codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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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) 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 *General Principles* also address the addition of essential nutrients to special purpose foods to ensure an adequate and appropriate nutrient content. The *General 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 *General Principles* in 1987 and subsequent amendments in 1989 and 1991, there has been a growing understanding of the role of nutrients and non-nutrient substances in foods in health and disease risk reduction. Changes in lifestyle and dietary habits have also prompted a growing interest from the industry to provide consumers with a wider selection of fortified foods. As well, advances in technology have provided new methods of achieving the goals of nutritional enhancement of foods. These changes suggest that a review of the *General Principles* may be timely with respect to:

1) new methods of achieving addition or enhancement of the levels of essential nutrients to foods, including biofortification,

2) the need for additional approaches to controlling the addition of essential nutrients to foods, including discretionary fortification, and

3) the addition to foods of bioactive substances.

Biofortification

Biofortification refers to the indirect addition of essential nutrients or 'other substances' to foods for the purpose of nutritional or health enhancement. Direct addition to the food at the stage of food processing has been the traditional means of adding nutrients to food. Recently, however, a growing number of

non-traditional methods or indirect addition are being employed at an earlier point of food production. Indirect addition can take different many forms, including: genetic 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).

As in direct addition, indirect addition can modify the level of the substance of interest in the food. Further, genetic modification can also alter the bioavailability of the substance by reducing the levels of antinutrients that inhibit bioavailability, or by enhancing the levels of compounds that promote bioavailability. A draft annex on the *Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutrition or Health Benefit* is currently being drafted to supplement the *Codex Guidelines for the Conduct of Safety Assessment of Foods Derived from Recombinant-DNA Plants*. Among the topics addressed in the draft annex is assessing the bioavailability of the modified substance and the potential for multiple chemical forms of a nutrient. There is also the potential for greater variability of the modified and related substances in genetic modification compared to the strict control of direct addition at the stage of food processing.

Unintended effects of genetic modification are well-recognized. However, such effects can also occur in other production methods used in nutritional and health enhancement of crop plants but have received less attention. For example, an unanticipated effect of increasing the selenium content of Brassica *spp*. is the reduced production of glucosinolates and phenolic acids [Finley, 2005]. There is also evidence of an interaction between selenium and glucosinolates from broccoli in animals fed selenium-enriched broccoli [Finley et al., 2005].

New methods of biofortification make it possible to indirectly add bioactive substances to certain types of food not readily achieved by traditional methods of fortification, such as fresh fruits and vegetables, eggs, nuts, fresh meat, fish and poultry. In some jurisdictions, direct addition of nutrients to these types of food is prohibited because these foods are already good sources of one or more naturally occurring nutrients. Research also indicates that consumers want a choice of unfortified foods, including those that are already considered 'healthy'. Questions of consumer acceptance of bioforitification of certain types of food would need to be considered, taking into consideration social and cultural context, for example, whether certain types of foods may be considered inappropriate for biofortification and whether this would depend on the substance being added.

Discretionary fortification

Discretionary fortification refers to the addition of essential nutrients for reasons other than those currently listed in the *General Principles.* Such addition would generally provide consumers with a greater choice and a broader variety of foods with added vitamins and mineral nutrients.

There are concerns that the *General 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. 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. Further, 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.

Setting maximum levels of addition

To preserve the intent of the *General Principles* in reducing 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, a risk-based approach would be required in setting maximum levels of addition and in clarifying the types of foods to which discretionary addition of essential nutrients would be considered

appropriate. A risk-based approach takes into consideration all sources of exposure, including intakes from supplements, and tolerable upper intake levels (UL) that have been established. Several models of applying a risk-based approach exist [Flynn et al., 2003; Health Canada, 2005; European Commission, 2006; Rasmussen et al., 2006; Kloosterman et al., 2007].

Issues which will need to be considered in setting maximum levels of addition in discretionary fortification include [European Commission, 2006] what factors should be taken into account in setting a maximum level for the addition of a nutrient to foods where there is not yet a scientifically established value for tolerable upper intake level for that 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.

