

(e) If FDA finds that there is substantial compliance with the guidelines for the nutrition labeling of raw fruit and vegetables or of fish, the agency will so state in the report, and the guidelines will remain in effect. FDA will reevaluate the market place for substantial compliance every 2 years.

(f) If FDA determines that there is not substantial compliance with the guidelines for raw fruit and vegetables or for raw fish, the agency will at that time issue proposed regulations requiring that any person who offers raw fruit and vegetables or fish to consumers provide, in a manner prescribed by regulations, the nutrition information required by §101.9. Final regulations would have to be issued 6 months after issuance of proposed regulations, and they would become effective 6 months after the date of their promulgation.

§101.43 Substantial compliance of food retailers with the guidelines for the voluntary nutrition labeling of raw fruit, vegetables, and fish.

(a) The Food and Drug Administration (FDA) will judge a food retailer who sells raw agricultural commodities or raw fish to be in compliance with the guidelines in §101.45 with respect to raw agricultural commodities if the retailer displays or provides nutrition labeling for at least 90 percent of the raw agricultural commodities listed in §101.44 that it sells, and with respect to raw fish if the retailer displays or provides nutrition labeling for at least 90 percent of the types of raw fish listed in §101.44 that it sells. To be in compliance, the nutrition labeling shall:

(1) Be presented in the store or other type of establishment in a manner that is consistent with §101.45(a)(1);

(2) Be presented in content and format that are consistent with §101.45(a)(2), (a)(3), and (a)(4); and

(3) Include data that have been provided by FDA in appendices C and D to part 101 of this chapter, except that the information on potassium is voluntary.

(b) To determine whether there is substantial compliance by food retailers with the guidelines in §101.45 for the voluntary nutrition labeling of raw fruit and vegetables and of raw fish, FDA will select a representative sam-

ple of 2,000 stores, allocated by store type and size, for raw fruit and vegetables and for raw fish.

(c) FDA will find that there is substantial compliance with the guidelines in §101.45 if it finds based on paragraph (a) of this section that at least 60 percent of all stores that are evaluated are in compliance.

(d) FDA will evaluate substantial compliance separately for raw agricultural commodities and for raw fish.

[55 FR 60890, Nov. 27, 1991, as amended at 61 FR 42759, Aug. 16, 1996]

§101.44 Identification of the 20 most frequently consumed raw fruit, vegetables, and fish in the United States.

(a) The 20 most frequently consumed raw fruit are: Banana, apple, watermelon, orange, cantaloupe, grape, grapefruit, strawberry, peach, pear, nectarine, honeydew melon, plum, avocado, lemon, pineapple, tangerine, sweet cherry, kiwifruit, and lime.

(b) The 20 most frequently consumed raw vegetables are: Potato, iceberg lettuce, tomato, onion, carrot, celery, sweet corn, broccoli, green cabbage, cucumber, bell pepper, cauliflower, leaf lettuce, sweet potato, mushroom, green onion, green (snap) bean, radish, summer squash, and asparagus.

(c) The 20 most frequently consumed raw fish are: Shrimp, cod, pollock, catfish, scallops, salmon (Atlantic/Coho, chum/pink, sockeye), flounder/sole, oysters, orange roughy, Atlantic/Pacific mackerel, ocean perch, rockfish, whiting, clam, haddock, blue crab, rainbow trout, halibut, lobster, and swordfish.

[55 FR 60890, Nov. 27, 1991, as amended at 61 FR 42760, Aug. 16, 1996]

§101.45 Guidelines for the voluntary nutrition labeling of raw fruits, vegetables, and fish.

(a) Nutrition labeling for raw fruits, vegetables, and fish listed in §101.44 should be presented to the public in the following manner:

(1) Nutrition labeling information should be displayed at the point of purchase by an appropriate means such as by a label affixed to the food or through labeling including shelf labels, signs, posters, brochures, notebooks, or

leaflets that are readily available and in close proximity to the foods. The nutrition labeling information may also be supplemented by a video, live demonstration, or other media.

