

(2) [Reserved]

(c) Data bases of nutrient values for raw fruits, vegetables, and fish that are not among the 20 most frequently consumed may be used to develop nutrition labeling values for these foods. This includes data bases of nutrient values for specific varieties, species, or cultivars of raw fruits, vegetables, and fish not specifically identified among the 20 most frequently consumed.

(1) The food names and descriptions for the fruits, vegetables, and fish should clearly identify these foods as distinct from foods among the most frequently consumed list for which FDA has provided data.

(2) Guidance in the development of data bases may be found in the “FDA Nutrition Labeling Manual: A Guide for Developing and Using Data Bases.”

(3) Nutrition labeling values computed from data bases are subject to the compliance provisions of §101.9(g).

(i) Compliance with the provisions of §101.9(g) may be achieved by use of a data base that has been developed following FDA guideline procedures and approved by FDA.

(A) The submission to FDA for approval should include but need not be limited to information on the following: Source of the data (names of investigators, name of organization, place of analyses, dates of analyses), number of samples, sampling design, analytical methods, statistical treatment of the data, and proposed quantitative label declarations. The values for declaration should be determined in accordance with the “FDA Nutrition Labeling Manual: A Guide for Developing and Using Databases.”

(B) FDA approval of a data base and nutrition labeling values shall not be considered granted until the Center for Food Safety and Applied Nutrition has agreed to all aspects of the data base in writing. Approvals will be in effect for a limited time, e.g., 10 years, and will be eligible for renewal in the absence of significant changes in agricultural or industry practices (e.g., a change occurs in a predominant variety produced). FDA will take steps to revoke its approval of the data base and nutrition labeling values if FDA monitoring suggests that the data base or nutrition labeling values are no longer rep-

resentative of the item sold in this country. Approval requests shall be submitted in accordance with the provision of §101.30 of this chapter.

(ii) [Reserved]

[61 FR 42760, Aug. 16, 1996, as amended at 66 FR 56035, Nov. 6, 2001]

Subpart D—Specific Requirements for Nutrient Content Claims

SOURCE: 58 FR 2413, Jan. 6, 1993, unless otherwise noted.

§101.54 Nutrient content claims for “good source,” “high,” “more,” and “high potency.”

(a) *General requirements.* Except as provided in paragraph (e) of this section, a claim about the level of a nutrient in a food in relation to the Reference Daily Intake (RDI) established for that nutrient in §101.9(c)(8)(iv) or Daily Reference Value (DRV) established for that nutrient in §101.9(c)(9), (excluding total carbohydrates) may only be made on the label or in labeling of the food if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in §101.13; and

(3) The food for which the claim is made is labeled in accordance with §101.9, §101.10, or §101.36, as applicable.

(b) *“High” claims.* (1) The terms “high,” “rich in,” or “excellent source of” may be used on the label and in the labeling of foods, except meal products as defined in §101.13(1) and main dish products as defined in §101.13(m), provided that the food contains 20 percent or more of the RDI or the DRV per reference amount customarily consumed.

(2) The terms defined in paragraph (b)(1) of this section may be used on the label and in the labeling of meal products as defined in §101.13(1) and main dish products as defined in §101.13(m), provided that:

(i) The product contains a food that meets the definition of “high” in paragraph (b)(1) of this section; and

(ii) The label or labeling clearly identifies the food that is the subject of the claim (e.g., the serving of broccoli in this product is high in vitamin C).

(c) “*Good Source*” claims. (1) The terms “good source,” “contains,” or “provides” may be used on the label and in the labeling of foods, except meal products as defined in §101.13(1) and main dish products as defined in §101.13(m), provided that the food contains 10 to 19 percent of the RDI or the DRV per reference amount customarily consumed.

(2) The terms defined in paragraph (c)(1) of this section may be used on the label and in the labeling of meal products as defined in §101.13(1) and main dish products as defined in 101.13(m), provided that:

(i) The product contains a food that meets the definition of “good source” in paragraph (c)(1) of this section; and

(ii) The label or labeling clearly identifies the food that is the subject of the claim (e.g., the serving of sweet potatoes in this product is a “good source” of fiber).

(d) “*Fiber*” claims. (1) If a nutrient content claim is made with respect to the level of dietary fiber, that is, that the product is high in fiber, a good source of fiber, or that the food contains “more” fiber, and the food is not “low” in total fat as defined in §101.62(b)(2) or, in the case of a meal product, as defined in §101.13(1), or main dish product, as defined in §101.13(m), is not “low” in total fat as defined in §101.62(b)(3), then the label shall disclose the level of total fat per labeled serving.

(2) The disclosure shall appear in immediate proximity to such claim, be in a type size no less than one-half the size of the claim and precede any disclosure statement required under §101.13(h) (e.g., “contains [*x amount*] of total fat per serving. See nutrition information for fat content”).

