fortification

Discretionary fortification refers to the addition of essential nutrients, at the discretion of the food manufacturer, for reasons other than those currently listed in the *Principles.* There are concerns that the *Principles* are too restrictive and limit the development of new products and result in barriers to trade that are not justified based on safety considerations.

Discretionary fortification would generally provide consumers with a greater choice and a broader variety of foods with added vitamins and mineral nutrients. Consumers could select foods with added vitamins and mineral nutrients more often and increase the amounts of vitamins and mineral nutrients in their diets. Whether or not this benefits their health would depend on the actual adequacy of intakes of the added nutrients. Changes in socio-economic situation, life styles, and dietary habits may put some population segments at higher risk of not achieving recommended intakes for some essential nutrients. Moreover some argue that optimal health may depend on higher levels of vitamins and minerals than those recommended on the basis of avoiding deficiencies or inadequate intakes.

A number of jurisdictions have sanctioned the practice of discretionary fortification in recent years and consider that the only restrictions on discretionary fortification should be based on safety considerations and on the possibility of misleading consumers, i.e., no specific nutritional rationale, such as a public health or special dietary purpose or the improvement of the nutritional quality of foods and diets, would be required.

To preserve the intent of the *Principles*, a risk-based approach would be required to identify the parameters that would have to be considered and introduced for discretionary fortification to reduce the risk of health hazard due to excess or imbalance of nutrients in the diet that could result from the indiscriminate addition of essential nutrients, for example including what foods could be fortified, which nutrients may be added, and the levels to which permitted nutrients could be added. 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].

Foods subject to discretionary fortification

Consideration would need to be given to the question whether there is a need to prohibit discretionary 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 would also need to be given as to whether staple foods may need to be excluded because of their ubiquity in the food supply and the potential that their discretionary 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 discretionary fortification: setting maximum and minimum levels of addition

A risk-based approach would take into consideration all sources of exposure, including intakes from supplements, and tolerable upper intake levels (ULs) where these have been established. Such an approach would inform guidance regarding the essential nutrients permitted for discretionary fortification as well as in setting maximum and minimum levels of addition.

In setting maximum levels of addition for discretionary 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 tolerable upper intake level 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.

In setting minimum levels of addition, consideration would have to be given to means to ensure that the consumer is not misled as to the nutritional quality of the fortified food, i.e., the minimum level of addition should result in some significant amount of the added nutrient. 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?

Non-traditional methods or indirect addition of essential nutrients to foods

Direct addition of essential nutrients to the food at the stage of food processing has been the traditional means of food fortification. Recently, however, a growing number of non-traditional methods or indirect addition methods (referred to by some as "bio-fortification") for essential nutrients are being employed at an earlier point of food production. Indirect addition can be done in a variety of ways, including modification of the plant or animal organism that is the source of the food (e.g., enhancing beta-carotene level in rice) and other approaches to changing food composition at the level of food production (e.g., modifying the growth medium or fertilizer for crop plants or the feed for food animals to increase levels of vitamins, mineral nutrients and other essential nutrients such as fatty acids).

New non-traditional methods of fortification make it possible to indirectly add nutrients to certain types of food, such as fresh fruits and vegetables, eggs, nuts, fresh meat, fish and poultry, something not readily achieved by traditional methods of fortification. In some jurisdictions, direct addition of nutrients to these types of food is prohibited because they are already good sources of one or more naturally occurring nutrients. Moreover, consideration would have to be given to whether some consumers may view certain types of foods inappropriate for bio-fortification and whether this would depend on the nutrient being added.

The applicability of the *Principles* to non-traditional or indirect addition of essential nutrients should be affirmed within the *Principles* with consideration given to the need for any potential additional restrictions for this type of nutrient enhancement, e.g., certain types of foods.

Summary

This Discussion Paper identifies the rationales for a review of the Codex *Principles for the Addition of Essential Nutrients to Foods* and poses 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 need for a broader choice of foods for consumers, greater flexibility for industry and fewer 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.

In summary it is important to note that the Draft Action Plan for Implementation of the Global Strategy on Diet, Physical Activity and Health (CL 2006/44-CAC, September 2006) highlights the role of CCNFSDU in the provision of advice on the use of sound nutrition principles in the production, processing and formulation of foods based on the population nutrient intake goals of the 2002 Expert Consultation. Revised General Principles for the Addition of Essential Nutrients to Foods that address all current relevant issues would be in line with the Action Plan.

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*.

Finley JW, Sigrid-Keck A, Robbins RJ, Hintze KJ. (2005). Selenium enrichment of broccoli: Interactions between selenium and secondary plant compounds. *J Nutr* 135: 1236-1238.

Flynn A, Moreiras O, Stehle P, Fletcher RJ, M ller DJG, Rolland V. (2003). Vitamins and minerals: A model for safe addition to foods. *Eur J Nutr* 42: 118-130.

Health Canada. (2005). *Addition of vitamins and minerals to foods – Health Canada's proposed policy and implementation plans*.