(2) Serving sizes should be determined, and nutrients declared, in accordance with §101.9 (b) and (c), respectively, except that the nutrition labeling data should be based on the raw edible portion for fruits and vegetables and on the cooked edible portion for fish. The methods used to cook fish should be those that do not add fat, breading, or seasoning (e.g., salt or spices).

(3) When nutrition labeling information is provided for more than one raw fruit, vegetable, or fish on signs, posters, brochures, notebooks, or leaflets, it may be presented in charts with horizontal or vertical columns or as a compilation of individual nutrition labels. Nutrition labeling that is presented in a linear display (see §101.9(j)(13)(ii)(A)(2)) will not be considered to be in compliance. The heading "Nutrition Facts" must be in a type size larger than all other print in the nutrition label. The required information (i.e., headings, serving sizes, list of nutrients, quantitative amounts by weight (except for vitamins and minerals), and percent of Daily Values (DV's) (except for sugars and protein) must be clearly presented and of sufficient type size and color contrast to be plainly legible, with numeric values for percent of DV highlighted in contrast to the quantitative amounts by weight and hairlines between all nutrients.

(i) Declaration of the number of servings per container need not be included in the nutrition labeling of raw fruits, vegetables, and fish.

(ii) Except for the statement "Percent Daily Values are based on a 2,000 calorie diet," the footnote required in §101.9(d)(9) is not required. However, when labeling is provided in brochures, notebooks, leaflets, or similar types of materials, retailers are encouraged to include the footnote.

(iii) When the nutrition labeling information for more than one raw fruit or vegetable is provided on signs, posters, brochures, notebooks, or leaflets, the listings for saturated fat and cholesterol may be omitted from the

charts or individual nutrition labels so long as the fact that most fruits and vegetables provide negligible amounts of these nutrients, but that avocados contain 1 gram (g) of fat per ounce, is stated in a footnote (e.g., "Most fruits and vegetables provide negligible amounts of saturated fat and cholesterol; avocados provide 1 g of saturated fat per ounce"). The footnote may also contain information about the polyunsaturated and monounsaturated fat content of avocados. When the nutrition labeling information for raw fish is provided on a chart, the listings for dietary fiber and sugars may be omitted if the following footnote is used, "Fish provide negligible amounts of dietary fiber and sugars."

(4) When nutrition labeling is provided for individual raw fruits, vegetables, or fish on packages or on signs, posters, brochures, notebooks, or leaflets, it should be displayed in accordance with §101.9, except that the declaration of the number of servings per container need not be included. For individual labels provided by retailers on signs and posters, the footnote required in §101.9(d)(9) may be shortened to "Percent Daily Values are based on a 2,000 calorie diet."

(b) Nutrition label values provided by the Food and Drug Administration (FDA) in Appendices C and D to part 101 for the 20 most frequently consumed raw fruits, vegetables, and fish listed in §101.44 shall be used to ensure uniformity in declared values. FDA will publish proposed updates of the 20 most frequently consumed raw fruits, vegetables, and fish and nutrition label data for these foods (or a notice that the data sets have not changed from the previous publication) at least every 4 years in the FEDERAL REGISTER.

(1) The agency encourages the submission of data bases with new or additional nutrient data for any of the most frequently consumed raw fruits, vegetables, and fish to the Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, for review and evaluation. FDA may incorporate these data in the next

revision of the nutrition labeling information for the top 20 raw fruits, vegetables, and fish.

(i) Guidance in the development of data bases may be found in the "FDA Nutrition Labeling Manual: A Guide for Developing and Using Data Bases," available from the FDA Office of Food Labeling.

(ii) The submission to FDA 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, and statistical treatment of the data. Proposed quantitative label declarations may be included. The proposed values for declaration should be determined in accordance with the "FDA Nutrition Labeling Manual: A Guide for Developing and Using Data Bases."

(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 representative 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