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TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION
PART 104 -- NUTRITIONAL QUALITY GUIDELINES FOR FOODS

Subpart B--Fortification Policy

Sec. 104.20 Statement of purpose.

(a) The fundamental objective of this subpart is to establish a uniform set of principles that will serve as a model for the rational addition of nutrients to foods. The achievement and maintenance of a desirable level of nutritional quality in the nation's food supply is an important public health objective. The addition of nutrients to specific foods can be an effective way of maintaining and improving the overall nutritional quality of the food supply. However, random fortification of foods could result in over- or underfortification in consumer diets and create nutrient imbalances in the food supply. It could also result in deceptive or misleading claims for certain foods. The Food and Drug Administration does not encourage indiscriminate addition of nutrients to foods, nor does it consider it appropriate to fortify fresh produce; meat, poultry, or fish products; sugars; or snack foods such as candies and carbonated beverages. To preserve a balance of nutrients in the diet, manufacturers who elect to fortify foods are urged to utilize these principles when adding nutrients to food. It is reasonable to anticipate that the Reference Daily Intakes (RDI's) as delineated in 101.9 of this chapter and in paragraph (d) of this section will be amended from time to time to list additional nutrients and/or to change the levels of specific RDI's as improved knowledge about human nutrient requirements and allowances develops. The policy set forth in this section is based on U.S. dietary practices and nutritional needs and may not be applicable in other countries.

(b) A nutrient(s) listed in paragraph (d) (3) of this section may appropriately be added to a food to correct a dietary insufficiency recognized by the scientific community to exist and known to result in nutritional deficiency disease if:

(1) Sufficient information is available to identify the nutritional problem and the affected population groups, and the food is suitable to act as a vehicle for the added nutrients. Manufacturers contemplating using this principle are urged to contact the Food and Drug Administration before implementing a fortification plan based on this principle.

(2) The food is not the subject of any other Federal regulation for a food or class of food that requires, permits, or prohibits nutrient additions. (Other Federal regulations include, but are not limited to, standards of identity promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act, nutritional quality guidelines established in subpart C of this part, and common or usual name regulations established in part 102 of this chapter.)

(c) A nutrient(s) listed in paragraph (d) (3) of this section may appropriately be added to a food to **restore such nutrient(s)** to a level(s) representative of the food prior to storage, handling, and processing, when:

(1) The nutrient is shown by adequate scientific documentation to have been lost in storage, handling, or processing in a measurable amount equal to at least 2 percent of the Daily Reference Value (DRV) of protein and of potassium and 2 percent of the Reference Daily Intake (RDI) in a normal serving of the food.

(2) Good manufacturing practices and normal storage and handling procedures cannot prevent the loss of such nutrient(s),

(3) All nutrients, including protein, iodine and vitamin D, that are lost in a measurable amount are restored and all ingredients of the food product that contribute nutrients are considered in determining restoration levels; and

(4) The food is not the subject of any other Federal regulation that requires or prohibits nutrient addition(s), or the food has not been fortified in accordance with any other Federal regulation that permits voluntary nutrient additions.

(d) **A nutrient(s) listed in paragraph (d) (3) of this section may be added to a food in proportion to the total caloric content of the food,** to balance the vitamin, mineral, and protein content if:

(1) A normal serving of the food contains at least 40 kilocalories (that is, 2 percent of a daily intake of 2,000 kilocalories);

(2) The food is not the subject of any other Federal regulation for a food or class of food that requires, permits, or prohibits nutrient additions; and

(3) The food contains all of the following nutrients per 100 calories based on 2,000 calorie total intake as a daily standard:

Nutrient	Unit of measurement	DRV or RDI 1	Amount per 100 calories
Protein	grams (g)	50	2.5
Vitamin A	International Unit (IU)	5,000	250
Vitamin C	milligrams (mg)	60	3
Calcium	g	1	0.05
Iron	mg	18	0.9
Vitamin D	IU	400	20
Vitamin E	do	30	1.5
Thiamin	mg	1.5	0.08
Riboflavin	do	1.7	0.09
Niacin	do	20	1
Vitamin B ₆	do	2.0	0.1
Folate	micrograms ([micro]g)	400	20
Vitamin B ₁₂	do	6.0	0.3
Biotin	mg	0.3	0.015

Pantothenic acid	do	10	0.5
Phosphorus	g	1.0	0.05
Magnesium	mg	400	20
Zinc	do	15	0.8
Iodine	[micro]g	150	7.5
Copper	mg	2.0	0.1
Potassium	do	3,500	175

¹RDI's for adults and children 4 or more years of age.

(e) A nutrient(s) may appropriately be added to a food that replaces traditional food in the diet to avoid nutritional inferiority in accordance with 101.3(e) (2) of this chapter.

(f) Nutrient(s) may be added to foods as permitted or required by applicable regulations established elsewhere in this chapter.

(g) A nutrient added to a food is appropriate only when the nutrient:

(1) Is stable in the food under customary conditions of storage, distribution, and use;

(2) Is physiologically available from the food;

(3) Is present at a level at which there is a reasonable assurance that consumption of the food containing the added nutrient will not result in an excessive intake of the nutrient, considering cumulative amounts from other sources in the diet; and

(4) Is suitable for its intended purpose and is in compliance with applicable provisions of the act and regulations governing the safety of substances in food.

(h) Any claims or statements in the labeling of food about the addition of a vitamin, mineral, or protein to a food shall be made only if the claim or statement is not false or misleading and otherwise complies with the act and any applicable regulations. The following label claims are acceptable:

(1) The labeling claim "fully restored with vitamins and minerals" or "fully restored with vitamins and minerals to the level of unprocessed ____" (the blank to be filled in with the common or usual name of the food) may be used to describe foods fortified in accordance with the principles established in paragraph (c) of the section.

(2) The labeling claim, "vitamins and minerals (and "protein" when appropriate) added are in proportion to caloric content" may be used to describe food fortified in accordance with the principles established in paragraph (d) of this section.

(3) When labeling claims are permitted, the term "enriched," "fortified," "added," or similar terms may be used interchangeably to indicate the addition of one or more vitamins or minerals or protein to a food, unless an applicable Federal regulation requires the use of specific words or statements.

(i) It is inappropriate to make any claim or statement on a label or in labeling, other than in a listing of the nutrient ingredients as part of the ingredient statement, that any vitamin, mineral, or protein has been added to a food to which nutrients have been added pursuant to paragraph (e) of this section.

[45 FR 6323, Jan. 25, 1980, as amended at 58 FR 2228, Jan. 6, 1993]

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