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.

Rasmussen SE, Andersen NL, Dragsted LO, Larsen JC. (2006). A safe strategy for addition of vitamins and minerals to foods. *Eur J Nutr* 45: 123-135.

PROJECT DOCUMENT

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, 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.

Since the introduction of the *Principles* in 1987, and their subsequent amendments in 1989 and 1991, there have been a number of changes in approaches to controlling the addition of essential nutrients to foods and in technologies for achieving addition or enhancement of essential nutrient levels in foods, suggesting that a review of the *Principles* may be timely.

Of greatest significance is the fact that a number of jurisdictions have now sanctioned the addition of essential nutrients for other reasons than those listed in the *Principles*, for example, Adiscretionary@ addition of vitamins and mineral nutrients to provide consumers with a greater variety of foods with added vitamins and mineral nutrients. The *Principles* thus no longer address all situations where essential nutrients are added to foods.

In view of the expanded purposes for nutrient addition now being sanctioned in many countries, the *Principles* need to be expanded to include discretionary fortification which does not meet the criteria of fortification, restoration, nutritional equivalence or special purpose and which does not, per se, maintain or improve the overall nutritional quality foods. The intent of the General Principle, ATo 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 achieve it, such as, for example, application of tolerable upper intake levels.

In reviewing the *Principles*, it will also be important to ensure that they apply equally to the augmentation or enhancement of essential nutrients in foods through non-traditional means as well as through traditional means, as similar considerations are appropriate regardless of the means used to increase the essential nutrient content of a food. The traditional means used to add essential nutrients to food is the direct addition of these substances to the food. Currently, however, augmentation or enhancement of the essential nutrients in foods of plant and animal origin is also being achieved through non-traditional methods such as modification of the animal or plant organism that is the source of the food (e.g., beta-carotene production in rice; changes to plant product composition by modifying the growth medium), and alterations to livestock feed composition resulting in nutritionally enhanced animal products (e.g., higher levels of nutrients in eggs or dairy products).

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 since the addition of essential nutrients for purposes other than fortification, restoration, nutritional equivalence or special purpose has been sanctioned in many jurisdictions. The nutritional enhancement of foods by means other than the traditional direct addition of nutrients to foods is a rapidly evolving area. Both may have a significant impact on the nutritional profiles of traditional foods and the intake of essential nutrients by consumers.

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.

It is worthwhile noting that Draft Action Plan for Implementation of the Global Strategy on Diet, Physical Activity and Health (CL 2006/44-CAC, September 2006) highlights the role of CCNFSDU in the provision of advice on the use of sound nutrition principles in the production, processing and formulation of foods based on the population nutrient intake goals of the 2002 Expert Consultation.

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 stated in the current *Principles* as well as the use of non-traditional means of augmentation or enhancement of essential nutrients in foods, including an examination of how to protect consumers against excesses, deficits or imbalances.

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 the addition of essential nutrients to foods for purposes other than maintaining or improving the overall nutritional quality foods. It would also assist governments in protecting consumers from health hazard due to the indiscriminate enhancement or augmentation of the essential nutrient in foods through non-traditional methods such as modification of plant or animal organisms that are the source of the food or through alterations to livestock feed composition.

The new work would also lessen impediments to international trade by providing clear guidance on considerations that need to be addressed when dealing with any of 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 other Codex Committees in the development of guidelines and standards. The new work in revising the *Principles* would complement the Annex on Food Safety Assessment of Food Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits (N02-2006, Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology) which states that the *Codex General Principles for the Addition of Essential Nutrients to Foods* are generally applicable to the safety assessment of a food derived from a recombinant-DNA plant modified for nutritional or health benefits. The revision of the *Principles* would strengthen that guidance in the Annex.

The Draft Action Plan for Implementation of the Global Strategy on Diet, Physical Activity and Health (CL 2006/44-CAC, September 2006) highlights the role of CCNFSDU in the provision of advice on the use of sound nutrition principles in the production, processing and formulation of foods based on the population nutrient intake goals of the 2002 Expert Consultation.

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

None foreseen.

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: THE TIME FRAME FOR DEVELOPING GUIDELINE SHOULD NOT NORMALLY EXCEED FIVE YEARS

Subject to approval by this (30th) Session of the Committee, the new work could commence following the 32st Session of the Codex Alimentarius Commission meeting (2009). Proposed amendments to the *General Principles for the Addition of Essential Nutrients to Foods* could be circulated for government comments at Step 3 in 2010 following the 31th Session of the CCNFSDU (2009). It is anticipated that the 32nd or 33rd Sessions of the CCNFSDU (2011; 2012) could advance the document to Step 5 and the 34th or 35th Sessions of the CCNFSDU (2013; 2014) could advance the document to Step 8. Therefore, the work could be completed in four to five years.

Start Date:	2009
Proposed Date for Adoption at Step 5:	2011-2012
Proposed Date for Adoption by the Commission:	2013-2014