

CODEX ALIMENTARIUS

INTERNATIONAL FOOD STANDARDS



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GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS

CAC/GL 9-1987

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INTRODUCTION

The Principles for the Addition of Essential Nutrients to Foods (the Principles) are intended to provide guidance to competent national and/or regional 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.¹

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.

Competent national and/or regional authorities may also consult FAO/WHO publications for further guidance on the addition of essential nutrients.

1. SCOPE

These Principles are intended to apply to all foods to which essential nutrients are added, not including vitamin and mineral food supplements², without prejudice to the provisions in Codex standards and guidelines for foods for special dietary uses.

The Principles are applicable, as appropriate, to both mandatory and voluntary addition of essential nutrients.

2. DEFINITIONS

For the purpose of these Principles:

- 2.1 **Essential nutrient**³ means any substance normally consumed as a constituent of food which is needed for growth and development and/or the maintenance of life and which cannot be synthesized in adequate amounts by the body.
- 2.2 **Substitute food** is a food which resembles a common food in appearance and texture and is intended to be used as a complete or partial replacement for the food it resembles.
- 2.3 **Nutritional equivalence** means that a substitute food is of similar nutritional value to its counterpart.
- 2.4 **Restoration** means the addition of essential nutrient(s) to a food in amounts to replace those lost during the course of good manufacturing practice, or during normal storage and handling procedures.
- 2.5 **Mandatory nutrient addition** is when competent national and/or regional authorities require food manufacturers to add specified essential nutrients to particular foods or food categories.
- 2.6 **Voluntary nutrient addition**⁴ is when food manufacturers choose to add specified essential nutrients to particular foods or food categories as explained in footnote 4.
- 2.7 **Population** refers to a national population or specific population group(s) as appropriate.

3. GENERAL PRINCIPLES

3.1 Fundamental Principles

3.1.1 Essential nutrients may be appropriately added to foods for the purpose of contributing to:

- preventing/reducing the risk of, or correcting, a demonstrated deficiency of one or more essential nutrients in the population;

¹ Different types of addition of essential nutrients for the purposes described in these Principles may be described by the term 'fortification' in certain Member Countries.

² See the *Guidelines for Vitamin and Mineral Food Supplements* (CAC/GL-55-2005).

³ 'Nutrient' definition: See section 2.5 of the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985).

⁴ Internationally, there are different regulatory approaches to how voluntary addition of essential nutrients is legally framed and/or managed by competent national and/or regional authorities. In all these approaches, some form of regulatory oversight is required. There are approaches whereby addition of essential nutrients is generally permitted within a regulatory framework that can restrict foods or categories of foods to which nutrients may be added and set specific limits for those nutrients. There are other approaches that may be described as conditional voluntary. In one example, the framework in place describes all the foods or categories of foods to which manufacturers may choose to add nutrients, along with the nutrients and levels of nutrients. In another of these examples, if a manufacturer chooses to make a statement on the label indicating that a nutrient has been added, then certain nutrients are required to be added at specified levels. Also, in another example, if a manufacturer chooses to add an essential nutrient to certain foods, they must do so in accordance with policies on addition of nutrients and/or meet requirements in place in relation to the nutrients and amounts for addition.

- reducing the risk of, or correcting, inadequate nutritional status or intakes of one or more essential nutrients in the population;
- meeting requirements and/or recommended intakes of one or more essential nutrients;
- maintaining or improving health; and/or
- maintaining or improving the nutritional quality of foods.

Competent national and/or regional authorities may request scientific rationale and evidence demonstrating fulfillment of one or more of the purposes listed above .

3.1.2 Competent national and/or regional authorities should determine whether addition of essential nutrients should be mandatory or voluntary. This decision may be based on severity and extent of public health need as demonstrated by generally accepted scientific evidence.

3.1.3 Specific provision may be made in food standards, regulations or guidelines that identify the food(s) and essential nutrients for addition and, where appropriate, the minimum and/or maximum amounts within which the essential nutrients should be present.

3.1.4 The labelling and advertising of food products to which essential nutrients have been added should not mislead or deceive the consumer as to the nutritional merit of the food.

3.2 Selection of Nutrients and Determination of Amounts

3.2.1 The addition of an essential nutrient, including the amount added, should be in line with one or more of the purposes identified in 3.1.1. The amount added should not result in either an excessive intake or an insignificant intake of the added essential nutrient(s), considering total daily intakes from all relevant sources including food supplements.

3.2.2 When an essential nutrient is added to foods, including addition for technological reasons, the total amount of the essential nutrient in the food should not exceed maximum amounts that may be set by competent national and/or regional authorities.