Setting minimum levels of addition

In providing more flexibility to the addition of essential nutrients to foods, questions may be raised whether such a practice would serve a public health purpose and would maintain or improve the overall nutritional quality of foods and diets. Additional issues that would need consideration in this regard include:

- Should discretionary fortification be considered only if there is a justifiable rationale? Under what conditions would discretionary fortification be acceptable. For example, should generally accepted scientific evidence be available to indicate that an increase in the intake of an essential nutrient can deliver a health benefit beyond meeting nutrient requirements, or should the food to which essential nutrients are added be demonstrated to serve a special purpose, such as meal replacement?

- What factors should be considered in setting minimum levels of addition to ensure that the consumer is not misled as to the nutritional quality of the fortified food? For example, should the minimum level be the same as the significant amount required to be present for a claim and/or declaration of the nutrient in nutrition labelling? What other criteria might be considered?

- Should discretionary fortification be prohibited for certain types of foods (e.g., beverages or foods 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.)?

- How should the impact of discretionary fortification on dietary intakes be assessed?

Addition of bioactive substances

For the purpose of this Discussion Paper, 'bioactive substances' refer to non essential substances of dietary origin that have a nutritional or physiological effect. They include known nutrients that are not considered 'essential' nutrients or for which dietary reference intakes have not been established (e.g., EPA/DHA) and food-related substances that are not considered 'nutrients' at present (e.g., lutein, lycopene, biopeptides). Excluded from this category of substances are food additives or substances such as food contaminants, pesticides, microbiological pathogens, or other food-borne hazards.

According to the *General Principles*, an *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. With respect to food fortification, vitamins and mineral nutrients have generally been the main focus of national policies and guidelines. However, there is a growing interest on the part of industry and consumers in a variety of food-related substances that have demonstrated or purported impact on health. Arguments similar to those for

discretionary fortification have also been put forward in support of an expanded flexibility in the types of substances added to foods.

While the use of many ingredients as sources of nutrients is not generally subject to specific regulation or guidelines, the addition to foods of some substances (other than vitamins and minerals or ingredients containing them) as extracts or concentrates may result in intakes that are significantly higher than those that could be ingested through eating an adequate and varied diet. The safety of such practices may be contested in some cases and the benefits are unclear; therefore, principles governing such practices would need to be developed or clarified. In some jurisdictions, the addition of bioactive substances to foods is controlled by novel food regulations with respect to food safety where the maximum level of addition is considered as part of premarket assessment.

With respect to setting the minimum level of addition, established reference intake values would be useful. However, such information is not available for several nutrients (e.g., specific fatty acids or components of dietary fibre) and non-nutrients of interest. It is understood that one purpose of adding to foods a substance expected to have health benefit is to make a health claim. Guidelines related to the authorization of health claims for foods generally address the need to determine the minimum level in the food of a substance that is the subject of the claim. For bioactive substances in particular, data are generally limited on their levels in foods and their intakes by different population groups. Where multiple beneficial health effects have been reported for the same substance, the establishment of a generally accepted reference intake value by an authoritative body may become important, as this need is not likely to be addressed by applicants seeking health claim authorization.

Questions listed under discretionary fortification are also applicable to the addition of bioactive substances to foods. In addition, the following questions also warrant consideration:

- Given the issues mentioned above, should the establishment of generally accepted reference intake values be a prerequisite for adding a bioactive substance to foods?

- Should some form of positive list of permitted substances be established? What processes should be put in place to facilitate updating the list?

- What information should be included in the list (e.g., the forms or sources of the substance)?

- What factors should be considered in determining appropriate forms of a substance for addition to foods for nutritional or health enhancement (e.g., bioavailability)?

In summary, this Discussion Paper identifies the rationale for a review of the Codex *General Principles for the Addition of Essential Nutrients to Foods* and poses several issues and questions to be considered in amending and/or clarifying the *General Principles*. In reviewing the *General Principles*, several objectives will be considered. While recognizing the need for a broader choice of foods for consumers, greater flexibility for industry and less barrier to trade, it is equally important to prevent the indiscriminate addition of nutrient and non-nutrient substances to foods for health protection, and to ensure that consumers are not misled regarding the nutritional quality of foods to which nutrient and non-nutrient bioactive substances are added.

References

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