

**CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES****PROJECT DOCUMENT FOR 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) 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 General Principles in 1987 and subsequent amendments in 1989 and 1991, there have been a number of changes in approaches to controlling the addition of vitamins and mineral nutrients to foods and technologies for achieving addition or enhancement of vitamin and mineral nutrient levels in foods, as well as increasing interest in non-nutrient bioactive substances, suggesting that a review of the General Principles may be timely.

1. Non-traditional methods are now being employed for the addition of vitamins and mineral nutrients to foods. The traditional means used to add essential nutrients to food is the direct addition of these substances to the food; this is what the Principles in their current format address.

Recently, 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

- genetic 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. The General Principles guiding the addition of essential nutrients to foods should generally apply equally to the augmentation or enhancement of essential nutrients in foods through non-traditional means as through traditional means and so would many of the Basic Principles included within the General Principles, as similar considerations are appropriate regardless of the means used to increase the essential nutrient content of a food. It is not clear whether the language of the current General Principles precludes non-traditional or indirect addition of

essential nutrients to foods.

3. A number of jurisdictions have sanctioned the addition of essential nutrients for other reasons than listed in the General Principles, for example “discretionary” addition to provide consumers with a greater variety of foods with added vitamins and mineral nutrients. Should the purpose for adding essential nutrients to foods 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 “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 achieve it, e.g. application of tolerable upper intake levels.
4. There is interest in the addition to foods of “bioactive substances” that are not essential nutrients. Such bioactive substances include substances which either occur in normal metabolism (e.g., metabolic intermediates and products of intermediary metabolism) or which otherwise have a direct measurable effect on a function of the body (e.g., phytosterols, phytoestrogens, salicylates). Bioactive substances may be directly added to foods, or modified in foods in their levels and/or bioavailability by other means (e.g. genetic modification). Many of the same principles guiding the addition of essential nutrients to foods could be applicable to other bioactive substances. However, with regard to the addition of bioactive substances, the General Principles would also need to address their safety and the need for a scientifically demonstrated nutritional or other health purpose in the food.

## **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 nutritional enhancement of foods by means other than the traditional direct addition of nutrients to foods is a rapidly evolving area which may have a significant impact on the nutritional profiles of traditional foods and the intake of essential nutrients by consumers. Addition of essential nutrients for purposes other than fortification, restoration, nutritional equivalence or special purpose has been sanctioned in many jurisdictions. The addition of bioactive substances that are not essential nutrients to foods is also a rapidly evolving area.

It is essential that consumers be protected from risk to health due to nutrient excesses or imbalances that may result from the augmentation or enhancement of the essential nutrients in foods through genetic modification of the animal or plant organism that is the source of the food, or through alterations to livestock feed composition. The addition of an essential nutrient to a food for any purpose must take into consideration all related health risks. The addition of bioactive substances

must also be guided by principles that result in consumers being protected from the indiscriminate addition of unsafe substances or in levels that are beyond those required for their function.

The work is also timely in view of the ongoing work of the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology on the Proposed Annex on Food Safety Assessment of Food Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits.

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 use of non-traditional means of augmentation or enhancement of essential nutrients in foods, the addition of essential nutrients to foods for purposes beyond those stated in the current General Principles including examination of how to protect against excesses, deficits or imbalances, and the application of the General Principles to bioactive substances other than essential nutrients.

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

The proposed new work would 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 genetic modification of plant or animal organisms that are the source of the food or through alterations to livestock feed composition. It would also 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 and to the addition of bioactive substances to foods.

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 is consistent with the Strategic Vision outlined in the Codex Alimentarius Commission, Strategic Framework (2003-2007). It would contribute to: Objective 1 - Promoting sound regulatory frameworks; Objective 2 - Promoting widest and consistent application of scientific principles and risk analysis, Objective 4 - Enhance capacity to respond effectively and expeditiously to new issues, concerns and developments in the food sector, and Objective 6 - Promoting maximum application of Codex standards.

**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 would "complement" the work of the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology on the Annex on Food Safety Assessment of Food Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits. The proposal from the Electronic Working Group on the Annex, to be discussed at the 6th session of the Task Force, recommends that guidance "texts" from CCNFSDU be followed during the safety assessment of a recombinant DNA plant modified for nutritional or health benefits. The revision of the General Principles for the Addition of Essential Nutrients to Foods would strengthen that guidance. On-going communication between this Committee and the Task Force while the two initiatives progress will be essential to ensure coherence.

**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, the new work could commence following the 31<sup>st</sup> Session of the Codex Alimentarius Commission meeting (2008). Proposed amendments to the General Principles for the Addition of Essential Nutrients to Foods could be circulated for government comments at Step 3 in 2009 following the 30<sup>th</sup> Session of the CCNFSDU (2008). It is anticipated that the 31<sup>st</sup> or 32<sup>nd</sup>

Sessions of the CCNFSDU (2009; 2010) could advance the document to Step 5 and the 33<sup>rd</sup> or 34<sup>th</sup> Sessions of the CCNFSDU (2011; 2012) could advance the document to Step 8. Therefore, the work could be completed in four to five years.