The maximum amounts mentioned above may be set taking into account

- a) upper levels of intake (UL) of essential nutrients established by scientific risk assessment based on generally accepted scientific data;
- b) the daily intake of essential nutrients from all sources.

When the maximum levels are set, due account may be taken of the daily intake reference values of essential nutrients for the population.

3.2.3 Where an UL is not available, the scientific evidence to support the safe addition of an essential nutrient should be considered including evidence for intakes that are unlikely to result in adverse health effects including consideration of the Highest Observed Intake⁵.

3.2.4 The severity of the adverse effect on which the UL is based may be reviewed to inform any restrictions on the addition of essential nutrients to foods.

3.2.5 When competent national and/or regional authorities establish minimum amounts for the addition of essential nutrients to foods they should ensure that these amounts are significant and in line with the intended purpose as identified in 3.1.1. In determining significant amounts, they may also consider conditions of use for a 'source' claim in the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997).

3.3 Selection of Foods

3.3.1 The selection of foods to which essential nutrients may be added should be in line with the intended purposes of nutrient addition as identified in 3.1.1, dietary patterns, socioeconomic situations and the need to avoid any risks to health.

3.3.2 Foods to which essential nutrients may not be added may be determined by competent national and/or regional authorities.

3.3.3 Essential nutrients should not be added to alcoholic beverages.

⁵ Highest Observed Intake – the highest level of intake observed or administered as reported within (a) study(ies) of acceptable quality. It is derived only when no adverse health effects have been identified (Source: Codex *Nutritional Risk Analysis Principles*).

3.4 Technological Aspects

3.4.1 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 of the nutrient. In addition, purity criteria should take into account FAO/WHO standards, international Pharmacopoeias or other recognized international standards.

3.4.2 The added essential nutrient should be sufficiently stable in the food under customary conditions of processing, packaging, storage, distribution and use.

3.5 Monitoring

3.5.1 It is important that competent national and/or regional authorities monitor population intakes from all sources including the essential nutrients added to foods to assess the extent to which the purposes identified in 3.1.1 are addressed and to ensure that any risk of excessive intakes is minimized.

3.5.2 Monitoring of total nutrient intakes should in principle use the same approach as used in deciding the addition of essential nutrients unless otherwise necessary for the specific nutrient concerned.

4 PRINCIPLES FOR SPECIFIC TYPES OF ADDITION OF ESSENTIAL NUTRIENTS

4.1 Mandatory Addition of Essential Nutrients to Address a Demonstrated Public Health Need

4.1.1 Where there is a demonstrated public health need for increasing the intake of an essential nutrient in the population, competent national and/or regional authorities may decide that this may be accomplished by mandatory nutrient addition. This need may be demonstrated by evidence of clinical or subclinical deficiency, suboptimal or inadequate nutritional status using biochemical indicators, estimates indicating inadequate or potentially inadequate intake of nutrients, or evidence related to another health outcome. While most addition to address a serious public health need is through mandatory nutrient addition, there may be some situations where a conditional voluntary approach may be used.

4.1.2 The food(s) selected as a vehicle for the added essential nutrient(s) should be habitually consumed in sufficient amounts by the target population.

4.1.3 The amount of the essential nutrient added to the food should aim to be sufficient to meet the public health need.

4.1.4 The intake of the food selected as a vehicle should be stable and uniform and the distribution of the population intake of the food, including the lower and upper percentiles, should be known.

4.1.5 The cost effectiveness of the mandatory nutrient addition to foods should be considered.

4.2 Addition of Essential Nutrients for Restoration

4.2.1 Where restoration is to serve as a justification for the maintenance or improvement of the nutritional quality of a food, especially in relation to a public health need, the following criteria should be considered:

- the food prior to restoration should be a significant contributor to the intake of relevant essential nutrients in the population
- the food prior to restoration would be subject to a reduction of relevant essential nutrients it contains during processing, storage or handling.

4.2.2 A food may be considered a significant contributor to intake of an essential nutrient based on its nutrient content and/or frequency of consumption.

4.3 Addition of Essential Nutrients for Nutritional Equivalence

4.3.1 Where nutritional equivalence is to serve as a justification for the improvement of the nutritional quality of a substitute food, especially in relation to a public health need, the counterpart food should be a significant contributor to the intake of essential nutrients in the population.

4.3.2 A food being substituted or partially substituted may be considered a significant contributor to intake of an essential nutrient based on its nutrient content and/or frequency of consumption.