(e) “*More*” claims. (1) A relative claim using the terms “more,” “fortified,” “enriched,” “added,” “extra,” and “plus” may be used on the label or in labeling of foods to describe the level of protein, vitamins, minerals, dietary fiber, or potassium, except as limited by §101.13(j)(1)(i) and except meal products as defined in §101.13(1) and main dish products as defined in §101.13(m), provided that:

(i) The food contains at least 10 percent more of the RDI for vitamins or

minerals or of the DRV for protein, dietary fiber, or potassium (expressed as a percent of the Daily Value) per reference amount customarily consumed than an appropriate reference food; and

(ii) Where the claim is based on a nutrient that has been added to the food, that fortification is in accordance with the policy on fortification of foods in §104.20 of this chapter; and

(iii) As required in §101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percentage (or fraction) that the nutrient is greater relative to the RDI or DRV are declared in immediate proximity to the most prominent such claim (e.g., “contains 10 percent more of the Daily Value for fiber than white bread”); and

(B) Quantitative information comparing the level of the nutrient in the product per labeled serving with that of the reference food that it replaces (e.g., “Fiber content of white bread is 1 gram (g) per serving; (this product) 3.5 g per serving”) is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with §101.2.

(2) A relative claim using the terms “more,” “fortified,” “enriched,” “added,” “extra,” and “plus” may be used on the label or in labeling to describe the level of protein, vitamins, minerals, dietary fiber or potassium, except as limited in §101.13(j)(1)(i), in meal products as defined in §101.13(1) or main dish products as defined in §101.13(m), provided that:

(i) The food contains at least 10 percent more of the RDI for vitamins or minerals or of the DRV for protein, dietary fiber, or potassium (expressed as a percent of the Daily Value) per 100 g of food than an appropriate reference food.

(ii) Where the claim is based on a nutrient that has been added to the food, that fortification is in accordance with the policy on fortification of foods in §104.20 of this chapter; and

(iii) As required in §101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percentage (or fraction) that

the nutrient was increased relative to the RDI or DRV are declared in immediate proximity to the most prominent such claim (e.g., “contains 10 percent more of the Daily Value for fiber per 3 oz than does ‘X brand of product’”), and

(B) Quantitative information comparing the level of the nutrient in the product per specified weight with that of the reference food that it replaces (e.g., “The fiber content of ‘X brand of product’ is 2 g per 3 oz. This product contains 4.5 g per 3 oz.”) is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with §101.2.

(f) “*High potency*” claims. (1)(i) The term “high potency” may be used on the label or in the labeling of foods to describe individual vitamins or minerals that are present at 100 percent or more of the RDI per reference amount customarily consumed.

(ii) When the term “high potency” is used to describe individual vitamins or minerals in a product that contains other nutrients or dietary ingredients, the label or labeling shall clearly identify which vitamin or mineral is described by the term “high potency” (e.g., “Botanical ‘X’ with high potency vitamin E”).

(2) The term “high potency” may be used on the label or in the labeling of a multiingredient food product to describe the product if the product contains 100 percent or more of the RDI for at least two-thirds of the vitamins and minerals that are listed in §101.9(c)(8)(iv) and that are present in the product at 2 percent or more of the RDI (e.g., “High potency multivitamin, multimineral dietary supplement tablets”).

(3) Where compliance with paragraphs (f)(1)(i), (f)(1)(ii), or (f)(2) of this section is based on a nutrient that has been added to a food (other than a dietary supplement), that fortification shall be in accordance with the policy on fortification of foods in §104.20 of this chapter.

(g) *Nutrient content claims using the term “antioxidant.”* A nutrient content

claim that characterizes the level of antioxidant nutrients present in a food may be used on the label or in the labeling of that food when:

(1) An RDI has been established for each of the nutrients;

(2) The nutrients that are the subject of the claim have recognized antioxidant activity; that is, when there exists scientific evidence that, following absorption from the gastrointestinal tract, the substance participates in physiological, biochemical, or cellular processes that inactivate free radicals or prevent free radical-initiated chemical reactions;

(3) The level of each nutrient that is the subject of the claim is sufficient to qualify for the §101.54 (b), (c), or (e) claim (e.g., to bear the claim “high in antioxidant vitamin C,” the product must contain 20 percent or more of the RDI for vitamin C). Beta-carotene may be a subject of the claim when the level of vitamin A present as beta-carotene in the food that bears the claim is sufficient to qualify for the claim. For example, for the claim “good source of antioxidant beta-carotene,” 10 percent or more of the RDI for vitamin A must be present as beta-carotene per reference amount customarily consumed; and

(4) The names of the nutrients that are the subject of the claim are included as part of the claim (e.g., “high in antioxidant vitamins C and E”). Alternatively, when used as part of a nutrient content claim, the term “antioxidant” or “antioxidants” (as in “high in antioxidants”) may be linked by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of a product label followed by the name or names of the nutrients with recognized antioxidant activity. The list of nutrients shall appear in letters of a type size height no smaller than the larger of one-half of the type size of the largest nutrient content claim or 1/16 inch.

[58 FR 2413, Jan. 6, 1993; 58 FR 17342, Apr. 2, 1993, as amended at 59 FR 394, Jan. 4, 1994; 59 FR 15051, Mar. 31, 1994; 60 FR 17206, Apr. 5, 1995; 61 FR 11731, Mar. 22, 1996; 62 FR 31339, June 9, 1997; 62 FR 49867, 49880, Sept. 23, 1997; 63 FR 26980, May 15, 1998; 66 FR 17358, Mar. 30, 2001]